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BIOMEDICAL RESEARCH IN THE VETERANS ADMINISTRATION

Report of the Committee on Biomedical Research
in the Veterans Administration
Division of Medical Sciences
Assembly of Life Sciences
National Research Council

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1977

NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

PREFACE

This report was prepared under the terms of contract V101(134) P-203 Part II in response to a request from the Administrator, VA for

> an assessment of the biomedical research effort including relevant aspects of the training program with respect to quality and to the manner and extent of its contribution to patient care provided by the Veterans Administration.

The NAS/NRC has reviewed the VA's biomedical research program on two previous occasions. Reports were issued in 1960 and 1968.

In compliance with Public Law 93-82, Part I of this contract provides for

> the conduct of an extensive review and appraisal of personnel and other resource requirements in VA hospitals, clinics and other medical facilities to determine a basis for the optimum numbers and categories of such personnel and other resources needed to insure the provision to eligible veterans of high quality care in all hospitals, medical domiciliary and nursing home facilities.

A Committee on Health Care Resources in the VA was established within the Assembly of Life Sciences to carry out the review specified in the first part of the contract. The two parts of the contract therefore were conducted as independent but closely associated efforts.

The Committee on Biomedical Research in the VA began its work by seeking opinions about the issues it should address in its study from people inside and outside the VA who had some knowledge of the VA's research program.* Data

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* A list of the individuals and groups testifying to the Committee and a summary of their views and opinions is given in Appendix A.

were collected from Central Office and visits were made to VA hospitals, clinics and support centers involved in research. The visits included evaluation of the quality of the research, and its management and impact on patient care. The Committee also carried out two adjunctive studies. The first was an analysis of the VA's bibliography. Citation analysis was used to assess VA publications in conjunction with a peer review process to validate the methodology. Concern about the use of human subjects in research led to the second adjunctive study. Patients participating in research protocols and the investigators responsible for the research were interviewed. The major aims of the study were to gauge patients' understanding and satisfaction with their involvement in research and evaluate the procedures used to protect the patients' rights and welfare.

The Committee is pleased to acknowledge the willing and courteous cooperation of VA staff. It is grateful to the chief medical director, the assistant chief medical director for research and development, the director of medical research and their staffs for their ready response to its requests. Special thanks must go to the staffs and patients of VA hospitals and clinics, where visits and activities caused considerable disruption. The Committee appreciates their interest and their willingness to assist its efforts. The Committee is indebted to the individuals and groups who presented their views to the Committee at the beginning of its work, and to the many scientists and physicians who contributed to this report. It would like to acknowledge Dr. Arnold Relman, who served with the Committee in the initial stages of the study (March-December, 1974). The Committee is espe-

cially grateful to those people who gave their time and effort to take part in the site visits. A list of the scientists and physicians who served as consultants to the Committee can be found in Appendix B.

ABBREVIATIONS USED IN THE REPORT

ACOS	-	Associate Chief of Staff
AI	-	Associate Investigator
BSSR	-	Bureau of Social Science Research
CDP	-	Career Development Program
CI	-	Clinical Investigator
CSP	-	Cooperative Studies Program
DM&S	-	Department of Medicine and Surgery
FY	-	Fiscal Year
HSC	-	Human Studies Committee
ISI	-	Institute for Scientific Information
MI	-	Medical Investigator
NAS	-	National Academy of Sciences
NCI	-	National Cancer Institute
NIH	-	National Institutes of Health
NIMH	-	National Institute of Mental Health
NRC	-	National Research Council
OMB	-	Office of Management and Budget
RA	-	Research Associate
R&D	-	Research and Development
RRAG	-	Regional Research Advisory Group
SCI	-	Science Citation Index
SMI	-	Senior Medical Investigator
VA	-	Veterans Administration
VA Care	-	NAS/NRC Committee on Health Care Resources in the VA

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CHAPTER 1

SUMMARY AND RECOMMENDATIONS

SUMMARY

The Committee unanimously and enthusiastically supports the independent funding in the VA of an intramural research program because:

- The VA offers a unique opportunity to carry out a wide variety of clinical studies involving a distinct patient population in a large number of hospitals under a single management.
- A high quality research program with its attendant focus on inquiry and creativity fosters an environment conducive to professional excellence in health care delivery.
- The overall national biomedical research effort will be more effective if the current pluralistic system of funding is maintained. Such a system prevents any single agency from monopolizing the nature and direction of research.

The Committee believes that the VA has made important contributions to medical science through its research program* and was impressed by some of the current special research programs, especially the career development and and cooperative studies programs. However, although the Committee's site visits showed that most investigators funded through institutional research

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* See Appendix C for a listing of some of the VA's most significant research accomplishments.

programs were carrying out research that was of acceptable quality or better, a sizable number were carrying out research of unacceptable quality. Similarly, a comparison with biomedical research outside the VA through bibliographic analysis confirmed that a sizable fraction of VA research is of less than satisfactory quality. The Committee has identified a number of problems and deficiencies compromising the program's effectiveness and productivity. Two generic problems surfaced repeatedly throughout the Committee's studies.

- The lack of a consistent Central Office policy to ensure that standards of excellence are uniformly applied in the review and approval of research programs.
- The difficulties and conflicts that are a consequence of merit review based on the excellence of the research effort in a system in which both professional and technical staff appointments are based on seniority and job security.

Despite these difficulties, the Committee believes that by instituting the recommendations it proposes the quality of the VA biomedical research program can be enhanced and the unique opportunities inherent in the VA system for contributing to the national biomedical research effort can be exploited more fully.

The Committee gives the highest priority to four recommendations. The first three are aimed at improving the overall quality of VA research:

- All individual investigator projects should be reviewed for merit regularly by Central Office merit review boards.

- Programs disapproved by these boards should not be funded except for phase-out support.

The Committee is convinced that the opportunity to do research is crucial in recruiting staff able to provide high-quality patient care. However, the VA's mission is not served by using research funds primarily for the purpose of retaining staff for their clinical or administrative contributions.

- Continuing research support should be provided to investigators only when their research is of high quality. Research funds should not be used to retain staff or to reward clinical skills and contributions.

The Committee's fourth major recommendation deals with the focus and direction of the VA research program. Because one of the most valuable contributions of the VA research program involves the character of its patient population and their health problems, the VA research effort should be oriented more closely toward the health problems prevalent among veteran patients and exploit the VA's unique resources for research to the fullest. With a few exceptions, these health problems are the same as those of the rest of the male population of similar age. Thus the benefits to be derived from concentrating on such problems would have applicability well beyond the veteran patient population per se.

- To provide the direction needed to ensure the best possible use of VA research opportunities, an advisory council should be established. The council should recommend priority areas, scope, and major policies for VA research and research training programs.

The Committee's recommendations are now presented in full under seven headings. These recommendations are discussed in more detail in Chapter 8. Other chapters of the report describe the VA's research program and present the findings of the Committee's study. Less general recommendations are made in these chapters, and they are italicized and discussed where they occur.

RECOMMENDATIONS

Objectives of Biomedical Research in VA Hospitals

The Committee recommends:

A. An advisory council should be established to recommend the priority areas, scope, and major policies for VA research and research training programs. Members of this council should be persons from outside the VA.

Policies, Organization and Management

The Committee recommends:

A. All research programs supported by the VA should be reviewed regularly by merit review boards. These boards should be comprised primarily of scientists who are not salaried by the VA.

B. Research should be funded in accordance with the recommendations of these merit review boards as far as it is possible within the financial means of the VA Central Office.

C. Programs disapproved by merit review boards should not be funded except for phase-out support. However, investigators should be informed of the reasons for the disapproval and allowed to resubmit proposals without prejudice.

D. Merit review boards should assess the research setting at the particular VA hospital when evaluating research programs, because environment is important in assuring high-quality investigation.

E. Discretionary funds should be allocated to a VA hospital to provide for research administration, common resources, and the support of exploratory or pilot projects, as well as the initial support of new investigators' research. These funds should not be used for the support of disapproved projects.

F. VA Central Office should examine the management of non-VA research funds awarded for research carried out in VA hospitals and take measures to ensure that appropriate support is provided for VA resources and facilities.

G. The impact of research programs on patient care services (e.g., clinical laboratory, nursing, radiology, supply,and engineering) should be recognized. If these services require expansion to shoulder extra work imposed by research, additional resources should be provided.

H. VA health professionals from the services just described should share in the deliberations of the hospital's research committee, especially if they are expected to carry out research procedures.

I. Evaluative methods should be developed by the VA Central Office to gauge the quality of the VA's research effort and its relevance to the VA mission. Evaluations should signal management difficulties and program needs. Policy changes recommended by the advisory council should be based on these evaluations.

J. Additional staff and resources will be required at the VA Central Office to implement the foregoing recommendations.

Recruitment and Retention of Staff

The Committee recommends:

A. Research funds should be provided as a recruitment incentive only to clinical and biomedical investigators expected to produce high quality research.

B. Continuing research support should be provided only for investigators when their research is of high quality. Research funds should not be used to retain staff or reward clinical skills and contributions.

Research Career Development

The Committee recommends:

A. Career development awards should be provided preferentially to qualified persons in VA hospitals with a closely affiliated medical school where both institutions have highly productive research programs.

B. Recipients of career development awards should have laboratories in the VA hospital, and qualified VA hospital staff investigators should serve as their preceptors.

C. The policy of review and selection of all career development program awardees by a non-VA committee should be continued.

Influence of Research on Patient Care

The Committee recommends:

A. Because poor quality care cannot be improved simply by adding a research program to a hospital, research funds should not be provided

primarily with this intent.

Medical School Affiliation

The Committee recommends:

A. A strong affiliation between a VA hospital and a medical school with demonstrated interest and competence in biomedical research ordinarily should be required as a basis for a research program at that hospital.

B. Except in unusual circumstances, research programs should not be instituted or maintained at VA hospitals unaffiliated with medical schools unless the program in these hospitals is centrally initiated and directed.*

C. The VA Central Office should develop means for evaluating and monitoring the strength and quality of an affiliation between a VA hospital and a medical school.

D. On the basis of this evaluation, affiliations between medical schools and VA hospitals should be continued or established only when this arrangement is deemed to be mutually supportive.

Influence of Research on Patient Welfare: Ways to Ensure Protection of Human Subjects

The Committee recommends:

A. The VA should continue to accept the guidelines of the Department of Health, Education and Welfare as the basis for assuring protection of veteran patients who are subjects of experiments.

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* Throughout this report, "central" or "centrally" means not only Central Office, but any individual, group, or facility designated by the Central Office to oversee a particular activity and the investigators involved.

In addition,

B. Each VA hospital should have its own human studies committee separate from that of its affiliated medical school.

C. The membership of the human studies committee should not overlap with that of the research committee and it should have representation of both lay and professional people.

D. Human studies committees in VA hospitals should establish a procedure for monitoring compliance with the guidelines for the protection of veteran patients.

E. VA hospitals should establish a grievance procedure for experimental subjects.

CHAPTER 2

DEVELOPMENT AND CURRENT STATUS OF THE VA RESEARCH PROGRAM

DEVELOPMENT OF THE PROGRAM

At the end of World War II, the VA was faced with the enormous task of expanding its facilities and improving the quality of its medical care delivery to accommodate the large number of newly eligible veterans. The concerns and effective lobbying of a number of VA officials and private citizens led to the passage of legislation designed to improve the quality of medical care in VA hospitals. Public Law 79-293 was signed by President Truman on January 3, 1946, creating the Department of Medicine and Surgery (DM&S) as one of three major departments within the VA. The DM&S was to be administered by a physician with the title of chief medical director, directly responsible to the Administrator of the VA and supported by, among others, an assistant chief medical director for research and education.* In creating this last administrative position, the early legislation acknowledged the importance of both research and education and their contributions to patient care.

Army Major General Paul Hawley, M.D., and Paul Magnuson, M.D., were the first individuals to assume the posts of chief medical director and assistant chief medical director. They initiated a plan for affiliating

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* Research and education has now been split into two branches: research and development (R&D) and academic affairs.

VA hospitals with medical schools that became VA policy* on January 30, 1946. Under this plan, which involved establishing a dean's committee for each affiliated hospital, medical schools would assist the VA in recruiting qualified staff capable of providing the high-quality medical care necessary after World War II. The affiliations brought many medical school faculty into VA hospitals to treat patients. Many of these faculty already were engaged in research and their example stimulated VA staff to similar activities. Many of the staff recruited to the VA by the dean's committees were attracted by the opportunity to combine research and teaching with patient care responsibilities. Finally, with the alliance of VA hospitals and medical schools came the development of an intellectual milieu in which the pursuit of answers to medical problems through research was encouraged.

VA research received its first impetus when a group of former World War II army officers--including Drs. Michael DeBakey, Charles Mayo, William Middleton, and Barnes Woodhall--began studies to follow-up the various diseases and disabilities from which servicement suffered. At first, most research was contracted out to universities and other institutions, partly because of the VA's lack of facilities and resources. This contract research initially was performed under the aegis of the NRC Committee on Veterans

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* VA DM&S Memorandum No. 2, January 30, 1946: Policy in Association of Veteran Hospitals with Medical Schools.

Medical Problems. Eventually the NRC established the Medical Follow-Up Agency to conduct follow-up studies of the diseases and disabilities of ex-servicemen.

During the 1950's, intramural research matured and became quite diversified until contract research accounted for only a minor part of the total program. Until 1958, the VA operated its medical research program under a general authority supported by several legislative actions of the Congress. In 1955, Congress began to appropriate funds specifically for VA research and on September 2, 1958 gave statutory recognition to the research program with the passage of Public Law 85-857. The law states that

> The functions of the Department of Medicine and Surgery shall be those necessary for a complete medical and hospital service, including medical research, as prescribed by the Administrator pursuant to this chapter and other statutory authority for the medical care and treatment of veterans. (underlining ours)

In 1966 such recognition was extended to education with the passage of Public Law 89-785.

Over the years the VA research program has supported the efforts of many individual investigators and groups. A special form of research, the cooperative study, was recognized as being particularly well suited to the VA.* The first (and very successful) cooperative study, an investigation

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* A cooperative study is a particular form of collaborative research in which two or more hospitals are involved; a common protocol is used in all the hospitals in the study. The cooperative studies program is discussed in Chapter 5.

of the effectiveness of chemotherapy for tuberculosis, was initiated in 1946 at the onset of the VA research program. Today as then, the VA continues to be the agency of choice for conducting cooperative studies. In 1956, the VA added another facet to its research enterprise, the career development program.*

Funding for VA research has grown from a modest $1.4 million in fiscal year (FY) 1947 to over $85 million in FY 1975. Table 2-1 lists these changes in funding over the years. After a period of rapid growth between 1956 and 1961, funding increased by about 7-10% per year until very recently. There will be no increase in funding in FY 1976 and 1977.

The program has grown into an enterprise that produced more than 6,000 scientific publications in 1974. It can be credited with a number of outstanding contributions to the diagnosis and treatment of disease. A partial listing of the most outstanding accomplishments in the program's 30-year history makes up Appendix C.

CURRENT ORGANIZATION OF THE PROGRAM

The organization of the VA's biomedical research program is shown in Figure 2-1. The program falls within the VA's Department of Medicine and Surgery and is headed by the assistant chief medical director for R&D. He

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* The career development program allows exceptional individual investigators to devote most of their time to research. This program is discussed in Chapter 4.

TABLE 2-1

Funding for VA Research[a]

Fiscal Year	Total VA and non-VA monies $ in thousands	VA research appropriations $ in thousands	Non-VA monies $ in thousands	Non-VA funds as % of total
1947	-	$ 1,400	-	-
1956	$ 6,939	5,379	$ 1,560	22.5
1960	21,901	17,344	4,557	20.8
1965	45,750	36,508	9,242	20.2
1970	77,710	57,320	20,390	26.2
1971	82,640	61,190	21,450	26.0
1972	87,640	64,800	22,840	26.1
1973	98,460	73,210	25,210	25.6
1974	-	78,430	-	-
1975	$117,470	$85,330	$32,140	27.4

[a] Data from budget staff, DM&S, VA Central Office.

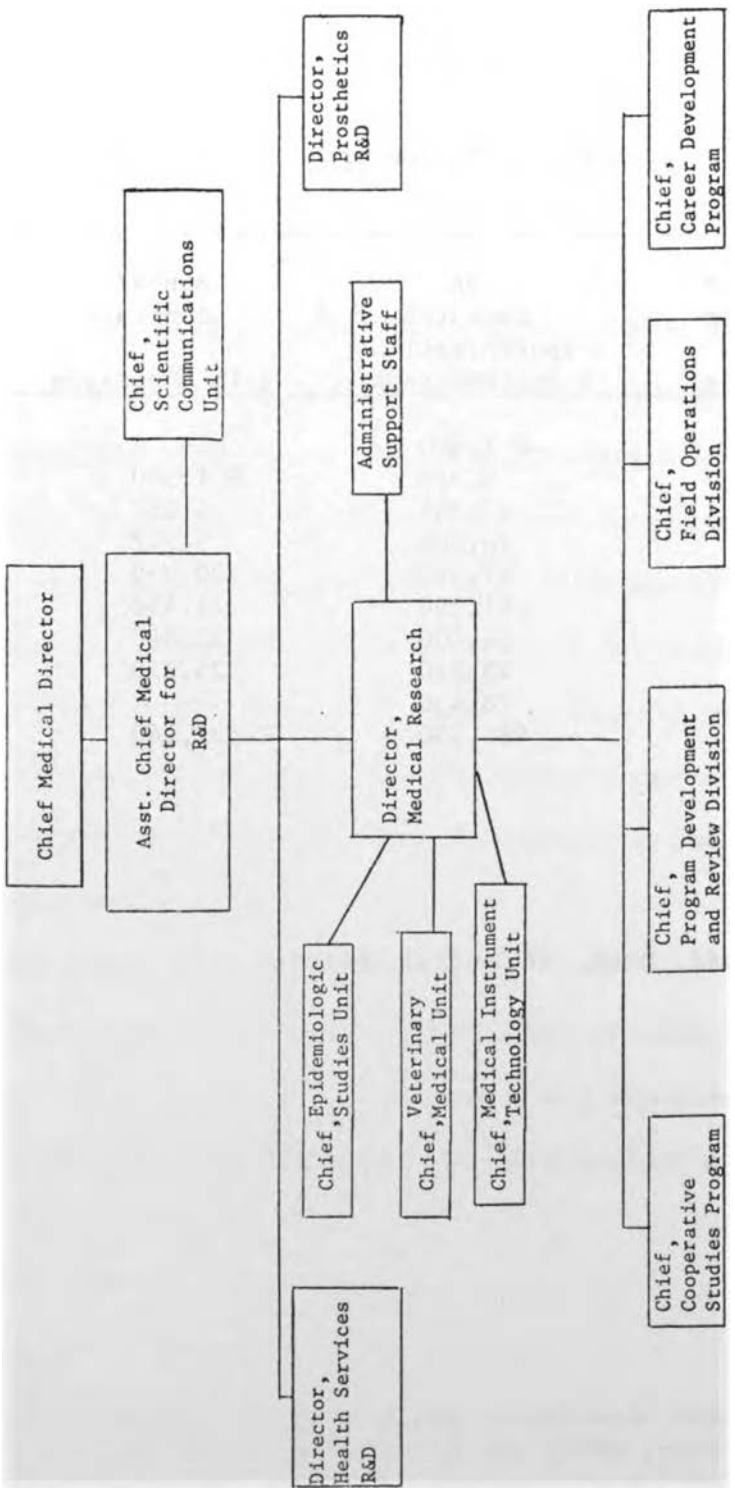

FIGURE 2-1

Organizational Chart of the VA Biomedical Research Program

is responsible to the chief medical director and ultimately to the Administrator of the VA.

As shown in Figure 2-1, the research program has three branches: prosthetics R&D, health services R&D, and medical research. The prosthetics program was not reviewed by the Committee. The health services R&D program is only in embryonic form and although some comments are made in this report relating to the program, it was considered premature and outside the expertise of the Committee to review it in detail. Thus the main focus of the Committee's activities has been the medical research program.

The medical research service allocates its resources in two ways. Most of the money is allocated to hospitals and clinics directly and these institutions have some authority to distribute the funds they receive. These so-called institutional funds account for about 75% of the total medical research budget. Other funds are given to investigators or groups directly and these are known as special research funds. Table 2-2 shows the medical research budget in FY 1976. A sum of $69 million was allocated for institutional funding in FY 1976, and $18 million was designated as special research funds.

The institutional research funds are allocated to a hospital or clinic for the support of individual investigators, common resources and administration. It should be noted here that the Central Office's merit review boards determine part of a hospital's budget because they recommend monies to be given to projects of individual investigators at that institution. These boards and their recommendations are coordinated by the program development

TABLE 2-2

VA Biomedical Research Program
Budget Breakdown for FY 1976[a]

Item	Funds Available	
Institutional Research		
VA Central Office	$ 680,000	
Field stations	67,262,504	
Reserve for one time needs and emergencies	935,261	
Total Institutional Funds		$ 68,877,765
Special Research		
Special labs or programs	1,064,845	
Centers for research on aging	750,000	
Cooperative studies program	6,500,000	
Career development program	9,250,000	
Other designated research	90,000	
Total Special Research Funds		17,654,845
Employee travel		964,000
Equipment for construction projects		1,000,000
PROGRAM TOTAL		88,496,610

[a] Data provided by medical research service, VA Central Office, January 1, 1976.

and review division whose chief is responsible to the director of the medical research service. Another major division shown in Figure 2-1 is the field operations division, which deals with much of the day-to-day communications between Central Office and the field, as well as the daily operation of the medical research program. The determination of a hospital's research budget is examined later in this chapter.

The two largest programs in the special research category are the career development program and the cooperative studies program, receiving approximately 11% and 7% of the total research funds, respectively. Each of these programs has a chief who administers the program. As shown in Figure 2-1, the chief is responsible to the director of the medical research service.

The other categories designated as special research are much smaller in size and are handled by the director of medical research service. They are usually programs for which the VA has a special need, such as an automatic data processing laboratory. VA efforts to investigate or develop new programs also are considered special research, e.g., centers for research on aging.

Figure 2-1 illustrates that a number of units oversee a specific aspect of research common to all the program elements. For example, the scientific communications unit is located in the office of the assistant chief medical director for R&D. This unit receives a variety of data from the field concerning research (including medical, prosthetic, and health service research), and compiles reports on VA research activities, including its annual report to Congress. The veterinary medical unit, within medical research service,

monitors animal facilities in the system, recommending the construction of new facilities and advising on appointments of veterinary consultants. The medical instrument technology unit advises the Central Office when new equipment is required and when it can be transferred. Finally, the epidemiologic studies unit carries out epidemiologic studies based on data from VA patient care records. Thus, Figure 2-1 summarizes the structure of the program at the Central Office level. There are several committees and individuals who advise the Central Office itself and their roles are discussed in the succeeding sections where policies and decision making are explained.

At the local level, the program is organized so that each institution receiving research funds has an associate chief of staff (ACOS) for research (in smaller programs this person may also be the chief of staff). An individual investigator is responsible to the ACOS for his research whether he receives institutional or special program funds. The ACOS is the intermediary between the investigator and the Central Office; he must administer the program and attend to the needs of investigators. He is advised in this by a local research committee and its various subcommittees. In the local institution, the ACOS is responsible to the chief of staff and ultimately to the hospital director.

OVERVIEW OF RESEARCH POLICIES

The VA was given a legislative mandate for research in Public Law 85-857. The objectives of the research program are based on this law and are

stated as follows:*

a) The mission of the Department of Medicine and Surgery is to provide the best medical care for eligible veterans.

b) Provision of the best medical care includes the obligation to support and encourage medical research.

Over the years, there has been debate about how research could best support the VA's patient care mission. For example, policies have fluctuated between the use of research funds to recruit and retain staff or only for the support of high-quality research. Similarly, a research project's relevance to the problems of VA patients as a determinant in receiving support has waxed and waned. Outside pressures as well as the frequent turnover of personnel at Central Office are responsible for these changes in policy.

Influences on Policy Makers

As a federal agency providing health care to a particular constituency (veterans), the VA is subject to considerable pressure from the constituency. Their concerns are heard through the veteran service organizations and through the congressional committees on veterans' affairs. These groups try to ensure that the program carries out research of special benefit to veterans and that the rights and safety of patients involved in research are

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* VA DM&S Manual M-3, Research and Education in Medicine, Part I, Revised April 2, 1962.

protected. Influence of another kind is exerted on the program through the Office of Management and Budget's (OMB) control of the purse strings. In addition to these external bodies, VA policies must also take into account the views and needs of VA field staff and the medical schools affiliated with VA hospitals. Any policies made at the Central Office are subject to the willingness and ability of the field staff and the affiliated medical schools to implement them.

Policy Makers

There is no high level advisory committee that sets policy for the research program. A special medical advisory group exists that advises the chief medical director on DM&S policies and this group has a subcommittee on research. The subcommittee was established to oversee the research program. However, in recent years it has given little guidance on the direction or focus of the program.

Much of the major policy making, then, is done by three key persons at the Central Office: the chief medical director, the assistant chief medical director for R&D, and the director of medical research service. In the last few years, the turnover of people in these positions has been rapid and each person has brought with him a different view of VA policies. This turnover of personnel, along with the external pressures on the VA, has led to continuous changes in policy and considerable confusion among those who have to implement these policies in the field.

Major Policies

The current major VA research policies will be described briefly; some of them are incorporated into written policy statements, whereas others have been expressed to the Committee by Central Office staff.

The VA stresses that its research program is not a system of extramural grants, but an intramural program "designed with its first priority to support research activities of full-time VA staff."* This same circular goes on to say that "emphasis ... must be on channeling VA research funds and facilities to investigators who have a major commitment and provide a major contribution to the care of veteran patients." Stated more succinctly, Central Office policy is to support the investigator more than the project. The Central Office considers research programs relevant to the VA mission if they satisfy the following criteria:

- The investigator plays an important role in the hospital apart from his own research (e.g., he is active in patient care, or administration, or supports other research).
- The project is clearly directed to the solution of a problem of major importance to the veteran patient.
- The research has a high likelihood of making a major contribution to medical science, although the problem is not unique to the veteran patient.

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* A VA telegraphic circular, January 7, 1971.

These guidelines are interpreted at several different levels because a second important policy is one of considerable decentralization in the allocation and management of research resources. This policy is justified by the view that local institutions should be able to judge better the importance of the investigator and his research to the hospital's mission than Central Office staff or some distant review board. VA policy does emphasize that its research program is designed to foster research of high-quality, but the relevance of an investigator or project to the particular institution or to the VA as a whole must be taken into account.

Other important attributes of the program that the VA recognizes as principles and objectives are stated in the M-3 policy manual:*

> The benefits of medical research are both direct and indirect. Better diagnostic and therapeutic measures are direct and tangible benefits which can be developed only through research. Equally important to veteran-patients is the attraction research holds for the finest physicians and allied professional personnel, drawing them to the VA medical program.

Recently these policies have been modified: less emphasis has been placed on the use of research funds for recruitment and retention in order to focus on the quality and relevance of the research itself. Nonetheless, recruitment and retention as well as use of research funds to encourage the development of a scientific milieu and strengthen medical school affiliations still are important facets of VA research policy.

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* VA DM&S Manual M-3, Research and Education in Medicine, Part I, Revised April 2, 1962.

Other than these broad outlines, the VA has not made plain the overall direction the program should take. For example, no policy has been determined on suitable topics for research, although it is generally assumed that they should be associated somehow with the problems of VA patients. What proportion of the program should be devoted to basic science and basic scientists, rather than applied science, or what amount of funds should be directed into specific areas of inquiry rather than independently conceived research are not spelled out in policy statements. It is acknowledged that a balance in each discipline or type is appropriate but the balance itself is determined on the basis of empirical judgment of Central Office staff and the previous history of the program, and not by clearly defined policies or decisions.

INDIVIDUALS AND GROUPS DETERMINING OPERATIONAL PRACTICES

The Central Office

Many of the day-to-day managerial decisions in the research program are made by Central Office staff. The research service is, however, advised on operating policies by a research advisory committee. This committee is composed of senior VA staff from field hospitals (including investigators salaried from the program or from patient care, chiefs of staff, and hospital directors). They usually have considerable knowledge about the research program and play an important role in advising the Central Office, especially in acquainting the Central Office with the views of field staff.

Both the cooperative studies program and the career development program have their own evaluation committees to recommend which studies or individuals should be approved for support. There are also merit review boards

for 15 subject areas to evaluate all individual investigator projects requesting over $25,000 a year in research funds. Apart from the career development program committee, which is composed only of experts from outside the VA, these review boards and committees are comprised of both VA and non-VA personnel. The Central Office also is advised by a group of VA investigators who are appointed as program specialists. The tasks of this latter group are to oversee one particular research area, keep the Central Office informed about the work being done in that subject area, and when necessary, recommend on funding levels for investigators within their area. At this time, there is a program specialist for each of 24 disciplines.

The Local Hospitals

Although the Central Office initiates policy and allocates research funds, considerable autonomy and flexibility exist at the local level. Funding and other resource allocation is the responsibility of the hospital's research committee and is handled administratively by the ACOS. In theory, the ACOS carries out the research committee's recommendations, but in practice he oftens has strong influence on the committee and considerable discretion in carrying out the committee's recommendations. The research committee usually is made up of clinical staff and investigators at the hospital. Where the research program is large, often several subcommittees are assigned to oversee animal facilities, space allocation, scientific review of projects before they are sent to the Central Office, and scientific review of smaller projects with locally determined support. Whenever research on humans is involved, these projects have to be approved by a human studies committee.

The hospital director and the chief of staff strongly influence the research program. The hospital director is ultimately responsible for what takes places in his facility, and he must be willing to make space available for research and allow physicians time to carry it out. Another influence at the local level is the affiliated medical school, which acts through its dean's committee and the VA staff members who have academic appointments. The importance the medical school places on research has a major effect on the quality of the VA hospital's research program and on the policies implemented at the local level.

FISCAL MANAGEMENT

The fiscal management policies of the research program have changed dramatically and frequently. Several years ago, the research service operated a system in which, apart from special research funds, each institution was allocated funds in two parts. The first part consisted of funds for individual investigators based on the review their project had received at Central Office. The second part provided funds for administration and common resources; it also included some extra money that could be used discretionarily at the local level, e.g., for funding first projects of new investigators. The size of the second allocation was determined by site visits or the Central Office before the hospital received a visit. In 1972, this system was swept away and replaced by a much more flexible system, in which the local institution had total control over review of projects and fund allocation. At present, the research program has settled into an intermediate system. Only projects requesting $25,000 or more per year have to

receive peer review at the Central Office level, but the local institutions still have considerable flexibility in fund allocation. The present management procedures will now be described in more detail.

Budget Allocation

The Central Office allocates funds to an institution for use in special research programs, administrative and common resource support, and individual investigator projects. Apart from special research programs where the funds are specifically designated (e.g., the career development program), the local institution can allocate its funds as it sees fit. As the guidelines state, "the [local hospital] research committee should allocate funding ... in accordance with its judgment as to the distribution that will best meet the needs of the hospital in support of the patient care, educational and research objectives that the program serves."*

The number of projects sent in for merit review varies according to the confidence the local research committee has in its own ability to carry out a satisfactory peer review. Some hospitals send in all projects for review, even programs requesting less than $25,000 per year. Other hospitals feel their local peer review is good and only send in the projects over $25,000 per year that Central Office requires to be reviewed by its boards.

The situation is best illustrated by following the course of an individual investigator's project. The investigator submits his project to the

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* VA Research Service Circular, March 5, 1975.

local research committee. If it is approved by them and if he is requesting more than $25,000 per year, the project is forwarded for merit review to one of the 15 subject area review boards at the Central Office. After reviewing a project, a merit review board makes a funding recommendation. The Central Office uses these recommendations to decide on the amount of funding to be given to a hospital. Central Office arrives at the total budget for a hospital by adding all the monies granted for projects reviewed by the merit boards to allowances for locally reviewed projects. Amount of funds for locally reviewed continuing projects usually are based on previous funding and on some judgment by the Central Office or program specialists about what is a reasonable allotment. Funding for new projects under $25,000 also is evaluated by the Central Office or program specialists.

The investigator whose project has been reviewed for merit may not receive the recommended amount. If the local research committee and/or the ACOS feels he deserves it, they may give the investigator more than the recommended amount by taking funds from common resources or from other investigators within the general research budget. Or, the local institution may give the investigator fewer funds and give the remainder to some other investigator or apply it to common resources. The only limit to the institution's flexibility is that it may not spend more than the total funds given to the hospital by the Central Office.

By permitting some local control, the VA feels it takes into account the quality of the research and the relevance of the project or investigator to the VA hospital's patient care mission. A second policy that distinguishes

the VA procedures from a strict merit system is that funds are sent to the hospital to cover 75% of the amount required the previous year for any project that the merit review board disapproved for funding. The second year 50% is sent, and if the project still has not been approved by merit review in the third year, no funds are provided, although the local hospital is still at liberty to fund the investigator if it so desires. The gradual phasing out of funding is designed to allow an investigator an opportunity to improve. It also means that an important staff member is not likely to lose all of his research funds after one review.

Table 2-3 is a breakdown of the numbers of individual investigators funded in FY 1975, excluding those receiving special research funds. Over 1,000 investigators had projects that had undergone Central Office merit review. Half of these investigators were funded at less than $25,000 in FY 1975, either because the local institution had sent in projects of less than $25,000 for review or because the amount requested was reduced to less than $25,000. Only 32 investigators funded at more than $25,000 had not been reviewed at Central Office. Most of these investigators' projects had been reviewed on site visits in 1972 before the institution of the present system, and therefore were deferred until 1976 for review. There is reason to believe that most of these projects now have been reviewed. The Central Office recently said that it has become much stricter about funding of projects over $25,000 that have not been through merit review. The tables does not indicate how many investigators received funds for projects which have been reviewed and disapproved.

TABLE 2-3

Number of Investigators Funded[a] in FY 1975[b]

	No. with Projects Merit Reviewed at Central Office	No. with Projects Not Merit Reviewed at Central Office	Total Investigators
Receiving > $25,000 (FY 1975)	538 (31%)	32 (2%)	570 (33%)
Receiving < $25,000 (FY 1975)	524 (30%)	642 (37%)	1,166 (67%)
TOTAL	1,062 (61%)	674 (39%)	1,736 (100%)

[a] Number of investigators shown include those receiving institutional funds but not those supported by funds from special research categories.

[b] Data from medical research service, VA Central Office.

Contingency Funds

In the two-part system, some funds were allowed as seed money for new or younger investigators. Under the present system, it is becoming increasingly difficult to put money aside for this purpose. The Central Office's response to this need in the present system was to institute four regional research advisory groups (RRAG's). Hospitals may send requests to these groups for additional research funds of an "emergency or nonrecurring nature," for instance, for a new staff member to initiate his research program or for urgently needed new or replacement equipment. These groups meet bimonthly and so are considered to respond to the immediate material and personnel needs that cannot be met through the annual budget. Although requests to RRAG's for research funding are encouraged during the recruitment of staff in important hospital positions (e.g., chiefs of service), RRAG's usually only consider requests once the investigator has been recruited to the VA. Thus, for most investigators, research funding cannot be guaranteed before they enter the VA system.

Non-VA Research Funds

In FY 1975, VA investigators were recorded as receiving $32 million in non-VA funds, and a large part of this came from the National Institutes of Health (NIH).* These funds can be administered by the investigator's VA

*The Committee found the data on non-VA funding to be extremely inaccurate. Some investigators do not wish the Central Office to know how much they receive in non-VA funding for fear of losing VA funds. It also became clear on the site visits that many more investigators regard the VA's reporting system as burdensome and so make little attempt to provide Central Office with accurate data.

hospital or, if the investigator has an academic appointment, they are often administered by the affiliated medical school.

Under the VA policies that have been discussed here, funds were distributed to 129 VA institutions with research programs. As shown in Table 2-4, the hospitals receiving the larger monies for research tend to be ones with strong medical school affiliations, and they usually are located in metropolitan areas. Such institutions receive 70% of the VA's total research funds. As the table indicates, very few neuropsychiatric hospitals receive substantial amounts of VA research funds. Table 2-5 shows the distribution of non-VA research funds among the groups of hospitals receiving VA funds. The hospitals that receive 70% of VA research funds also receive 76% of the non-VA funds. In total, 87 VA hospitals were receiving support from sources outside the VA.

MANAGEMENT OF PERSONNEL AND OTHER RESOURCES

Many resources needed for research but not provided by the research service itself are available to investigators through the patient care program. For example, the medical care of patients on research protocols is paid for by the medical care budget unless the patient is hospitalized specifically for research purposes. The salaries of physician-investigators on the hospital's staff come from the patient care budget, and a number of other resources naturally are available because of the hospital setting. This indirect support is considered perfectly appropriate because research is seen as an integral part of the patient care mission.

TABLE 2-4

Distribution of VA Funding to VA Hospitals in FY 1975[a]

Type of Hospital	Level of VA Funding	No. of Hospitals Receiving This Level of Funding[b]	Total VA Funding to Group
General medical and surgical	$1 million or more	34 (34)	$61,001,340
Neuropsychiatric		1 (1)	1,106,080
General medical and surgical	$500,000 to $1,000,000	22 (19)	16,257,300
Neuropsychiatric		1 (1)	611,540
General medical and surgical	$100,000 to $500,000[c]	23 (19)	6,475,530
Neuropsychiatric		5 (4)	1,567,860
General medical and surgical	Less than $100,000	26 (14)	1,135,560
Neuropsychiatric		17 (6)	513,220
TOTAL		129	$88,668,430

[a] Data provided by budget staff, DM&S, VA Central Office.

[b] Figure in parentheses indicates number in group with a medical school affiliation; this affiliation may be nominal in some cases.

[c] Includes two outpatient clinics.

TABLE 2-5

Distribution of Non-VA Research Funding in FY 1975[a]

Type of Hospital	Level of VA Funding	Total non-VA Funding	No. of Hospitals In VA Funding Level	No. of Hospitals Receiving Non-VA Funds
General medical and surgical	$1 million or more	$24,205,880	34	34 of 34
Neuropsychiatric		90,750	1	1 of 1
General medical and surgical	$500,000 to $1,000,000	5,538,750	22	20 of 22
Neuropsychiatric		None	1	None of 1
General medical and surgical	$100,000 to $500,000	2,051,230	23	21 of 23
Neuropsychiatric		131,790	5	4 of 5
General medical and surgical	Less than $100,000	49,640	26	3[b] of 26
Neuropsychiatric		69,150	17	4[b] of 17
TOTAL		$32,137,190	129	87[b] of 129

[a] Data from budget staff, DM&S, VA Central Office.

[b] Includes one hospital receiving no VA research funds.

A major implication of these arrangements is that considerably more than $88 million earmarked for medical research in FY 1976 actually is being used for research. The arrangements described also point out that a balance must be achieved between research and patient care needs. It is possible that research may suffer because it must be subordinate to patient care needs, yet the possibility also exists for research to overburden patient care resources. Conversely, it should be noted that research may provide patients with access to some physicians and highly-specialized patient care technologies that might not have been available otherwise.

Personnel

Professional staff. In general, the research service does not pay the salaries of principal investigators. Most of them are physicians and dentists with staff positions and therefore salaried from the patient care budget.* Exceptions are the group of 175 investigators in the career development program and the group of 262 investigators salaried from research service, who are almost all Ph.D.'s.+

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* In April 1975, 1,736 investigators received institutional research funds, of whom only 262 were salaried from research. The Central Office records a total of 3,256 investigators in the research program as a whole, but this figure includes co-investigators on projects and investigators in special research programs.

+ Figures from medical research service, VA Central Office for FY 1975.

Most of the Ph.D.'s are either clinical psychologists are biochemists. In either case, the Central Office generally does not approve their appointments. Most of these people are recruited at the Civil Service GS-13 level or below, and Central Office approval is not needed until the GS-14 level. Therefore, it is at the discretion of the local hospital to decide whether it wishes to support Ph.D. scientists. However, many of the Ph.D. investigators could be categorized as basic scientists, and VA policy guidelines exist for the employment of basic scientists:

> [b]asic scientists may be supported as investigators in the VA facilities if their programs have an impact on the patient care mission of the VA. For example, this may result from direct consultation on clinical or laboratory problems: or from collaboration with clinicians so as to stimulate and facilitate the effectiveness of the research team; or from significant contributions to the educational and training programs at the station; or from research accomplishments of such outstanding merit that they bring credit upon the VA. *

Although Ph.D. scientists salaried from the research budget may have some clinical or administrative duties, their primary responsibility is to do research. Career development program investigators also are allowed to devote 75% of their time to research. However, the investigators with clinical appointments, who make up the majority of the program, have to find time for research while simultaneously carrying out their clinical responsibilities. How much time the investigator spends on research depends on the

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* VA Telegraphic Circular, July 1, 1971.

investigator's enthusiasm and on the attitude of the chiefs of service and hospital director towards research in their institution.

Support staff. Under Civil Service procedures, technicians can be hired for research in one of four categories: temporary (120 days); part-time; term appointment (one to three years, renewable for a fourth year); and permanent (tenure acquired after a six-month probationary period). Many technicians in the system have permanent Civil Service tenure. As a result they have to be transferred to another research project or onto the hospital's patient care rolls when their project ends. A large proportion of the VA research budget today is committed to the salaries of technicians with Civil Service tenure. Until recently the VA was limited to 1,000 term employees; this ceiling has now been lifted to 2,000. It is expected that hospitals will hire more technicians on term appointments when new technicians are recruited.

Space

Since the hospital director is responsible for allocating space, his attitude towards research is a major determinant of whether the research service gets adequate and suitable space. The VA has no policy on how much space should be given to each investigator (except guidelines for the construction of new facilities), and it is the ACOS and research committee at each hospital who resolve the needs of each investigator with the amount of space available.

Although research space is being included in newly constructed VA hospitals, there have been no construction funds for research facilities per se

in recent years. Permission to build two facilities has been given by Congress and these contructions have begun, but the construction of several other important facilities that have not received congressional attention has been delayed. Funds are available for minor alterations and improvements, but construction funds for such projects are limited to $50,000.

Equipment and Common Resources

The VA provides funds to each hospital's research program for administration, common resources, and animal care facilities. Common resources often mean specialized equipment such as an electron microscope, but they also may include salaries for an engineer assigned to research service or a statistician who is a resource for all investigators. The VA is flexible about the use of its specialized equipment--it can often be transferred from one hospital to another as needs change. Even within each hospital, all equipment generally is regarded as a common resource rather than the property of one investigator, a policy that prevents much duplication of equipment.

Research supplies and equipment are ordered through the hospital's supply service. Similarly, the hospital has to provide engineering services, including maintenance of laboratories and equipment.

Resources from Other Patient Care Services

The research service is highly dependent on the cooperation of a number of other services, including the nurses, clinical laboratory and radiology. A detailed discussion of the interaction between research and patient care services can be found in Chapter 3, where findings from the site visits are described.

CHAPTER 3

SITE VISITS TO VA INSTITUTIONS

Early in the study the Committee decided to make a series of site visits to VA hospitals with research programs to evaluate the quality, management, and impact on patient care of research in the VA. Although other measures were being used to evaluate quality, the Committee felt that investigators' research should also be evaluated by direct inspection. In addition, it was considered important to hear the views of investigators and other VA staff, including the associate chief of staff for research (ACOS), the chief of staff and chiefs of service, about the administration of the research program at the local level and at the Central Office. Only by visiting a number of institutions could the Committee truly understand the role of research in a hospital and its impact on patient care.

During May to November 1975, subgroups of the Committee visited twelve VA hospitals and one outpatient clinic receiving VA research funds. These 13 institutions had received funds for FY 1976 ranging from $48,000 to more than $3 million. The chapter begins with a brief discussion of the procedures used for the site visits before summarizing the findings and conclusions.

METHODOLOGY FOR THE SITE VISITS

Sampling Procedures

The 13 institutions visited comprised about 10% of all the institutions receiving VA research funds. Details of the sampling procedures by which institutions and their investigators were selected are given in Appendix D,

but several factors should be explained here. In each of four geographic regions of the United States (northeast, south, midwest, and west), three hospitals were visited: one receiving more than $1 million, one receiving between $300,000 and $1 million, and one receiving less than $300,000 in VA research funds. In this way, the size of research program was used as a stratifying variable in the sampling design. Originally it was intended to stratify based on the degree of medical school affiliation, but this measure was found to be unnecessary because closeness of affiliation is highly correlated with the size of the research program. As the discussion will show, the affiliation strength in the selected hospitals was quite variable. The sample also included both neuropsychiatric and general medical and surgical hospitals, although this variable was not included in the sampling design.

Initially the Committee planned to evaluate 20% of the investigators receiving institutional funds in each hospital* in addition to the career development program (CDP) and cooperative studies program (CSP) investigators. After the first round of site visits the sample was increased to 40%, because a 20% sample was not large enough to give a good overall picture of the quality of research in an institution. When an institution had three or less investigators, all were evaluated. Investigators were selected for evaluation by a stratified random sampling method based on funding levels, so that projects of various sizes would be analyzed.

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* See Chapter 2 for a description of institutional funds.

Arrangements for Site Visits

To ensure uniformity in the information collected on site visits, a checklist of issues to be covered in the visits was prepared (see Appendix D). A common core agenda (also contained in Appendix D) was used on each of the site visits which lasted two days in hospitals with large research programs, and one day in hospitals with few investigators. The agenda indicates the groups which the site team interviewed.

In each region of the country, three site visits took place simultaneously. The three site teams were made up of subgroups of the Committee joined by appropriate consultants. On the day following the visits, the entire Committee met together at a central location. This arrangement allowed each of the site teams to share its impressions with the others so that the Committee received full benefit from the visits.

The site teams varied in size depending on the size of the research program. On all visits the Committee members comprised the majority of the team. The Committee tried to arrange it so that each member visited a large, medium, and small size research program at some point. Attempts also were made to assign each participant to hospitals where his scientific expertise was most useful in evaluating the selected projects. Eventually 10 out of the 14 Committee members went on at least one site visit.

In many cases, it was necessary to recruit other scientists to the site teams to provide additional scientific expertise. These consultants were nominated by Committee members. Nineteen scientists served as consultants at one time or another. An NAS/NRC staff member accompanied the site team on

most of the visits.

Quality Evaluation

A total of 100 investigators were visited, interviewed, and evaluated during the site visits.* This sample included 88 individual investigators receiving institutional funds out of the total of 225 institutionally funded investigators in the hospitals in the site visit sample or about a 40% sample. As there were 1,736 institutionally funded investigators in the system at the time, about 5% of these investigators were evaluated. Although principal investigators salaried from research funds rather than patient care were not specifically selected, 12 such investigators did appear in the sample. These people are usually Ph.D. scientists whose primary occupation in the VA is research. There were 262 research salaried principal investigators in the VA at the time of the site visits, so that about 5% of them were sampled.

CDP investigators also were evaluated on site visits. These investigators were purposefully selected to make sure that every level of the program was examined. Twelve investigators out of the 175 in the program were selected for analysis: one senior medical investigator, one medical investigator, four clinical investigators, and six research associates.

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* Twenty investigators participating in cooperative studies were interviewed, too, but the resultant evaluations of these studies are found in Chapter 5, in which cooperative studies are discussed in detail. The same chapter includes the findings from visits to the three cooperative studies support centers.

The site visitors were asked to give a numerical rating to each investigator's research. To allow for inconsistencies in standards applied by site visitors in assigning ratings, the quality of research eventually was assessed by combining these numerical ratings into three descriptive categories:* excellent, acceptable, and unacceptable. The classification of research was based on both numerical ratings and the written evaluations provided by the site visitors. All the site visitors were familiar with the NIH evaluation procedures for research and probably used similar standards of quality. In some instances site visitors made the comparison explicit, e.g., by writing in their reports: "this project would not be funded by the usual NIH study section criteria."+

Several differences exist between the Committee's evaluations and those performed by the Central Office merit review boards or their study section counterparts at NIH. The site visitors met the investigators in person and saw the work being performed. Review boards must evaluate a written proposal and estimate its potential for making a contribution to science. The site visitors also had received the investigator's research proposal and publication listing as background material, yet their visits with investigators were

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* Attempts were made to increase uniformity by having Committee members take part in several site visits, some of them visiting as many as six institutions. In addition, most investigators were evaluated by at least two scientists and the rating was made jointly.

+ Study sections are the NIH boards that review projects and assign funding priorities.

brief and part of the time was spent inspecting facilities and discussing the research environment of the hospital so that the review of projects was broad and less focused on the quality of the science. Furthermore, because it was impossible to assemble a team of manageable size that could provide specific expertise in all fields in which investigators worked, some of the evaluations unquestionably probed less deeply into the details of an investigation than would a study section or merit review board. Despite these differences, the Committee believes that the visitors were able to evaluate the investigator and his work by standards common to biomedical research assessment.

Questionnaire to Investigators

Because there was little time during the interviews for investigators to discuss the research program, a questionnaire in which investigators could express their opinions was sent to them before the visit. This questionnaire was used as background information for the interviews and site visitors discussed specific points with investigators when appropriate. In addition, these questionnaires provided a useful set of data about investigators' views and some of the results of the analysis are included in this chapter.

The questionnaire was sent to all institutionally funded and CDP investigators evaluated in all the site-visited hospitals except for those visited on the first round. These 86 investigators returned 75 questionnaires. In an effort to get as many open and informative answers as possible, these questionnaires were returned to the Committee rather than the local VA administration, and respondents were promised that their answers and identities would be treated as confidential. The questionnaire and the covering letter

which was sent to investigators can be found in Appendix D.

QUALITY OF THE RESEARCH PROGRAM

It is instructive to compare the quality of the research carried out by the three classes of investigators, shown in Table 3-1. Site visitors felt that most CDP investigators were doing excellent work. This high quality was not unexpected, because investigators are selected at the Central Office level and there is strong competition for the appointments.*

Among the investigators whose projects were funded from institutional funds, the quality varied more. The majority were carrying out research that was of acceptable quality or better. However, 36 projects were judged to be unacceptable. Investigators salaried from research funds whose primary occupation was research produce somewhat better work than those whose primary occupation was patient care (6 out of 12 of the former were rated as excellent). The Committee was disappointed to find that four investigators with the primary occupation of research were doing unacceptable work, precisely because the sole reason for employing such scientists in the VA is to conduct research.

The number of projects in the unacceptable category may reflect two policies that do not promote strong quality control in the VA. The first allows projects disapproved by Central Office merit review boards to be funded through local discretionary use of funds. A second policy allows smaller

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* For further discussion of the program, see Chapter 4.

TABLE 3-1

Scientific Evaluation of Individual Investigators in Site-Visited Hospitals

Type of Investigator	Total	Quality Assessment		
		No. Rated Excellent	No. Rated Acceptable	No. Rated Unacceptable
Institutionally funded project, primary occupation patient care	76	16	28	32
Institutionally funded project, primary occupation research	12	6	2	4
Career development program	12	8	2	2
	100	30	32	38

projects (under $25,000) to be reviewed and funded solely at the local level, so that an estimated third of the projects are never exposed to the standards of Central Office review.

In the expectation that quality of research might be related to the type of review received, projects reviewed at Central Office were compared with those which had only received local review. Table 3-2 shows the results of this analysis. In the site visitors' judgment, the merit-reviewed projects did seem to be of higher quality than those which received only local review, although they rated a number of approved merit-reviewed projects as unacceptable. Yet site visitors rated the work of two investigators who had been disapproved in merit review as excellent. Some differences in perspective evidently exist, perhaps because of the site visitors' opportunity to see the research actually under way. However, the review boards do not seem to be using excessively rigorous standards, approving several projects that site visitors felt were of unacceptable quality in their ongoing phase.

Although the Committee was troubled by the wide variations in quality of institutionally funded projects, its concern was somewhat lessened by an analysis of the distribution of funds. Table 3-3 shows two sets of funding data. The first shows how appropriations were distributed among merit-reviewed and non-merit-reviewed projects. The investigators whose projects had been merit-reviewed and approved account for a much larger proportion of research funds expended than investigators who had been disapproved or not centrally reviewed for merit. A similar picture is presented in the second

TABLE 3-2

Comparison of Investigators with Merit-Reviewed and Locally Reviewed[a] Projects in Sample Evaluated on Site Visits

Investigators' Work	Investigators Rated Excellent	Investigators Rated Acceptable	Investigators Rated Unacceptable	Total
Merit-Reviewed - approved[b]	16	21	10	47
Merit-Reviewed - disapproved	2	7	8	17
Not Merit-Reviewed	4	2	18	24
	22	30	36	88

[a] This table includes only institutionally funded investigators and not those in the career development program.

[b] Investigators' work was considered "approved" if one of their projects had been approved. In some cases an investigator had several projects, including at least one which had been reviewed and disapproved. Occasionally an investigator was found to be working on and spending most of his funds on the disapproved projects. This situation should improve as the Central Office policy for reviewing an investigator's whole program at one time takes effect. The Committee therefore did not find it necessary to make a recommendation on this problem.

TABLE 3-3

Distribution of VA Research Funds by Type of Review and Quality of Research for Sample of Institutionally Funded Investigators[a,b]

I. Type of Review

Investigator's work	No. of Investigators in Group	Total Funding to Group/Year	Average Funds/ Investigators/Year
Merit-Reviewed - approved	47	$1,818,395	$38,689
Merit-Reviewed - disapproved	17	$ 391,720	$23,043
Not Merit-Reviewed	24	$ 254,849	$10,618
Total	88	$2,464,964	$28,011

II. Quality of Research

Quality (as rated by site visitors)	No. of Investigators in Group	Total Funding to Group/Year	Average Funds/ Investigators/Year
Excellent	22	$ 864,022	$39,200
Acceptable	30	$ 977,500	$32,583
Unacceptable	36	$ 623,442	$17,318
Total	88	$2,464,964	$28,011

[a] Data on funds from VA Central Office for FY 1975.

[b] Principal investigators' salaries, whether from medical research funds or patient care budgets are not included in this table nor in the body of the text.

section: investigators rated as doing high-quality work received the largest share of the funds. The group of 22 "excellent" investigators received 35% of all the funds for the sample of investigators evaluated. The work of the larger group of 36 investigators rated as "unacceptable" received only 25% of the total.

In summary, most institutionally funded VA research is acceptable or even excellent, and the large proportion of VA research funds are distributed to these projects. However, the Committee was disturbed about the wide variation in quality of research and the not insignificant amount of funds supporting investigators whose work was not of acceptable quality. This concern has led to a series of recommendations about funding policies and mechanisms that should ensure better quality control within the VA (see Chapter 8).

Table 3-4 summarizes another analysis; a comparison of the quality of research in the three sets of site-visited institutions: those with large, medium and small research programs. Although the large and medium research programs include a number of investigators whose work is unacceptable, the proportion of unacceptable projects is greater in the institutions with small research programs. However, the quality of research was not uniform among the hospitals in each set. For example, the large research program set included two hospitals where only a few investigators' work was judged unacceptable, and two hospitals where more than half of the investigators were rated unacceptable.

Thus the overall size of the research program is not the only determinant of whether research in the institution will be of high quality. Evidence

TABLE 3-4

Comparison of the Quality of Research in

Hospitals with Large, Medium and Small Research Programs

Size of Research Program	No. Rated Excellent or Acceptable	No. Rated Unacceptable	Total No. of Investigators[a]
Large (>$1 million) (4 hospitals)	41 (63%)	24 (37%)	65 (100%)
Medium (<$1 million $300,000) (4 hospitals)	16 (67%)	8 (33%)	24 (100%)
Small (<$300,000) (4 hospitals and 1 outpatient clinic)	5 (45%)	6 (55%)	11 (100%)
	62	38	100

[a] Includes both institutionally funded and CDP investigators.

is presented below that the standards set by the research administration in the institution and the commitment of the affiliated medical school to outstanding research also are important in fostering a VA research program that encourages excellence and discourages mediocrity.

MEDICAL SCHOOL AFFILIATION

Site visitors concluded that the single most important factor that fosters a flourishing, high-quality research program in a VA hospital is the nature of the relationship with its affiliated medical school. If the medical school is dependent on the VA for faculty, research space,or teaching beds, it is likely to take an interest in a VA hospital, but unless the medical school itself emphasizes superior research, the closeness of the affiliation may not produce a strong VA research program.

For example, of the four VA hospitals with large research programs that were visited, the two with several outstanding investigators were those where the affiliation was strong and mutually beneficial. In the third, it was clearly the VA hospital that had the financial and physical resources and the scientific capability, whereas the affiliated school contributed little. This hospital, which did not have the active collaboration of a strong medical school, did not have a research program of high quality. This hospital was in a state of flux in regard to its affiliation as well as the leadership of its research program, conditions that may help to explain its relative weakness. The fourth hospital's administrators seemed to be blocking improvement of the VA research program. The affiliated medical school, which had a strong research orientation, was belatedly trying to strengthen the affilia-

tion and the programs in the VA hospital. The school was meeting considerable difficulties, particularly regarding research space for newly recruited staff because of the VA administration's inertia and lack of interest.

The group of hospitals with medium-sized research programs might best be characterized as having close affiliations with medical schools although both partners lack research vigor. Only one hospital with a medium-sized program had a more promising future for research; here the affiliation and the medical school itself were new and enthusiasm was running high on both sides. The VA and the medical school were working very closely to identify suitable areas of research activity. These areas were intended to coincide with the patient care needs of the VA so that staff could be recruited to develop both research and patient care programs. The plan seemed to be working out well.

Two of the hospitals with small research programs also had become affiliated recently. In one case, the staff of the hospital and the affiliated medical school seemed to be unenthusiastic about any effects of the relationship on the development of VA patient care and research programs. In the other hospital, attempts were being made to develop a research program and the local VA administration was highly supportive. However, both the VA and the medical school lacked experience and sophistication in developing research and needed guidance. Of the other two hospitals with small programs, one had no affiliation at all and the site team felt that research funds in that hospital were being wasted. The fourth hospital was awaiting an affiliation with a medical school but its needs and opportunities for research had not been realistically assessed.

The Committee encountered a curious exception to its general conviction that a strong medical school is needed to develop a strong VA research program. It found one outpatient clinic which had no affiliation with a medical school but had a small, active, high-quality research program. This institution may harbor a unique program, and it does not provide an easily replicable model. The clinic had a small staff that concentrated mostly on treating psychological and psychiatric problems. The research was headed by a productive, charismatic investigator who seemed to have infused his interest in research into the whole staff. The Committee is not aware of any parallel situation elsewhere in the system, but it recognizes that in some unusual circumstances a thriving research program may exist in the absence of an affiliation. Such exceptions are rare and each should be examined carefully. In general, a close and strong affiliation is the best means of assuring the quality of a VA hospital's research.

THE LOCAL ADMINISTRATION OF THE RESEARCH PROGRAM

The quality of the research program in an institution is influenced strongly by the attitudes of the ACOS, the research committee, the hospital director and the chief of staff. The chiefs of staff and hospital directors the teams met on site visits had a variety of views about research. Some were enthusiastic and promoted research activities, some were passively supportive, and others who gave lip service to research seemed to be resisting its intrusion into their institution. This resistance included severe limitation on the time an investigator could spend on research and restriction of space for research activities. If the senior hospital staff are not sup-

portive, a research program is not likely to flourish.

The local research administration (i.e., the ACOS for research and the research committee) played a major role in determining the success of a research program. They set standards for the quality of research through the review and funding mechanisms. The ACOS also was a key figure in determining whether the needs of research in the institution were met. For example, his initiative often decided how well and how rapidly the Central Office responded to local research needs. His advocacy of research interests in the local institution influenced the time and resources allocated to research. However, even some potentially effective ACOS's had become frustrated and demoralized because they were not supported by the chief of staff and hospital director.

Interaction Between VA Central Office and Field Staff

Local administrators expressed a variety of views about Central Office, differences that seemed to depend largely on their understanding of current policies. As mentioned, the frequent changes in funding policies over the last few years have been disruptive. As one ACOS quipped, "[One] never knows when another change of policy will fall from the brow of Zeus." Those ACOS's who have kept abreast of the present framework seem to be able to work within it to meet the needs of local investigators, and they seem to be reasonably satisfied with Central Office management. Others seem to be embattled with Central Office every step of the way and thus resent it.

Difficulties in the relationship frequently concerned contingency funds. In the former Part I-Part II system, research funding was flexible enough to allow the local administration to respond to equipment or recruitment emergencies. Under the present system, no such flexible funds are included in the budget allocation from the Central Office. Nonetheless several institutions have tried to maintain contingency funds by siphoning monies from each investigator's budget. As the budgets have tightened, this skimming has become increasingly difficult, causing some anxiety among the ACOS's who had relied on contingency funds. The Central Office has tried to respond by providing a plan for rapid response to emergency situations: the four regional research advisory groups (RRAG; see Chapter 2). Several ACOS's have complained that since these groups meet only infrequently, they cannot respond to immediate needs.* And because RRAG's may only consider funding new investigators after they have been recruited into the system, research funds cannot be promised to an investigator before he joins the VA. However, it was interesting to find that those ACOS's who had relied entirely on the RRAG's rather than trying to maintain a contingency fund of their own were satisfied with the RRAG mechanism.

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* Until recently RRAG's met on a quarterly basis; because of complaints from the field they have now begun to meet once every two months.

Two conclusions can be drawn from this example. First a greater stability in funding policies would avoid needless disruption of the system: necessary changes in policy should be introduced gradually with adequate warning and the effect of policy changes should be evaluated. Secondly, much better communication is needed between Central Office and the field so that policies can be explained and ACOS's are aware of the opportunities open to them in responding to the research needs of their institution. Central Office also needs to understand the problems faced at a local level. Recently, conference calls have been instituted between Central Office and all ACOS's, newsletters from the research advisory committee have been suggested, and the same group has become involved in site visits. The Committee supports these innovations and feels that even more emphasis should be placed on information exchange between Central Office and the field.

Local Funding Policies and Procedures

Frequent policy changes, particularly the oscillation between central and local control of funds coupled with the many views about supporting research at different hospitals, have led to inconsistent practices among these institutions. Some administrators sent in all their projects for merit review while others did not; some followed the Central Office recommendations, whereas others used their own discretion in allocating funds. Site visitors concluded that the local funding policies and procedures of review were a major determinant of the quality of the research in that institution.

The Central Office currently encourages local judgment in fund allocation to allow the relevance or usefulness of the research to the institution as well as its scientific merit to be taken into account. One hospital even had appointed a committee specifically charged to assess the relevance of both the investigator and the proposed project to the hospital's mission.

Because a hospital's research committee can include in its evaluation of the research the importance of the investigator to the institution, it has been quite acceptable to use research funds to retain staff. Several hospitals visited had quite an explicit policy of using research funds as a fringe benefit to make the VA a more attractive place for a clinician. Where the research committee was effective and set high standards, this use of funds was kept to a minimum. In other hospitals with no real core of research distinction, the policy of using funds for retaining staff had been particularly debilitating. The Committee concluded that using research funds to retain clinical staff had lowered the quality of research in many of the site-visited hospitals. This practice had allowed unacceptable work to be funded, including some projects that had been disapproved by merit-review boards.

Apart from this influence on the quality of research, the policy of allowing considerable local judgment to be used in fund allocation is a prickly one. Most members of the hospital's research committee are investigators in that institution and any committee that does not allocate funds according to Central Office recommendations is open to allegations about favoritism and bias. One ACOS commented that he would welcome a policy in

which all projects were merit-reviewed and where disapproved projects could not be funded, because he has to juggle the hospital's need for the "disapproved" research applicant's clinical contribution against the applicant's injured pride and scientific ambition.

Various attempts had been made to try to ensure fair reviews but with limited success. In one instance, the research committee included all the investigators in the hospital. On the surface, this idea seemed to be conducive to a very democratic process, but in fact it merely produced a bland review process in which investigators were reluctant to criticize each other. Another institution had three committees to review projects, an extremely ponderous process. The need for three bodies highlighted the lack of a single group of well respected investigators in that institution.

The Local Administration: Investigators' Views

To complete this section, investigators' opinions about the functioning of the research committee in their hospital are presented. Dissatisfaction was considerable in some institutions, not unexpected given the difficult position of research committees just described. For instance, investigators approved by merit review were irritated that part of their recommended funding was being used to support disapproved investigators. Site visitors heard complaints that the research committee was biased, that fund allocation was a mysterious and not wholly fair process, and that the research committee did not have adequate expertise to review projects. In one or two cases, site visitors discerned considerable truth in these complaints. Nevertheless 76% of all investigators surveyed were satisfied with their research commit-

tee, based on their answers to the questionnaire.

Other than their dissatisfaction with the system of funding, investigators complained about the lack of vigor and effectiveness of the local research administration. Some investigators were burdened by red tape and felt that the local administration was not sufficiently active in helping them with this problem. In several hospitals, the site visitors agreed with the investigators that the ACOS and research committee were not familiar with the changing needs of biomedical research or the available sources of research funds from inside and outside the VA.

THE VA AS A RESEARCH SETTING: INVESTIGATORS' VIEWS

The site visitors spent part of their time with individual investigators discussing how satisfactory they found the VA as a setting for research and identifying some of the difficulties investigators encountered. In addition, the questionnaire for research investigators focused on these same points.*

To gauge investigators' general satisfaction with the VA, this question was asked: "Compared to other positions you have been in, to what extent does your present situation allow you the opportunity you need to pursue your research efforts effectively?" It should be noted that the sample was not likely to include the most discontented people because they already

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* As described earlier, 75 responses to questionnaires were received from the investigators who had been evaluated on site visits, including institutionally funded investigators and CDP investigators.

would have left the VA for more "satisfactory" situations. Table 3-5 lists the responses of those investigators who were in site-visited hospitals between July and November 1975, and shows that most investigators found the situation satisfactory. However, many who answered "satisfactory" or even "very well" went on to point out some problems of doing research in the VA. The sample was divided into three groups: investigators whose primary occupation was research; investigators in the CDP; and investigators whose primary occupation was patient care. Because the amount of time these groups spend on research is different and so are the purposes of their presence in the VA, these groups feel differently about their research situation. As shown in Table 3-5, investigators whose primary occupation is patient care seem to have the most problems. The Committee also questioned whether the size of the research program had any effect on the satisfaction of investigators as attitudes towards research vary among these different institutions, but few differences were found among the three sets of hospitals (those with large, medium, or small research programs).

The Committee especially scrutinized investigators whom site visitors considered to be doing excellent research. These highly productive people did not see as many obstacles to their work, as 11 out of 22 in this group answered that they were "very well" satisfied with their research situation, compared to 9 out of 53 in the balance of the sample. However, 10 out of the 22 excellent investigators were in the primary occupation research category or CDP. These groups have considerable freedom to pursue their research, a benefit that was likely to have influenced their response.

TABLE 3-5

Investigators' Satisfaction with the Research Situation in the VA

Primary Occupation of Investigator	Very Well	Satisfactory	Some Problems	Totally Unsatisfactory	No Response
Patient care	12	19	23	3	-
Research	4	5	1	-	-
Career development program	4	2	1	-	1
TOTAL	20	26	25	3	1

Investigators' satisfaction with the VA was probed further by another question: "Assuming that geographic, personal, and other factors were not involved, where would you prefer to pursue your research?" Table 3-6 is a breakdown of answers to this question. Few answered "NIH" or "other research institutions," 28 investigators answered "medical school" but an almost equal number (23) preferred the VA. It is clear that many investigators find some unique opportunities for research in the VA.

Finally, investigators were asked if they had considered leaving the VA in the last three years and whether they expected to remain in the VA over the next three years. A large number (48) seemed to be satisfied in the VA, whereas 25 respondents had either seriously considered leaving or did not anticipate remaining in the VA. Their reasons for leaving were not specifically tied to research. One or two mentioned problems with red tape and bureaucratic procedures; the majority mentioned salary, retirement, or preference for a position in a medical school.

Investigators also answered questions about VA research policies, and Table 3-7 summarizes the responses to four questions about funding policies. In regard to the fund level of projects which should be merit-reviewed, 56% of the investigators felt that the $25,000 cutoff point for merit review was appropriate. Site visitors felt that in hospitals with high-quality research projects, the desire for having all projects merit-reviewed was stronger than elsewhere. The questionnaire showed that investigators generally were content with the control the local institution had over the allocation of funds.

TABLE 3-6

Investigators' Preference for Institutional Setting for Pursuing Research

Institution	Number of Respondents
NIH	4
A medical school department	28
A VA hospital	23
VA or medical school	6
VA or NIH	1
Other (a research foundation)	1
No response or no preference	12
	75

TABLE 3-7

Investigators' Responses on VA Policy Questions

1) Merit Review

Responses	Number Responding
a) All, or more, projects should be centrally reviewed	18
b) $25,000 project is appropriate size for review	41
c) Only very large projects ($100,000) should be reviewed	11
d) No projects should be centrally reviewed	3
e) No response	2
	75

2) Hospital Control over Research Funds

Responses	
a) Present amount of control appropriate	44
b) Hospital should have complete control	8
c) Hospital should be held to allocating funds as recommended in merit review	15
d) No response	8
	75

3) Relevance Should Central Office place more or less emphasis on relevance to the VA mission?

Primary Occupation of Respondent	Responses			
	More	Less	About Right	No Response
Patient care	11	10	32	4
Research	--	4	6	-
Career development program	--	2	4	2
	11	16	42	6

4) Should investigators seek funds outside the VA?

Responses	Number Responding
a) Yes	61
b) No	6
c) No response	8

However, investigators who had been merit-reviewed and approved but had not received the recommended level of funding because some of their appropriation had been diverted elsewhere were quite dissatisfied. Most investigators believed the level of emphasis on relevance to the VA mission also was about right. It was expected that the group of investigators salaried from research (mostly basic scientists) would feel that relevance to the VA mission was overemphasized but 6 out of 10 of them felt that the present emphasis was "about right," a proportion comparable to the responses from the rest of the sample.

The fourth policy question concerned funding from sources outside the VA. Table 3-7 shows that the majority feel that VA investigators should seek funds outside the VA. This belief seems to be borne out in practice as 35 investigators responding to the questionnaire had received non-VA funds in FY 1975 and/or FY 1976. In addition, 19 of the remaining 40 investigators had applied for non-VA funds at some time while being employed in the VA.

It is appropriate to include the site visitors' impressions about non-VA funding here. In general, it seemed that institutions with better research programs encouraged investigators to seek non-VA funds. In facilities where the internal review was loose and the resulting quality mediocre, there was little interest in encouraging investigators to seek outside funding. In some institutions, seeking outside funds was not without risk. One investigator had had his VA funds reduced after the local administration found he

was receiving non-VA funds. *The Committee believes that an investigator should not be penalized if he takes the initiative and has the ability to obtain outside funds. However, the VA needs better information about the non-VA funds investigators are receiving if it is to provide and account for resources for their research.* Because most of these non-VA funds are administered through the affiliated medical schools, often neither the VA hospital nor the Central Office know which investigators are receiving such funds.

For the issues described so far, investigators seemed to accept VA policies. Some investigators complained very strongly, however, about bureaucratic procedures and the slow response of the VA to everyday needs. These problems will now be discussed as separate items and site visitors' assessments are included.

Time

Investigators in the sample, especially those with clinical and administrative duties, frequently commented on the difficulty in finding time for research. As noted, investigators salaried from patient care seem to have more problems in carrying out their research than do CDP investigators or investigators salaried from research. The difficulty in finding time for research activities may account for this greater proportion.

The VA's mission is, of course, a clinical one, and those needs must be met. As an ACOS for research explained, "Chiefs of service are apt to resent junior staff members spending inordinate amounts of time in the laboratory and leaving the clinical load to others." The extent of the problem depends on the local administration and on the staffing situation in the hospital.

In one hospital, a highly competent investigator was criticized because he was spending more than 50% of his time on research. In another institution with an extensive research program, the chief of staff desired that a formal policy on research time be established because he wanted to encourage research yet had to make sure patient care needs were met. On the questionnaire, investigators were asked if they would prefer a formal policy allowing a specified amount of time for research. This question was most relevant to investigators whose primary occupation is patient care and 28 in this group answered "yes" and 24 answered "no" (five gave no response). Considering the investigators' general dislike of formal policies and red tape, this response is an indication of the extent of the problem.

The Committee believes that the quality of research is affected by this problem. Site visitors often rated a project as poor because the investigator was able to spend so little time on it. Sometimes the investigator did not seem to have any genuine interest in research, and he had allowed clinical and administrative duties to take up all his time. Other investigators may have been genuinely interested in research but they were overburdened. A site visitor's report illustrates this point: "It is questionable, in view of the investigator's present clinical and teaching load, his inexperience and the lack of scientific support, if his research should be supported at all. But in another environment he might flower."

For these reasons, the Committee believes the time an investigator will spend on research should be specified in the research proposal. If necessary, he should be released from some clinical obligations to be able to

spend that amount of time on research, and hospital directors should be allowed to justify extra staff positions on this basis.

Technical and Administrative Support

Investigators enumerated a series of problems with the technical and administrative support with which they are provided. One general complaint concerned the inertia of the system. Several investigators were particularly bitter about long delays in getting funds for research that they had been promised before they came to the VA. Supply and engineering services were taken to task because of the delays in getting these services to respond to research needs. Administrative support problems included the general lack of secretarial support in the VA, and the difficulties in getting the ACOS and his office to respond to requests for supplies, equipment, or secretarial help. Another burdensome procedure to both the ACOS and investigators is the quarterly accounting system. Under current policy, all funds have to be accounted for at the end of each quarter, and unexpended funds have to be returned to the VA Central Office. Given the slowness of response in the VA system and the delays and deferred expenditures that are a reasonable part of research itself, this policy--an albatross to all concerned--seems unnecessary. *The Committee recommends that a yearly accounting system should be considered for research.*

The problem of technical support is one of quality more than quantity. Under the civil service tenure system, technicians cannot be dismissed when they are no longer needed unless all employees with lower seniority are dismissed along with them. A technician may be very competent in one project,

but may not have the appropriate background and knowledge to provide adequate technical support in another. This development is not unexpected, because biomedical science has become so highly specialized. The process frustrates investigators and leads to much general inefficiency. It also means that research budgets are increasingly locked into paying salaries of technicians who have civil service tenure, leaving little leeway for supplies and even for important equipment. In one extreme example, 90% of a hospital's research budget was being spent on salaries principally for support staff. *The Committee concludes that hiring employees for term appointments should be much more widely implemented now that the ceiling has been lifted for the VA.*

Space and Equipment

Investigators rarely commented on the provision of equipment and common technical resources, and only in one or two situations did the site visitors think that research was hampered because of a lack of suitable equipment. Space, however, was a more scarce commodity. The main problem has been the difficulty in getting funds for renovation over the last few years. At one hospital the lack of funds for remodelling was hindering recruitment as no research facilities were available for new staff. The affiliated medical school was very actively involved in trying to improve patient care at that VA hospital through recruitment. The difficulties and delays in remodelling therefore were causing the VA-medical school relationship to deteriorate. In several of the hospitals visited, the lack of funds had lowered the quality of the animal care facilities. Some of these institutions were doing a good job under trying circumstances, but the lack of funds had meant delays of 10 years or more in remodelling these animal facilities.

IMPACT OF THE RESEARCH PROGRAM ON PATIENT CARE

Much of each site visit was spent in attempting to assess the influence of research on patient care. This issue was discussed with hospital directors, chiefs of major bed services, and many other health care professionals in the hospitals, including nurses, social workers, pathologists, and radiologists. First, some ways that research can affect patient care were identified. These interfaces between research and patient care are summarized next, followed by more detailed expositions of what the site visitors observed.

The most direct influence of research on patient care is in the institution of new and better procedures and treatments. Appendix C lists some of the VA's major contributions to medical care through its research activities. The most immediate impact of research on care observed on site visits is the involvement of patients in research protocols designed to test new methods of treatment. The impact on these patients may be positive, negative or both. Patients may benefit because the new methods are better than the old, but they may be subject to unknown risks or side effects because of the experimental nature of the study. In a subsequent section, an assessment is made of how well participants' rights and safety are protected in the VA hospitals visited.

Research also may directly affect access to care for better or worse. Although a patient is not involved in research, he may have access to newer diagnostic and therapeutic procedures because of the presence of research in a hospital. But if physicians become more interested in research than in

treating patients, access to care could be limited for some patients and the care delivered could be inadequate. Similarly, if nurses and other health care professionals are overburdened by research-related tasks, research may be detrimental to the general provision of patient care.

The availability of high-quality care also is influenced by other indirect effects of research on patient care, such as the overall quality of the staff and the influence of research on the general hospital environment. Research opportunities may be responsible for attracting high caliber staff, especially physicians. These physicians may attract others, and health professionals who aren't physicians may become interested in the VA because of the intellectually stimulating environment fostered by a research program. The scientific milieu may itself lead to a more critical approach to the care of patients.

The Direct Impact of Research on Patient Care

Surprisingly few patients are actually involved in research at any particular time, but many of the investigators evaluated were anticipating using human subjects for some part of their research project. Further discussion of the numbers of patients involved in research can be found in Chapter 6 and the Committee's evaluation of the safeguards for patients in the site-visited hospitals is made later in the present chapter.

The findings from site visits led the Committee to believe that the direct impact of research on patient care is a modest but beneficial one. The Committee found no evidence at all that research had limited patients'

access to care--in several situations, better care was available because of a research project. For example, in one psychiatric hospital an investigator had given complete medical examinations to 167 inpatients to screen them for one of his research studies. Many of the patients were found to have hitherto unrecognized secondary illnesses--including tuberculosis, diabetes, and epilepsy--and subsequently were treated for these conditions. In another institution, an investigator had designed a questionnaire to determine the special problems of Vietnam veterans so that the appropriate services could be made available to them. The questionnaire was so successful in providing a comprehensive assessment of a patient's needs that it was incorporated into the standard initial examination at that institution.

In some institutions, patients had access to specialized diagnostic and therapeutic procedures because of a particular investigator's research interests. In one hospital, a diabetic and endocrine clinic would not have existed without the CDP investigator who ran it. In the same hospital, a specialized radioisotope procedure (technetium scanning) would not have been available to evaluate 400 patients with skeletal disorders without the research program which involved using technetium scanning for dental conditions.

In addition to the immediate impacts of research on patient care observed, it is clear that research has a more long-range direct impact on care if it leads to improved understanding and management of disease. Therefore, the Committee tried to evaluate the potential of current research pro-

jects to improve future patient care. This evaluation is difficult to make with any degree of certainty, especially for basic scientific research, but site visitors' comments suggest that many of the projects do have such a potential. For example, it was reported that the results of one investigator's work

> should have major and immediate impact on the delivery of medical care through his development of methods to stimulate the immunologic response and prevent the suppression of immune mechanisms in a number of conditions such as Hodgkin's disease, lupus, other immunologic deficiencies, auto-immune disease, and neoplastic syndromes.

Another investigator was thought to be on the verge of developing "an easier and more sensitive method to diagnose and follow 'benign' prostatic hypertrophy and prostatic carcinoma through a fingerprinting of the mucopolysaccharides on a two-dimensional gel system."

The investigators also were asked, "In what way do you see your research as contributing to patient care?" The responses were open-ended. Of the 57 investigators with clinical or administrative duties and not salaried from the research program directly or the CDP, 41 replied that their research would improve patient care either directly because they were treating patients with a particular disease, or more indirectly through a fuller understanding of the processes of disease. Other indirect effects were revealed in responses such as: "it makes me a better physician/teacher," "it keeps me here," "it sets up a critical environment," and "it attracts other professional staff to the VA."

The nine CDP investigators answering the questionnaire all said that their research had clinical importance and one mentioned that his program helped to attract high-quality staff.

Eleven salaried investigators whose primary occupation was research answered this question in the questionnaire or on the site visit. Three investigators (two biochemists and a clinical psychologist) saw themselves as contributing by being resource people for other investigators or clinicians. Two (clinical psychologists) actually treated patients in their research procedures and felt they were making a contribution that way, and the other six (four biochemists, a physiologist, and a microbiologist) answered that their research could result in better understanding of a disease or better treatment. In several cases, the site visitors felt that the talents of these full-time investigators were not being exploited to the fullest. It was only in hospitals with large research programs and strong research orientation that the full-time investigators were interacting effectively with clinical investigators. *The Committee recommends that only institutions with large research programs should employ investigators whose primary occupation is research.*

Indirect Impact of Research on Patient Care

The site visitors met with an almost universal conviction on the part of VA professional staff that research is an important recruitment incentive for many competent physicians. This belief was emphasized repeatedly not only by investigators themselves, but by many of the chiefs of staff

and chiefs of major services interviewed. These chiefs often volunteered that they themselves would not be in the VA if there were no opportunities for research. In addition, they felt it would be impossible to staff their services with able physicians without the recruitment device of research. The questionnaire asked site-visited investigators, "What factors influenced your decision to seek employment in the VA system?" Of the 57 physician-investigators whose primary occupation is patient care, 30 spontaneously mentioned research or research opportunities in their answer, as shown in Table 3-8. The greatest attraction usually was the opportunity to combine teaching, research, and patient care. Although the Committee concluded that research was a crucial factor in recruitment, in some cases site visitors were not so convinced that research was necessary to retain physicians in the VA. This skepticism was based on specific observations of certain investigators who spent little time on their research and appeared to lack enthusiasm for it. The Committee felt that funds for these investigators could be removed without risk of resignation or impairment of their clinical contribution to patient care. In one institution where many senior physicians were getting research funds, this retention device may have been a negative influence on the environment. The institution was clearly lacking the stimulating environment necessary to recruit younger physicians so vital to a research program and a hospital. In several hospitals, physicians with little talent or real interest in research felt that only by doing research could they become members of the hospital's elite. *The Committee believes*

TABLE 3-8

Research as a Factor Influencing Recruitment of Professional Staff into the VA

Primary Occupation of Respondent	No. Who Mentioned Research	No. Who Did Not	Total in Group
Patient Care	30	27	57
Research	8	2	10
Career development program	7	1	8
TOTAL	45	30	75

that such motivation usually leads to unproductive research and is a misuse of research funds. Research committees can detect this sort of misuse and the Committee urges them to eliminate it. Research funds should not be used solely for the purpose of rewarding clinical skills and contributions, but if means can be found to give recognition to excellent clinicians, so much the better. The allocation of research funds as a status symbol that merely adds to individual prestige but not to knowledge is an improper use of research funds.

Nurses, social workers, and other health professionals were queried about what attracts people to their services. Most of them also thought that a lively, stimulating environment was important to recruitment. Both a research program and the academic affiliation of the hospital were felt to be important in developing that type of environment.

A stimulating environment such as they described existed in several of the hospitals visited. Its absence in others, however, demonstrated that a research program cannot produce this environment by itself. A strong medical school affiliation and a geographic location in an area that offers cultural amenities also help to attract good staff. Nevertheless, research is one important factor and it can have a marked effect on the ability to recruit staff and the attitudes to patient care. As the site visitors remarked about one hospital, "[we] believe the research program has had and continues to have a general beneficial effect upon care--sometimes directly, although more often through helping to create a lively intellectual environment that helps to attract and hold competent physicians who provide high-quality care."

Interaction of Research with Hospital Services

Chiefs of auxiliary services in the site-visited hospitals were interviewed to learn something about the influence of research on the whole hospital and on their services in particular. The chief of nursing or her representative was polled in each hospital, as were the chiefs of social work services in certain institutions. Although social workers did not seem to be as involved with research as the nurses, their comments were much the same as the nurses. With one or two exceptions, the informants were strongly convinced of the benefits of research, and many were trying to introduce research programs into their own departments. They all had a similar complaint: they were not in a position to be kept informed about planned or ongoing research in their hospital.

Many research protocols involving patients result in extra tests or procedures for nurses to perform, and except for some cooperative studies in which a position of research nurse is designated, no provision is made in the budget for this extra nursing care. Instead, regular patient care staff must absorb the load. In one or two of the institutions where research was taking up a lot of nursing time, nurses were noticeably dissatisfied with this state of affairs. Yet the main concern was not funding as much as the general lack of information about research needs. Most nurses felt that their role was slighted: they were not treated as an important element in the research despite all the work they shouldered. In one institution, the nurses had studied the situation and found that research procedures were producing an excess workload requiring the equivalent of 22 full-time nurses, yet no extra

nurses were hired. In general, the nurses were willing to perform these extra duties but felt that work could be planned better if a nurse were a member of the hospital's research committee. A number of nurses had requested membership and had been turned down. In one hospital, a chief nurse was a member of both the research committee and its subcommittee on human studies, and her involvement had increased the nurses' interest and awareness of research in that hospital. Her influence on the human studies committee had also resulted in a number of changes beneficial to patients involved in research. The Committee concludes that making nurses members of these committees is an efficient method for informing nurses in a more general way about research in the institution as well as alerting them to specific work needs.

The second level of complaint about lack of communication concerned the nurses who were actually carrying out the research procedures. It was suggested that if these nurses were better informed about the research project and its goals and recognized as important participants, they would be more concerned about collecting careful and accurate data. They also would be able to instruct patients better about a project and answer their questions. The nurses also requested more feedback about the results of research so that they could apply the information in everyday patient care. Similar statements were made by one of the chiefs of social work, who felt that social workers should be involved with subjects of experiments from the outset to handle the questions and problems that arise for patients and their families.

In many of the hospitals, site teams also met with chiefs of radiology, clinical laboratory, and pharmacy. They also commented that research projects

result in many extra tests or procedures for their services. In some institutions these services were informed about the additional procedures before a project was begun; in others, they were not. Clinical laboratories seemed to be the only beneficiaries of extra resources from research. In several institutions, an extra technician was employed in the clinical laboratory and salaried from research funds. Several chiefs of clinical laboratory also reported that some special tests became available in the hospital because investigators would carry them out in their research laboratories. Thus a trade-off of sorts had emerged.

The major complaint of the chiefs of radiology and clinical laboratory was that they had difficulty in getting funding for research projects proposed by their services. They felt that they were not given a fair hearing by research committees who are oriented toward internal medicine and surgery. The Committee believes that the potential of research carried out by radiologists, pathologists, and staff who are not physicians should be paid more attention locally and by the Central Office. Although these individuals should not be considered ineligible for research support or categorically considered unable to produce worthwhile projects, it should be recognized that many of these services are staffed by persons selected for patient care activities rather than for their competence as investigators. The Committee is encouraged that the VA's health services research and development program is attempting to educate VA staff about research methodology, which may improve research opportunities for nurses and social workers. More could be done at the local institutions if experienced investigators helped nurses,

social workers, radiologists, and pathologists to develop their ideas into sound research protocols. Such teamwork may be especially necessary for projects that are more medical than related to health services research.

At most hospitals, the teams interviewed chiefs of two support services that interact with research: engineering and supply. In some institutions, research service did all its own maintenance work; in other institutions where research relied completely on engineering and supply services, the investigators were often disgruntled. Unlike the nursing, radiology, and clinical laboratory services--where it is difficult for staff to differentiate between research and patient care requests--engineering and supply can readily discriminate between research and patient care. They usually give patient care needs first priority, which sometimes results in less attention to the needs of investigators. One chief of supply service suggested that in large research programs an extra person should be assigned to supply to deal specifically with research orders. This excellent suggestion could also be applied to engineering service.

The Committee concludes that provision of extra funds or resources to support services may be necessary in hospitals with large research programs to provide for the increased demands upon patient care resources. The chiefs of these services should be consulted about the demands that will be made on their services as research protocols are developed. Given the level of interest shown, particularly by nurses, much more effort should be made to inform and educate other health professionals about research. Support services personnel should therefore be allowed to attend the research committee

meetings and make their opinions known. Health professionals other than physicians also should be encouraged and assisted in instituting research in their own areas.

Research Using Human Subjects

The Committee undertook a study of patients involved in research protocols and the findings from this study are described in Chapter 6. Although no patients were interviewed on site visits, the Committee did attempt to assess the impact of research on patients as perceived by nurses, social workers, and veteran service organization representatives who have direct communication with patients. They also met with members of the human studies committee (HSC) at each institution to learn more about the functioning of these committees.

In several cases, nurses mentioned that research subjects often received better care than those not participating in research because of the doctor's special interest and the more careful monitoring by other staff. Although some nurses and social workers had heard patients complain about being "guinea pigs," this epithet was not specifically associated with research but rather with the number of residents, interns, and medical students who examined and treated the patients. In one hospital nurses said that they heard some complaints from patients that they were being used as guinea pigs although no educational or research programs involving patients existed. Interviews with representatives of veteran service organizations revealed that when such complaints were brought to their attention, the patient was more concerned with the number and youth of staff members involved in his care than with actual

research. In most cases, these service organization representatives knew little or nothing about research in progress in the hospitals with which they were associated. *The Committee feels that more effort should be made to explain to veteran patients why so many students, residents and interns seemed to be involved in their care. A broader understanding about research and training programs by the veteran constituency and their families would help to allay fears of being used as guinea pigs.*

To approach the subject of HSC's, a description of the VA's policy changes on the use of human subjects in experiments that occurred during the period of site visits is necessary. Since 1970, VA regulations had mandated that research protocols involving human subjects be submitted for review and approval by an HSC. However, in March 1975, a VA circular was issued that revised these regulations and brought them into alignment with the regulations of the Department of Health, Education and Welfare. In particular, the new regulations specified that the HSC should consist of at least five members, two or more of whom should not be VA employees nor directly connected with any research within the VA facility.* This revision led to a reconstitution of HSC's in VA hospitals with research projects using human subjects. In June 1975, another circular spelled out specific procedures to be followed in drafting consent forms and obtaining consent from subjects in research protocols. These changes were taking effect over the period of the Committee's

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* See VA Interim Issue 10-75-8, March 10, 1975.

visits and therefore some HSC's interviewed were undergoing alterations in composition and methods of procedure. Nonetheless, some useful insights were gained.

In general, the HSC's placed great emphasis on their responsibility toward patients. In one or two cases the HSC was more interested in following the letter rather than the intent of the law, but only in one hospital was there evidence that safeguards for patients were seriously lacking. In this hospital it appeared that the regulations were being ignored: the HSC chairman could not remember signing his approval for the two projects involving human subjects, yet one of these carried considerable risk. Nor had the patients been informed that they were to be subjects in an experiment. However, most HSC's were conscientiously concerned with how to best protect the rights and safety of patients. The common denominator of all discussions with the HSC's was their uncertainty about the definition and scope of their role. From the interviews it was clear that many HSC's perceived some of the questions posed by the site visitors as suggestions that might help them function more effectively.

The Committee examined the composition of the HSC's in relation to their activities i.e., in their recommending of revisions to protocols or changes in consent forms. In one situation where the research committee and the HSC met as one body the Committee concluded that this was not in the best interests of the patients. *Because of their disparate functions a hospital's HSC and research committee should have separate membership and should meet separately.*

Many HSC's were dominated by scientists or physicians and lay members generally deferred to their judgment. Under these circumstances the rights and safety of patients are not sufficiently protected. *The Committee concluded that additional representation on the HSC's of concerned members of the community, including consumers of VA health care would be desirable. These representatives should not be employed by the VA.*

In two hospitals the VA used the HSC's of affiliated medical school or university, an alternative permitted in the current regulations. In one of these cases, the volume of projects the HSC had to deal with was so large that only a few minutes could be devoted to any one. When the Committee questioned members of these HSC's about the special requirements of the VA patient population, it found that they had not contemplated the possibility that VA patients might be thought of as a dependent population requiring special considerations. In one of these hospitals, medical school investigators were carrying out research involving VA patients but considered VA patients to be no different from patients who were research subjects in university hospitals. *The Committee has recommended that the option for a VA hospital to use the HSC of its affiliated university or medical school should be discontinued, and that each VA hospital should have its own HSC.*

Considerable time was spent with the HSC's discussing their functions and the issues they had found difficult to resolve. The most common reasons for sending back projects for modification were for procedural changes, that is, revised wording or additions to consent forms. Even so, consent forms often had specific items missing. For example, information was not always

given about specific risks of the research procedure, alternative treatments available to the patient, and what a patient could expect if no treatment were instituted. A promise to the patient that his care would not be compromised if he did not participate in research was also frequently absent from the consent forms. Although the standards and regulations for consent forms were being revised at the time of the site visits and it is clear that more care is being taken with consent forms of projects currently being reviewed, some of the older approved projects still may be recruiting patients with unrevised consent forms. Aside from the return of consent forms for rewording, members of HSC's who met with the Committee could remember few projects returned to investigators for revision of research protocols and none that were finally rejected on substantive ethical grounds.

Some of the human studies committees interviewed were attempting to broaden their task and had explored such issues as the difficulty in informing patients fully, the circumstances in which patients give consent, and whether in some cases a patient is in full enough control of his faculties to give informed consent.

Although several HSC's took great care over approving projects, none were involved in checking compliance with human studies procedures in their hospitals in any regular way. Opinion was divided about how vigorous or extensive monitoring should be. Some committees were considering speaking to patients about their involvement in research and in one hospital a member of the HSC did speak to patients. Other committees thought that interviewing patients was not a part of their role and felt that it could interfere with

the relationship of the patient to his physician. In no hospital was there a process for subjects to express their grievances. Veteran service organization representatives believed that their function was limited to assuring a patient of his service benefits. The Committee has recommended that a grievance mechanism be instituted. No representatives interviewed considered the protection of patients' rights to be in their mandate. None of the committees had investigated whether consent forms were signed and included in the patients' charts, nor did they know who was responsible for obtaining consent from the patients. One institution--partly under the influence of a very energetic chief nurse--had developed some guidelines of its own: a central record of all patients on research was to be kept; the head nurse of a ward would take part in the consent procedure and witness the signing of the consent form; and the patient was to be given a copy of the consent form.

Finally, the Committee was concerned about the effects of regulations on the use of human subjects in experiments on the course of research, but they were not assessed systematically on the site visits. (Results of a special study that included investigators' views about regulations for human studies are included in Chapter 6.) The effects of the regulations were discussed with the HSC's. Some of their members felt that at first investigators had considered compliance with the regulations a nuisance, but that they eventually had come around to accepting them. HSC's believed, however, that adherence to the regulations would make investigators more concerned with subjects' rights when they proposed and developed research protocols and prepared their consent forms.

SUMMARY

The site visits were the Committee's most important source of information. Although the Committee was impressed by the quality of research being done by CDP investigators, it was concerned about the wide range of quality among those investigators receiving institutional research funds. Therefore procedures and policy changes have been suggested to ensure that only high-quality research is supported. At this time considerable local discretion is used in the allocation of funds. For that reason the policies and customs of the local research administration are important determinants of the quality of the institution's research. A second important factor was the strength of the medical school affiliation and the medical school's own commitment to excellence in research.

The conduct of research appears to be impeded by certain administrative procedures. The VA should investigate and make appropriate changes to alleviate the problems. Perhaps the greatest obstacle is the difficulty investigators have in finding time to do research. The VA's primary commitment is to patient care, but some steps should be taken to allow investigators with clinical duties to devote more time to research. Any measures of this sort should be accompanied by appropriate quality control to ensure that only investigators capable of effective research are given extra time for research.

An important mission of the site visits was to evaluate the impact of research on patient care. Both the direct and indirect influences of research on patient care were found to be positive. VA research has made important contributions to medical care in the past and from its assessment of ongoing

projects, the Committee believes that it will continue to do so in the future. There was no evidence that patients' access to care had been limited by research; indeed, many patients had access to new and more advanced treatments and procedures because of the presence of research. Research also has been important in bringing able staff into VA hospitals. Research may be a burden to support services and steps should be taken to alleviate some of the problems encountered. Finally, the review of HSC activities resulted in some recommendations for changing procedures to protect the rights and safety of patients who participate in research projects.

CHAPTER 4

THE CAREER DEVELOPMENT PROGRAM

The career development program (CDP) was initiated in 1956 and has continuously grown ever since. In FY 1976, $9.25 million was allotted for the program, about 10% of the total VA research budget. Because this program occupies an important position in VA personnel strategy, uses a substantial portion of the budget, and generally is held in high regard by the Central Office, it was appropriate for the Committee to investigate it in some detail. Information was gathered from the Central Office and site visits. Some assessment of the program's quality has been made in Chapter 3. Here the program is discussed more thoroughly.

DESCRIPTION

The program allows a selected physician or dentist to spend 75% of his time on research in a VA hospital and provides salary and research funds during his tenure in the program. Currently the program consists of five levels. Most investigators do not spend their whole careers in the program but use it as an opportunity to develop their talents as researchers before going on to staff positions where they will divide their time between research, teaching and patient care.

The highest position in the program is the senior medical investigator (SMI), open to outstanding investigators who are expected to continue to produce excellent research. As can be seen in Table 4-1, the SMI position is different from the others in several respects. The position can be

renewed as long as productivity is maintained, the level of research funding is negotiated with the medical research service and investigators are nominated for the position by high level Central Office staff. (Applications for other positions are initiated at the local institution.) Like other CDP investigators, SMI's are reviewed and selected by the career development committee, a group of scientists and physicians from outside the VA.

The next level is the medical investigator (MI) position where research accomplishment also is a prerequisite. However, MI's are nominated by local hospitals rather than the Central Office and the positions are not renewable. The clinical investigator (CI) level requires evidence of ability to function as an independent investigator, and it is designed to encourage younger investigators to develop their research talents. A CI is expected to have a sponsor to provide some guidance for the project. The research associate (RA) position is open to junior investigators; they are expected to have a preceptor to support and advise them. The RA level was originally intended as an entry into the program and only an aptitude for research needed to be demonstrated. Competition for these positions became high: all the applicants had had previous research experience. It became difficult in the VA and elsewhere for beginning investigators to accumulate fellowship or other research experience needed to qualify for a RA position, so a new entry level for the program was established--the associate investigator (AI). Applicants for this lowest rung in the program are expected to have completed board specialty training but should not be more than two years beyond it.

All levels are salaried from the program rather than the hospital's budget but the different levels receive varying amounts of funds for research (see Table 4-1). Investigators also may receive additional institutional research funds or may seek additional funding from outside the VA.

SIZE AND SCOPE

At the beginning of FY 1976, 175 investigators were distributed among the various levels of the program, listed in Table 4-1. It is noteworthy that 146 of the 175 investigators are in RA or CI positions. Both these levels are designed to allow younger investigators the opportunity to develop their research interests. That the majority of CDP investigators are in training positions has considerable bearing on subsequent discussions.

The Committee wanted to know in what type of hospital investigators would be found. As summarized in Table 4-2, most CDP investigators were found in hospitals with large research programs which generally have close university affiliations. It is expected that investigators should be located in these hospitals and the Committee believes such placement should be encouraged. These hospitals have enough established investigators to provide the appropriate environment and support for the young investigators who constitute most of the program.

Some of the hospitals with very large research programs (over $2 million) have a number of CDP investigators. It was surprising, however, that two hospitals in this group should have no CDP investigator at all. These hospitals should be encouraged to use the program to develop their research staffs more.

TABLE 4-1

Investigative Positions in the CDP[a]

Program Level	Number in Level (July 1, 1975)	Term	Research Funding	Supervision
Senior medical investigator	8	4 yrs (renewable)	Negotiable	No
Medical investigator	21	6 yrs (non-renewable)	$ 40,000	No
Clinical investigator	58	3 yrs (non-renewable)	$ 20,000	Yes, sponsor
Research associate	88	3 yrs (non-renewable)	$ 5,000	Yes, preceptor
Associate investigator	None[b]	2 yrs (non-renewable)	$ 2,000	Yes, preceptor
	175			

[a] Data from CDP, VA Central Office.

[b] Appointments began July 1, 1976.

TABLE 4-2

Location of Investigators in the CDP[a]

Research Funding to Hospital	No. of Hospitals in Group	No. of Hospitals with CDP	No. of CDP Investigators in these Hospitals
> $ 2 million	9	7	42
$ 1-2 million	23	22	97
$500,000-1 million	24	19	27
Less than $500,000	71	5	9
TOTAL	127	53	175

[a] Data from CDP, VA Central Office, July 1, 1975

The Committee discussed at some length how far the research of CDP investigators should be oriented toward the common health problems of veteran patients, but it did not come to agreement. All of the Committee agreed that CDP investigators should not be forced to investigate only the most prevalent medical disorders of VA patients and that it was important for investigators to have first-class preceptors. Therefore the Committee was able to come to the following resolutions. *In certain circumstances it may be appropriate to use the CDP to recruit and train investigators for particular research areas. This move should be made only if more senior investigators are available to develop a high-quality training program in that area. The Committee feels that the talent and promise of CI's and RA's should be primary criteria for receiving an award and attention should be given to their opportunity for well supervised training. Their projects should be appropriate to the VA, but perhaps the most that can be done to direct research to veterans' problems is to expect participants to have their laboratories located in the VA, appoint VA staff as their preceptors, and encourage them to interact with VA staff and patients as much as possible.*

ACHIEVEMENTS

Two aspects of the program's achievements were examined: the quality of the research and the contribution of the program to the progress of medical science and the agency's objective of using the program as a means of recruiting talented people for the VA. The policy states that "[t]hrough the program the VA is able to attract and retain potential and experienced

investigators who also perform as clinicians and teachers."*

Good evidence exists that the positions in the program are highly sought after. For example, in the 19 years since the CDP began, 682 investigators have applied for the CI position and only 52% have been accepted, and 611 investigators have applied for the RA position since it was initiated in 1962 and only 68% have been accepted. The Committee believes that high caliber physicians have been recruited to the VA through the CDP. Many physicians remain in the VA after completing their term in the program, illustrated by Table 4-3. The first set of data summarizes the results of a study carried out in 1970 that assessed the current affiliations of CI's in the program between 1957 and 1968. As can be seen, 40% remained in the VA and another 35% went into medical schools. The second set is from a more recent study of RA's remaining in the VA system. Again, over 40% of the RA's in the program between 1962 and 1972 stayed with the VA. It is not known how many still are involved in research, nor whether they are pursuing research of importance to veteran patients either inside or outside the VA. However, the information does show an encouragingly high retention of investigators in the VA. The Committee feels that this follow-up of CDP investigators is important, and it encourages the VA to continue these studies.

As was described in Chapter 3, special efforts were made on the site visits to interview at least one investigator in each level of the program

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* VA Central Office Policy Statement, August 19, 1975.

TABLE 4-3

Current Affiliation of Former Investigators in the CDP

Clinical Investigators[a]	Number	% of Total
VA full-time	74	36
VA part-time	8	4
Other federal institutions, including military	7	3
Medical schools	72	35
Private practice or other private organizations	41	20
Other--deceased, or no longer in medicine	4	2
	206	100

Research Associates[b]	Number	% of Total
VA full-time	99	33
VA part-time	34	11
Other federal institutions, including military	9	3
Medical schools	93	31
Private practice or other private organizations	68	22
Other--deceased, or no longer in medicine	1	< 1
	304	100

[a] Derived from the "Veterans Administration Clinical Investigator Program," Journal of the American Medical Association, 211:640, 1970.

[b] Data provided by CDP, VA Central Office from a 1972 follow-up study.

(except, of course, the AI level, which had no occupants at that time). The site visitors expressed considerable satisfaction with the program. The 12 investigators interviewed were almost all doing very high-quality work. *The Committee believes that such quality is assured by having the selection made by the career development committee at the Central Office. Therefore, this procedure should be continued.*

Looking at long term accomplishments of the program, some outstanding research has been carried out, especially by SMI's. Present and former SMI's and the areas of their work and achievements are listed in Appendix C. All these people are regarded as leaders in their fields. The VA can be proud of the CDP and the Committee believes it should continue to be emphasized strongly.

THE PROGRAM IN PRACTICE

On site visits, the Committee asked CDP investigators what they thought about the program. Although some specific problems were mentioned, all the investigators seemed to feel that it offered them outstanding opportunities. The prevailing attitude of CDP investigators was epitomized by what one senior investigator said: "I have been offered other positions but none of them have offered the opportunities inherent in my present position."

Certain problems in the program were identified on site visits. The first one concerns the location of the investigator's laboratory. Some young investigators in the program had their laboratories in the medical school. The VA and the investigator cannot interact well unless the investigator is physically located in the VA hospital; the Committee was pleased when the

Central Office recently established this policy.* Many times RA's and CI's had medical school faculty as their preceptors. These relationships had worked out well in some cases, but in others site visitors felt it had separated the CDP investigator from the VA. In one extreme example, it seemed that an investigator was getting no support whatsoever, as his nominal preceptor had moved to another university. The Committee believes that the preceptor usually plays a critical role in the investigator's development and that the commitment of the preceptor should be monitored throughout the whole project. The preceptor's role is especially important in institutions with smaller research programs and fewer experienced investigators. In such institutions it is not likely that the general milieu can substitute for the close individual attention of a preceptor.

A second major problem involves the time allowed for research. In theory, investigators are allowed to spend 75% of their time on research. However, the Committee met some investigators in the program, especially junior participants, who had heavy clinical responsibilities.

The issue of investigators' time came to the Committee's attention when the recent salary bonus for physicians came into effect. CDP investigators were excluded from this bonus because there is no difficulty in recruiting and retaining investigators, and the law was specifically designed to alle-

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* VA DM&S, Research and Development letter, July 30, 1975.

viate the recruitment problem. Investigators were allowed the option of taking staff positions in order to qualify for the bonus. About 40% submitted a letter of intent to do so. The Committee was curious about why so many investigators would be willing to sacrifice a CDP position, which gave them considerable prestige as well as freedom to do research, for a salary increase. In many cases, the CDP position seemed not to be very different from a position on the clinical staff. Because many investigators were expected to discharge extensive clinical obligations, they believed they would be devoting about the same time to research whether they transferred to the clinical staff or not. *If the quality and purposes of the program are to be maintained, the Committee believes that the research time of CDP investigators needs more protection and CDP positions should be well differentiated from clinical staff positions. Vigilance will be particularly important at the new AI level, which may be viewed as a way to get more young physicians on board to perform clinical duties.*

In order not to mislead, it must be said that only 17 investigators did leave the program and transfer to staff positions. The large numbers who submitted letters of intent did so as a protest against their exclusion from the bonus. It has been commented that this exclusion may improve the program. Because investigators will have to make a financial sacrifice, the exclusion should separate those who are genuinely interested in research from those who are not. For individuals with a genuine interest, research does have intrinsic satisfactions. *Nevertheless, the Committee believes that investigators should not be penalized for doing research, and warns that care*

must be taken not to give investigators that impression.

SUMMARY

The Committee was impressed by the CDP's quality. Through the program, a number of very talented people have been recruited to the VA. Although the Committee would encourage research into problems of special importance to veteran patients, CDP investigators, particularly those in the junior levels, can be oriented towards these problems only when established investigators in the VA are available to serve as preceptors.

CHAPTER 5

THE COOPERATIVE STUDIES PROGRAM

Early in its work, the Committee received considerable testimony to the importance of the cooperative studies program (CSP). As a result, the program was studied in some detail. Information about the program was sought from the VA Central Office, representatives of the Committee attended a meeting of the CSP evaluation committee, and a large proportion of the ongoing cooperative studies were reviewed by the Committee during its site visits. Visits to the three cooperative studies support centers included a detailed review of four ongoing studies. In addition, teams visiting the 12 VA hospitals in the general site visit sample met with many investigators participating in cooperative studies in those hospitals. Finally, to broaden the Committee's perspective, information was sought about cooperative studies going on outside the VA from several individuals who were familiar with such studies. The Committee's findings and conclusions about the CSP are presented in this chapter.

THE VA'S UNIQUE ABILITY TO CARRY OUT COOPERATIVE STUDIES

Every physician hopes that the treatment he provides his patient will be effective. However, the efficacy of many procedures in medical practice is unproved. There are also many examples of procedures which were part of the conventional wisdom but which were eventually shown to be ineffective. Therefore, clinical trials need to be carried out to test new procedures before they become dogma and to validate the efficacy of many standard procedures. The human and economic cost of ineffective procedures is large and

can be diminished through properly controlled clinical trials.

The VA has played an important role in carrying out such clinical trials through its CSP. It has a large patient base under one management, a situation that enables the VA to perform clinical trials in which large numbers of patients can be treated according to a uniform protocol. Before considering further the features that give the VA this unique capability, some of the VA's past contributions will be summarized.

One of the earliest VA cooperative studies was initiated in 1946 to study the effectiveness of chemotherapy for tuberculosis, which led to a major medical revolution. The VA was able to close down or convert to general medical and surgical use all of its tuberculosis hospitals and the impact was similar on medicine outside the VA. This achievement is perhaps the most well-known of all VA contributions to medical science; it is the prototype for other VA cooperative studies.

In psychiatry the VA CSP had a major impact. Cooperative studies evaluated the therapeutic effectiveness of psychotropic drugs. The findings led to shortening the length of hospitalization for many psychiatric patients.

More recently, cooperative studies of patients with mild hypertension who were treated with antihypertensive agents demonstrated dramatic reductions of deaths from stroke and heart failure when blood pressure was kept within normal limits. The VA's current study on coronary artery bypass surgery is representative of the contribution the system makes through its cooperative studies. This surgery has been performed on thousands of people, inside and outside the VA, at enormous human and economic cost without adequate evidence of its

efficacy. By instituting randomized clinical trials for this procedure, the VA is serving thousands of patients with heart disease and the whole medical profession. These studies are only illustrations and the VA CSP has made similar contributions to medicine in many areas.

Along with the direct answers obtained in cooperative studies, often important spin-offs are obtained from the studies. For example, the data collected in cooperative studies are of high quality; imaginative analysis may lead to a better understanding of the natural history of a disease, better diagnostic procedures for a disease, or an understanding of the medical complications of a particular procedure. In particular, the coronary artery bypass surgery study reduced complications from coronary arteriography.

Another byproduct of a study simply may be the upgrading of patient care in the participating hospitals. This sort of improvement has been noted particularly in unaffiliated hospitals, where physicians may be exposed to newer techniques and procedures when they participate in a cooperative study. In all studies the procedures are worked out thoroughly and standardized throughout the participating hospitals, which in itself may upgrade patient care. For example, the standardization of a surgical technique in one cooperative study led to an improvement in operative mortality. Similarly, in many of the medical studies, procedures for measuring blood titers of drugs or natural substances are defined in detail, resulting in more precise and reproducible measurements. Other improvements may result from the sharing of knowledge and generation of new ideas that occur when groups of physicians are brought together by the study. Individual investigators also may develop

research activities as sidelines to the main study. Useful information can often be gained from these spin-off studies with very little additional funding. Thus cooperative studies are the only way to find answers to some clinical problems. Moreover, the answers they provide are richer and fuller.

Turning now to some of the reasons why the VA is uniquely able to carry out cooperative studies, its large numbers of patients under one management must be emphasized. If a disease is rare, a large pool of patients is essential if enough cases are to be accumulated to draw significant conclusions. For both common and rare diseases, the implementation of a standard protocol in each of the participating hospitals is essential if undesirable variation is to be avoided. The single management of a large number of clinical facilities greatly simplifies the recruitment of centers into a study. It also makes the administration of the study feasible. Outside the VA, conflicts are common among investigators, coordinating centers, steering committees, and so on, all of which are separate entities. In the VA all these come under one management so that issues can be more easily resolved.

The VA also has an advantage in that the patient population is in some respects more stable than those at large university referral centers, the other common setting for clinical trials. Most VA patients will receive some form of continuing care through a VA hospital, and the patient follow-up so essential to clinical trials is likely to be more complete. In addition, less control over treatment is exercised in the referral centers. What occurs more frequently in referral centers than in the VA is that the referring physician may choose a particular treatment for his patient--thus truly

random assignment of patients is impossible.

Perhaps the final advantage the VA has in cooperative studies is an attitudinal one. Many VA staff take pride in the VA's accomplishments in the cooperative studies program, and therefore are more willing to participate themselves. Secondly, individually-initiated research is not as important for many VA staff members as it is for staff in university centers; this is why they may cooperate more easily. The issues involved in recruiting investigators to cooperative studies will be detailed later.

The VA, then, has considerable advantages and experience in carrying out clinical trials. *The Committee believes that the VA should continue to place a major emphasis on the program in the future. Although its discussion has focused on clinical trials, the Committee also believes the VA has important contributions to make in other types of studies involving multihospital collaboration. Three examples are: epidemiology, studies of the natural history of disease, and health services research. Some of these studies could be carried out under the aegis of the CSP, whereas other studies could be developed through other programs under the general research and development umbrella of the VA.*

OVERVIEW OF THE PROGRAM

The CSP budget is $6.5 million for 1976, about 7% of the total funds for medical research. These figures do not include the $3.5 million that the VA receives for collaborative studies sponsored by the National Cancer Institute (NCI), because these studies are administered separately within the VA. *The VA should consider whether it is appropriate that the NCI studies*

are managed separately. With its experience and expertise in handling multi-hospital studies, the CSP unit should be able to administer the NCI studies effectively.

Table 5-1 lists the budget breakdown for the CSP for FY 1976 and shows the range of studies in which the VA is involved. The figures are not necessarily an accurate reflection of the relative costs of the studies, since some may be nearing completion and only would receive funds for data analysis. Other studies are only just beginning. Although the costs of cooperative studies vary considerably according to type of study, number of hospitals involved and lifetime of the study, they rarely cost less than $200,000. The average cost of a study is about $400,000. Costs are set forth in Table 5-2, which lists the 15 full-scale cooperative studies carried out since 1967.

Like the rest of the VA's biomedical research program, these figures are not a true indication of cost because they do not include principal investigators' salaries nor the cost of the medical care for patients in the studies. Both of these indirect costs are paid from general medical care budgets.

Paying principal investigators' salaries from the medical care budgets of the participating hospitals poses a problem for the program. The principal investigator has to carry out all his clinical duties in addition to the time he spends on the cooperative study. In one case, a study had to be abandoned because appropriate clinical scientists were in such short supply that they would not have time to be involved in the cooperative study.

TABLE 5-1

Cooperative Studies Program, FY 1976[a]

Studies	Funding	
		[b]
Hypertension #6	$ 64,532	(32,726)
Hypertension #7	52,106	
Hypertension #8	788,613	(372,065)
Hypertension #9	-	
Hypertension #10	-	
Unstable angina	1,656	
Hypertension compliance	42,060	
Hepatitis post-transfusion	157,280	(53,584)
Hepatitis needle-stick	307,610	(7,992)
Hepatitis drug abuse	91,323	
Day treatment care	40,063	
Suicide prevention	7,004	
Aphasia therapy	124,762	
Aspirin/angina	310,475	
TB rifampin	500	
Coronary artery surgery	258,443	
Sickle-cell trait	151,317	
Prostatic cancer (NCI-funded)	8,960	
Quality control laboratory	5,805	
Vasodilator therapy	470,136	
Methadone	7,919	
Crohn's disease (NIH-funded)	-	
Analgesia	194,561	
Ward milieu	285,332	
Renal dialysis	115,754	
Sleep therapy	129,282	
Bowel preparation	240,234	
Urinary tract infection	4,500	
	3,860,227	
Support Facilities		
Aspirin/angina lab (Durham)	18,096	
West Haven, Connecticut	500,212	
Perry Point, Maryland	470,558	
Neuropsychiatric lab (Perry Point)	56,813	
Hines, Illinois	473,752	
Central research pharmacy (Washington, D.C.)	91,887	
CSP Chief's Office (Miami)	12,167	
	1,623,485	
Other		
Contracts	168,382	
Reserved for payment of non-VA personnel	225,000	
Not allocated at this time	622,906	
GRAND TOTAL	$6,500,000	

[a] Data provided by CSP, VA Central Office. This breakdown lists fund allocations as of 10/17/75. Approximately $600,000 remained unallocated. Those funds were used for planning of studies, initiation of approved studies, and increased allocations to the above studies when new hospitals were recruited.

[b] Figures in parentheses show amounts for which the VA will be reimbursed by other agencies.

TABLE 5-2

Costs of Cooperative Studies Begun and Completed Between FY 1967 and 1976[a]

Study	Total Costs ($ in thousands)[b,c]	Number of Fiscal Years Study was Funded
Sickle-cell trait	1,132.4	5
Hepatitis post-transfusion #2	888.4	4
Hepatitis needlestick	885.5	5
Methadone	761.9	4
Hepatitis drug abuse	479.9	4
Hypertension #6	478.1	4
Rifampin Chemotherapy of TB	457.0	6
Foster care	378.7	6
Hypertension #7	359.3	4
Diabetic retinopathy	239.5	4
Psychiatry project #17, lithium	57.6	5
Reiter's disease	53.2	5
Psychology of aging	48.3	3
Decubitus ulcer	40.2	3
Delirium tremens	8.1	2

[a] Data provided by CSP, VA Central Office. Some studies have been considered complete although the chairman's office will receive some funds for preparation of manuscripts in FY 1977.

[b] Costs do not include travel, use of special laboratories, or support at statistical centers.

[c] This table may not give a true indication of average costs of studies. A few studies were initiated before FY 1967 and were still not completed in FY 1976. These studies would not be recorded here. For example, the analgesia study began in 1957. Study costs FY 1967- FY 1976 = $1,419.1 thousand (costs prior to 1967 are not available).

The Committee recommends that if such difficulties occur, the problem could be alleviated by providing funds in the cooperative study for at least partial payment of the physician-investigator's salary. Funds would therefore be available for more staff, and the investigator could be released from some of his clinical duties. This arrangement is sometimes made for the study chairman and it could be extended to participating investigators. Some VA cooperative studies are supported by other agencies; when such arrangements are made the VA should be compensated for investigators' time.

The VA also is unique in that it provides free medical care to all patients, whether on research studies or not. Patients on cooperative studies outside the VA may be expected to pay (usually through third party payment) for their treatment, which may involve many extra tests and procedures.

Taking into account both the direct and indirect costs of studies, it is clear that although the VA has many special advantages in carrying out cooperative studies, they are very costly nonetheless. The amount of actual research funds required per study is large, the cost in physicians' time is great, and the number of physicians willing to participate in cooperative studies is a finite resource that should not be wasted. In summary, the utmost care should be taken to ensure that any cooperative studies that are carried out are important according to the following criteria.

- Studies should require a large-scale approach rather than simpler means to reach an answer.
- Studies should explore important medical problems that affect large numbers of people, or although rare, are severely debilitating.

- Medical investigations should be of particular relevance to the VA patient population and the VA mission in caring for such patients.

The ongoing cooperative studies were reviewed by the Committee. They concluded that some studies were of high quality and others were not; some studies were seeking answers to critical questions, whereas other studies seemed to be of lesser importance. In several cases, the Committee was ambivalent about whether the results would justify the costs. When the Committee reviewed the ongoing program, it became concerned about procedures for identifying and initiating cooperative studies. If the VA is to use its resources wisely, the identification of studies is of crucial importance.

IDENTIFICATION AND INITIATION OF STUDIES

At present, most cooperative studies originate from a physician or a group of physicians on the staffs of individual VA hospitals. Occasionally, a government agency may request the VA to conduct a study in an area of its particular interest, often with special funding provided.* Only infrequently are cooperative studies identified by the Central Office or support centers.

Study proposals are screened by the VA Central Office research staff for their feasibility and their relevance to VA interests. After this screening, the studies are assigned to a support center. The support center works with the study's proponent and some of the investigators he has

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* The VA's special resources could be used more fully if this opportunity were publicized more.

recruited for it to develop a study design. After one or two meetings of this planning group, the study is reviewed by the CSP evaluation committee. Either it is approved for funding, rejected, or most commonly, sent back for some modification before final approval at a later meeting. Once approved by the evaluation committee, it is usual, although not automatic, for the study to be initiated. These steps will now be considered in more detail.

Identification

After reviewing the ongoing cooperative studies, the Committee was convinced that optimal use was not being made of VA resources. Although the Committee encourages individual investigators to propose cooperative studies, this mechanism is not satisfactory when used by itself. *The Committee recommends that a procedure be developed for the central identification of studies. Panels of qualified scientists from within or outside the VA should meet periodically to identify important clinical problems suitable for cooperative studies.*

Proposals of individual investigators also could go through an initial screening by the appropriate scientific panel before being sent forward for planning. At present, the screening is carried out only by Central Office staff. Central Office involvement in the initial screening may, of course, still be necessary because they are aware of fiscal and other constraints on the CSP.

Central direction of cooperative studies is not altogether new. Before its conversion to a support center in 1974, the central neuropsychiatric research laboratory at Perry Point had directed many psychiatric and

behavioral science cooperative studies; indeed, a number of important cooperative studies were conducted under its auspices. The productivity of psychiatric and behavioral science research has decreased markedly since the lab facility was discontinued, and there seems to be no likelihood of reestablishing its effectiveness under current procedures. Because the staffs of VA neuropsychiatric hospitals lack the research background necessary for identifying promising research studies, the central research lab was important. Restoration of the former productivity of psychiatric and behavioral science cooperative studies will require reinstatement of central identification and management of studies.

The centralized development and monitoring of cooperative studies programs is of further value in that it increases the opportunity to enhance linkage with the science base so essential to clinical studies.

Although central identification of cooperative studies may be more necessary in some areas than in others, the Committee does recommend that a panel should be set up for each major clinical discipline. When a problem is identified as suitable for a cooperative study, it may be appropriate to select a person within the VA system to develop the study and become its chairman. (For psychiatric studies, continuing central direction of the study may be necessary.) The Committee hopes that the development of these procedures would lead to better forward planning in the program and more deliberate attention to diseases that should be investigated. *If these methods were instituted to identify studies, the Committee would recommend that the program be expanded and a larger proportion of the VA's research funds given to it.*

The Planning Phase

The Committee believes that despite the problems, cooperative studies are generally well executed. Much of this success is due to the involvement of the CSP support centers (or the provision of some other outside biostatistical support) in the design, development, and monitoring of the studies. As soon as studies are approved for planning, access is provided to people trained in statistics and in study design. In general, the VA is able to carry well designed studies because of the early involvement of the support centers or outside statistical consultants.

The support centers have existed as such for only a short time, and many of the ongoing studies were designed with the help of non-VA consultants. It is hoped that the support centers will develop enough to deal with all the cooperative studies and provide not only adequate, but imaginative study designs.

The planning phase involves recruiting hospitals and investigators into the study. This task is discussed in the next section. One weakness in the planning phase lies in the estimation of the number and availability of subjects necessary for the study. Many of the ongoing studies have run into problems in recruiting adequate numbers of patients, perhaps because of overestimations of patient suitability based on record reviews. If it is necessary to lay down stringent requirements for patient entry into the study, then care should be taken that these requirements are absolutely and clearly understood when such estimates are made. If these requirements prove to be so restrictive that not enough patients can be recruited, then it would be

more appropriate to reconsider the requirements before the study is initiated rather than part way through it.

Initiation

Completed study designs are put before the CSP evaluation committee. The regular body consists of people with diverse scientific expertise and familiarity with cooperative studies; a specialist in the area of the study under review will be recruited as an ad hoc member. The committee appears to act only as a body for scientific review. The members take this function seriously, but they are less concerned about the broader policy issues of the CSP. This deficiency reinforced the Committee's concern that no group existed that discussed the more general issues in the program, including the identification of important areas for study.

The CSP evaluation committee would be necessary even if scientific panels for cooperative study identification were formed. Once planned, studies still would need to be reviewed because fiscal constraints and scientific standards make it unlikely that all studies could be funded. The evaluation committee could draw on the identification panels to get some idea of the importance of the proposed studies. It would be appropriate for the evaluation committee to oversee the CSP in toto, including the balance among different problem areas. In addition, the committee could be more actively involved in the ongoing studies. Although much of the oversight of an ongoing study is a function of the individual study's operations committee, there are times when proposed changes in design are of sufficient import for the operations committee to return the study to the evaluation committee for

general advice or their opinion about whether the study is worth continuing. For example, if a major change in the sample size were necessary, the evaluation committee might advise on whether to proceed with the revised study. The evaluation committee does review each study at three-year intervals, but their review may be appropriate on other occasions. *Thus the Committee would like the evaluation committee to oversee all ongoing cooperative studies, coordinate the recommendations of the identification panels, and report through appropriate channels to the advisory council previously recommended by the Committee to oversee the total VA research program.*

EXECUTION OF COOPERATIVE STUDIES

Management of Studies: the Study Chairman, Support Centers, and Operations Committee

Cooperative studies are a large and complex undertaking, and to utilize VA resources and personnel best, careful planning, monitoring, and data analysis is required. Although this has not always been the case, it is intended that the particular CSP support center working with the study proponent should carry out these functions. The operations committee is responsible for a more general oversight, and its activities will be discussed later.

Site teams representing the Committee visited all three CSP support centers. The West Haven center is the most nearly fully developed of the three; Perry Point is gradually emerging as a support center after being a central neuropsychiatric research laboratory; and Hines is still in transition from providing biostatistical support only to local hospitals. All

three centers have problems in hiring staff, particularly biostatisticians. To compete in the job market for biostatisticians with appropriate qualifications, it is necessary to offer positions at the GS-14 and 15 levels. However, the VA administrative staff will not readily agree to GS-15 biostatisticians for support centers. Even when such positions are approved within the VA, the delays and uncertainties in dealing with the Civil Service Commission make it extremely difficult to hire professional staff for the support centers. *Steps should be taken to alleviate these recruitment problems, at least at the VA administrative level.* The cumbersome bureaucracy has slowed the development of the support centers, and a number of able biostatisticians have been lost through delay.

Because of the recent establishment and slow development of the centers, the ongoing studies had received very different types of biostatistical and computer support. In several cases, a biostatistician from outside the VA had been used as a consultant in the development of the study, but monitoring and analysis had been handed over to the support center. Changing statisticians in the middle of a study is disruptive at best, and it can be detrimental.

Because of the shortage of personnel, many studies have been forced to purchase biostatistical and computer support through contract with a private agency. This seems to be adequate but it is not an optimal situation. It is more expensive than intramural support, and as the study is not usually the contractor's highest priority, contractors are felt to be generally less sensitive to the needs of VA participants than are support center staff.

Even when all support has been handled intramurally, the individuals or groups responsible for monitoring the study have varied. In some studies the study chairman rather than the support center has monitored most of the research. The quality of the support also has been variable. In some studies handled by support centers, the design, monitoring, and analysis have been thorough and imaginative; in others, it has been barely adequate. The Committee hopes that as the support centers stabilize, the problems and delays in getting studies underway will be alleviated. Cooperative studies provide rich sources of data and the Committee hopes that the support centers will design analyses to exploit this data as fully as possible. Given the above difficulties, the support given to cooperative studies in the VA has been impressive. As mentioned, much of the success of the studies relates to that early involvement of biostatisticians and data analysts.

There should be more than one support center. The Committee supports the VA's idea that each center should have a somewhat specialized role. Studies should be assigned to a center according to its specialty, and one or two specialists in that discipline should be employed in the center. However, some flexibility in study allocation should be allowed, because it is stimulating for the support center staff to be exposed to different medical problems. It also seems appropriate that the funding for each support center comes out of the whole CSP budget rather than the budgets of the individual studies done there. This gives the center a measure of independence and ensures some stability in funding.

The support centers and study chairmen monitor much of patient enrollment, quality and completeness of forms, and completeness of patient follow-up, etc. Each study is also overseen by the operations committee of that particular study. The operations committee is made up of non-VA personnel with expertise appropriate to the study, and it usually meets twice a year to review the study's progress. The operations committee can recommend to the CSP chief that a study be stopped if the question is answered before the full sample size is reached, if adverse effects outweigh the benefits of a treatment, or the performance of the study is poor. Three studies have been stopped by their operations committees in the last two years. One was stopped because of poor performance; the other two were stopped because they answered the problem earlier than anticipated and did not need to go to the full sample size. An operations committee can request that the study be continued beyond its projected time if necessary.

There is one final way in which the VA has attempted to make the data accumulated at different hospitals more uniform. In several studies, centers have been set up to interpret and analyze particular types of test results, e.g., electrocardiograms. The VA Central Office has suggested that uniformity across participating centers could be achieved further by setting up a research laboratory to analyze all laboratory samples for cooperative studies. When transport of specimens is not possible, this laboratory could set standards and periodically evaluate the laboratories handling these specimens. *The Committee agrees that a research laboratory would improve the uniformity and the statistical reliability of the information collected in*

the studies.

Participating Hospitals and Investigators

Of the 127 institutions receiving VA research funds in FY 1976, over half were involved in one or more cooperative studies. Almost all the hospitals participating in cooperative studies had received research funds of more than $500,000 for FY 1976. The research-oriented hospitals strongly affiliated with medical schools generally participate in cooperative studies. At this time, with little or no training provided for investigators participating in cooperative studies, it is preferable that these are the hospitals involved because they are where the competent investigators are located. However, if programs training physicians to participate in cooperative studies could be developed, other hospitals with less research orientation should be encouraged to become involved. These institutions do have many patients, and if their staff were suitably trained they could provide an important resource for cooperative studies.

It is crucial that all participating investigators are adequately trained for cooperative studies. Although some attention is paid to the clinical and research abilities of an investigator, the special understanding required for participation in a cooperative study is rarely examined. For example, it is especially important in cooperative studies that investigators adhere to the protocol rigidly because several hospitals are involved. Some familiarity with biostatistics, epidemiology, and computer analysis also would be advantageous. *The Committee suggests that the support centers offer short courses on these topics for investigators participating in*

studies. If such courses were instituted, it would be possible to invite investigators in hospitals with less active research programs to participate in cooperative studies. Once investigators have been through these training courses and have participated in a cooperative study, they should be encouraged to participate again. Cooperative studies are a special type of research and those who have had experience with them are urgently needed. *In addition, the Committee recommends that a program could be established for selected VA clinical investigators in which they would be given a thorough training in research methods for cooperative studies. Such investigators could form a base for the program. They would be expected to make a long-term commitment to cooperative studies and play a major role in their design and execution.*

The willingness of investigators to participate in cooperative studies may be a limitation to any expansion of the program. There are intrinsic rewards in participating in cooperative studies, but in a medical-academic system that emphasizes individual achievement, disincentives to participation loom large. Cooperative studies allow no opportunity to produce and develop original ideas--indeed, individuality is discouraged--and resulting publications have many names on them. Obviously, little prestige is to be gained from involvement in a study. However, some incentives encourage investigators to become involved. Participating investigators usually are provided with a part-time secretary, research nurse, or technician, and in the VA system this help is a considerable benefit. The most important incentive may be the opportunity for an investigator to meet and interact with people in

his own field. *The Committee believes that more thought should be given to increasing the incentives to participate.* For instance, an investigator's time could be freed by paying a substitute to take over certain duties. This substitute could be paid out of the cooperative study's funds. The opportunities for the participants to meet together should be increased because frequent meetings keep interest high and serve to inform participants about new developments.

Site visits revealed that the quality and degree of involvement of investigators participating in studies varied greatly. Sometimes investigators were highly committed to studies and knew a lot about them; in other cases, investigators showed little knowledge or enthusiasm. It is essential that investigators are interested and enthusiastic about the studies if they are to recruit the expected numbers of patients and adhere to the protocol rigorously. If investigators do not enter enough patients into the study or produce an acceptable quality of data, they should be asked to drop out of the study.

Travel is an essential element in the success of cooperative studies. Visits by the study chairmen or support center staff to participating hospitals are necessary to monitor performance in the study and evaluate the quality of the collected data. Such visits also help to keep enthusiasm for the study high. For these reasons it is imperative that cooperative studies have sufficient travel funds. At present, funds are insufficient, meetings of investigators are infrequent, and visits to participating hospitals are rare. *The Committee recommends that travel budgets for cooperative studies*

be increased.

Protection of the Rights and Safety of Patients Participating in Cooperative Studies

By definition, cooperative studies require the involvement of many patients. In 1975, it is estimated that 18,785 patients were entered into cooperative studies.* Ethical issues are always involved when patients are the subjects of research. Only ethical issues of particular importance in cooperative studies will be discussed here, along with the special safeguards for patients in these studies.

The rights and safety of patients involved in cooperative studies are protected by a number of different groups. Each support center has a human studies committee (HSC), which reviews the studies under development in the center before they are sent to the CSP evaluation committee. This HSC review is repeated yearly once a study is underway. The HSC acts then as a subcommittee of the study's operations committee. The CSP evaluation committee may deal with some ethical issues itself. In addition, the study is reviewed by the HSC in each of the participating hospitals. Finally, the operations committee considers ethical issues in deciding whether the study should continue.

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* This figure includes 10,000 patients entered in the sickle-cell trait study and 1,075 patients entered in the ward milieu study. The degree of patient involvement in these two studies is very low.

Most cooperative studies are clinical trials, and therefore they often involve the random assignment of patients to drugs or placebo or to two or more different drugs or procedures. Before a study is undertaken, the scientific and medical evidence which justify carrying out the study and randomizing patients needs to be assessed. *The Committee believes that the CSP evaluation committee should include this assessment as part of its review of a study. In addition, when support center HSC's review studies to ensure that the rights and safety of patients are protected, they also should consider this underlying ethical issue.*

The operations committee continuously reviews the data accumulated during an ongoing study and decides at what point the study should be stopped. The ethical aspect of their role is an important one. It would be extremely difficult to let those involved decide when to stop or modify a study. To allow the participating investigators to know results when the study is in progress would place them in an ethical dilemma in treating their patients.* An outside group to review the evidence and make the decision takes the burden off the investigators, which is in the interests of the patients and the study.

The Committee was impressed by the support center HSC's commitment to protecting veteran patients. However, these committees are composed only of

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* In addition, it is highly probable that knowledge of results would bias investigators and the study.

lay people and are somewhat disadvantaged in having no medical members. On some occasions the committees have sought outside medical opinion, but they have felt that a physician as permanent member of the committee might exert too strong an influence. *The Committee feels that one physician not associated with the VA should be a member of each support center's HSC. Other medical specialists should be called on as consultants, when necessary.*

The Committee was pleased to learn that recently the support center HSC's have begun visiting participating hospitals and talking to patients about their involvement in research. This innovation is very necessary if the HSC's are to monitor human subject participation effectively. Each study also is reviewed by the HSC's in each of the participating hospitals. (These committees are discussed in Chapters 3 and 6.) *The Committee recommends that HSC representatives from each participating hospital should meet with the support center HSC to discuss and resolve ethical issues inherent in a study.* This could be a useful learning experience for all concerned as well as a valuable protection of patients' rights.

Finally, one ambiguity remains about the role of support center HSC's. They act merely in an advisory capacity, although the Central Office has stated that without their approval studies would not begin. HSC's receive no feedback about whether their recommendations are carried out; they learn what happened only when they review the studies a year later. *The HSC's should be informed about whether the evaluation committee upholds or rejects their recommendations. If any differences of opinion arise, then they should be resolved openly to the satisfaction of both the HSC and evaluation Committee.*

SUMMARY

The Committee believes that the VA has made major contributions to medicine through the CSP. Because the VA has such unique capabilities, the Committee recommends that greater emphasis be placed on this program. Such an expansion, however, should only be contemplated if better methods for identifying studies are initiated and suitably qualified investigators are available to carry them out. Panels of clinical investigators in various scientific disciplines should meet together to identify important problems for cooperative studies that are also appropriate to the VA mission, and to ensure an adequate linkage of the clinical aspects to the relevant science base.

Some attention needs to be paid to how investigators are recruited into cooperative studies, to their training, and to incentives that will make them more willing participants. In addition, travel budgets should be increased so that the participants can meet together more frequently and that study chairmen and support center staff can visit the participating hospitals regularly. Frequent meetings help to maintain interest and ensure high quality and uniformity in the execution of these studies.

Finally, it is believed that the rights of patients participating in the CSP could be better protected by including a physician as a member of each support center HSC and enabling representatives of each participating hospital HSC to meet with the HSC of the appropriate support center.

CHAPTER 6

STUDY OF PATIENT INVOLVEMENT IN RESEARCH IN VA HOSPITALS

BACKGROUND AND STUDY OBJECTIVES

When the Committee began its work, the VA was revamping its procedures to protect human subjects in research projects. On some of the early site visits, it appeared that these newer, more restrictive guidelines had not been disseminated or put into operation at some hospitals. Therefore, the Committee was concerned about the adequacy of procedures actually employed in protecting VA hospital patients and obtaining their consent for participating in research. This concern was reinforced by the interest of the National Commission on the Protection of Human Subjects in Biomedical and Behavioral Research, which had begun to look into the special problems of "dependent" persons: children, prisoners, and other institutional inmates whose freedom of choice to participate in research might be limited. Many veteran patients are dependent on the VA hospital system for their care, and, since the national commission had explicitly decided not to visit VA hospitals, the Committee felt a strong obligation to undertake its own study of patient involvement in research.

It was not possible to undertake the study until late in the life of the Committee--after most of the site visits had been made. There was neither time nor money enough for a large study. Accordingly, the surveys of patients and investigators reported below are limited in objectives and scope.

The Committee's primary focus in the study was the adequacy of the process of obtaining informed consent. The patient's understanding of his

participation in research and the conditions under which he agrees to take part are essential features ensuring patient protection. The patient study accordingly dealt with how subjects perceived their participation in research; how the process of obtaining informed consent was actually carried out, as perceived by subjects and investigators; and what, if any, relationships existed between the process of obtaining consent and subjects' perceptions. The principal questions that the study addressed are:

- Do patients know they are taking part in a research project?
- What is their understanding of the purpose and design of the research and their role in it?
- Are patients aware of their rights--that participation is voluntary and that refusal would not jeopardize their access to medical treatment, that they are free to drop out? Did they feel any pressure or inducement to join the study?
- Are they aware of the potential risks and benefits of the experimental procedure?
- How well do participants recall the process by which their consent to participate was obtained?
- How much do they know about the medical treatment or procedures that are being employed?
- Are subjects satisfied with the information they received? Did they feel well prepared for their experience?
- How do principal investigators describe the process of obtaining informed consent?

- What are investigators' attitudes toward the process of obtaining informed consent, and toward the process of human studies committees' (HSC) review of research?

STUDY DESIGN

To answer these questions, a two-part study was designed: veteran patients who were currently subjects in medical or psychological research in selected hospitals were interviewed, and principal investigators of projects involving these patients were mailed a questionnaire.* The interview and questionnaire are reproduced in Appendix E.

To minimize patients forgetting the circumstances of their invitation to participate in research, yet still including a sizable number of subjects, the study included patients who had been enrolled up to 75 days prior to interview, but not more. About 65% of patients had been enrolled in their research projects less than 30 days before being interviewed, and only 11% were more than 60 days.

The Committee was unable to sample from the whole population of human subjects involved in VA biomedical research. Because of costs, patient interviews could be conducted at only a limited number of sites, thus forcing

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* The interview schedule and the questionnaire were constructed in collaboration with the Bureau of Social Science Research (BSSR), Washington, D.C., whose interviewers contacted principal investigators and conducted patient interviews at the hospitals. Patient interviews generally required 20-30 minutes. BSSR coded and tabulated interview and questionnaire results, and NAS/NRC staff and Committee members performed most of the analysis.

the interviewing to be carried out in hospitals with relatively large research programs involving substantial numbers of human subjects. However, it was possible to choose from hospitals that were geographically dispersed across the country (northeast, midwest and west coast); thus hospital location was the only characteristic controlled in the study design.

Because of these restrictions, the Committee interviewed all the patients then in research projects in the chosen hospitals rather than trying to minimize random error by restricting interviews to only those projects which had some specific minimum number of patients participating. This decision precluded certain refined statistical analyses (e.g., variations among individual research projects) but enhanced confidence that the results of the study were a fair representation of conditions in each of the chosen hospitals.

Selection of Patients for Interview

It is not clear just what proportion of VA research projects involve human subjects directly. In 1973,* 2,547 out of 3,658 VA investigators reported using human subjects in their research, but as the VA does not keep central records on the subject, it is not easy to determine where the human subjects are participating, how extensive their involvement is, or how many are involved at any particular time.

On the basis of a preliminary inquiry, it had been estimated that 17,500 patients were taken into research projects between February 1 and March

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* Data is taken from the medical research information system, VA Central Office FY 1973 and includes principal and co-investigators.

31, 1975, the period corresponding to the length of time interviewing was expected to take place in 1976. As expected, the largest number of these patients were in the group of hospitals with the largest programs, i.e., those with research budgets of $1 million or more. Therefore, the Committee had hoped to find as many as 10-15 patients taken into individual projects over the period during which it expected to interview patients. Such numbers turned out to be rare, even in the hospitals with the largest research programs.

To select sites, VA hospitals with the largest amounts of VA research funds (19 of the 31 with $1 million or more in VA funds and 3 of those with funds from $375,000 to $1 million) were surveyed. Estimates of the number of subjects in research were obtained from the associate chief of staff for research in each hospital, who in turn obtained estimates from each of the individual investigators, the only source of information about patients on research protocols. Because many projects at every hospital were unsuitable for the Committee's purposes, four hospitals with programs that would yield enough patients to interview within the temporal and financial limits of the study were selected for the interviewing program. Research projects were selected in each, names of available patients were obtained from investigators, and all available patients on those projects were then interviewed.

Initial Criteria for Choice of Research Projects

- Project needed to include patients who could be interviewed not more than 10 weeks after they signed the consent form or intake of new patients was expected during the interviewing period.

- Evident patient involvement in the research, i.e., the project would have to require something of which the patient would necessarily be aware: undergoing a surgical procedure, taking an experimental drug, participating in an experimental treatment, or requiring the patient's time and attention, or causing him some inconvenience. Routine observations, blood samples taken for experimental purposes, special analyses of routinely collected urines, or review of patient charts were not considered sufficient patient involvement.
- Subjects or entire projects were excluded if the subjects were female, not veterans, volunteers with no research-related illness, patients for whom proxy consent was required, or patients judged by the investigator to be terminally ill or too sick to be interviewed.
- Projects studying frank psychosis or severely disabling psychiatric disorders were excluded to avoid difficult interviews.

Project Selection

By the criteria, 79 projects were selected from the original 194 listed for the 4 hospitals, as shown in Table 6-1. More than 100 projects had to be eliminated because they did not fit the criteria listed. Investigators' estimates of the numbers of patients to be taken in were found to be quite inflated. In every project, the actual number of active research patients whom the investigator could identify for interview was far smaller than had been projected. Only 188 patients were participating in eligible research

TABLE 6-1

Patient and Project Selection Pool

	Projects Listed by ACOS	Expected Intake, No. of Patients	Projects Selected	Projects With Patients Interviewed	No. of Patients Interviewed
Hospital A	59	2,200	20	13	36
Hospital B	21	85	13	7	23
Hospital C	37	1,047	21	13	50
Hospital D	77	1,111	25	17	47
TOTAL	194	4,443	79	50	156

projects during the interviewing period and of these, 156 were actually interviewed.

Table 6-2 is an analysis of the attrition caused by elimination of projects at one hospital. Detailed analysis of the attrition rate at another hospital produced similar results. The Committee returned to those projects for which there had been too little information or no active patients, but it was still unable to add any patients. Among the selected projects, some never took in any patients within the interviewing period, which accounts for the difference between the third and fourth columns in Table 6-1.

Patient Selection

As explained above, patients were excluded if they were female, not veterans, or volunteers with no research-related illness.* Patients for whom proxy consent was required or patients judged to be too sick to be interviewed were not suitable participants. Investigators gave the interviewers the names of all eligible patients who were active on the project and expected to be present at the hospital at any time during the interview period; interviewers determined that a consent form had been signed by each patient and the date of signature was noted. At the request of the VA, this information was obtained from staff rather than from the patient records to protect their confidentiality. Interviewers then approached the patients in their hospital wards or when they came for routine visits to the clinic. The Committee attempted to have all of the available patients on each study

* Three or four volunteers inadvertantly slipped past the screening process.

TABLE 6-2

Shrinkage of Patient and Project Selection Pool at One Hospital

Reason for Rejection	No. of Projects	Estimated No. of Patients
Too little information	4	120
Too little patient involvement	16	342
No active patients (within time limit)	9	106
Study ended	2	31
Women subjects only	4	51
Non-veteran patients	1	40
Inappropriate studies	2	21
Patients screened by investigators but not accepted for their study	15	180
Patients too sick to be interviewed	1	6
	54	897

that met eligibility criteria interviewed and succeeded in interviewing 156 out of a possible 188. Table 6-3 summarizes the distribution of patients interviewed and not interviewed. No pattern is apparent in the reasons for not interviewing a patient, except that about half of these patients who failed to keep appointments were being treated for drug addiction or alcoholism, two categories of patients who are unreliable in keeping appointments and following treatment regimens. At Hospital C scheduling problems resulted in six patients being discharged before the interviewer was able to make contact with them. Otherwise, the distribution of eligible patients not interviewed is roughly proportional to the size of the interviewee pool. No other systematic biases are discernible.

Classification of Research Projects

The 156 patients interviewed were involved in diverse biomedical research projects, as Table 6-4 shows. Most (34) of these studies were evaluating the therapeutic efficacy of drugs. Ten other studies focused on diagnostic techniques, and three evaluated surgical or radiologic techniques. The remainder did not fit any of these categories: one compared behavioral treatments for alcoholism, another examined biofeedback for migraine headache, and the third applied a novel kidney dialysis technique.

The 50 studies varied in the amount of time and effort they required of patients. Some were quite short-range, involving the patient for only a day or two in simple procedures that were undemanding, while others involved long

TABLE 6-3

Distribution of Prospective Subjects for Interview in the Four Selected Hospitals

Hospital	No. of Projects With Patients Interviewed	No. of Patients Interviewed[a]	No. of Projects Having Some Patients Not Interviewed	Number of Patients Not Interviewed by Reason: Missed Appointments, Failed to Appear	Discharged Before Interviewer Could Reach	Refused To be Interviewed	Too Ill To Be Interviewed	Misc.[b]
A	13	36	2	5	-	2	1	1
B	7	23	1	6	-	1	-	-
C	13	50	5	-	6	1	1	2
D	17	47	3		1	1	3	1
TOTALS	50	156	11	11	7	5	5	4

[a] The number of patients interviewed per research project ranges from 1 to 16. Twenty projects had only one or two patients active during the interview period.

[b] Includes one death, one patient dropped from study by the investigator, one voluntary withdrawal, and one who had been in the study for longer than ten weeks.

TABLE 6-4

Number of Patients Interviewed by

Disease/Disorder Being Treated

Disease/Disorder	No. of Projects	No. of Patients
Cardiovascular (including hypertension)	6	41
Arthritis	4	6
Gastrointestinal	8	17
Cancer	7	11
Drug or alcohol addiction	5	24
Obesity	2	3
Infection	4	22
Neurologic (including pain)	10	26
Renal	2	4
Metabolic	2	2
	50	156

hospitalization (30 days or longer), many diagnostic or evaluative tests, or frequent or extended revisits on an outpatient basis for follow-up.

The survey included a broad range of research as well as a spectrum of diseases/disorders. The many principal investigators and the four human studies committees responsible for these projects guaranteed that patients' experiences with the informed consent process was varied. The patients themselves ranged widely in age, race, education, income, and occupation. Some were outpatients, and others were in hospital. Therefore, the Committee believes that the interviews embraced a diverse patient population and a broad spectrum of research. Because of the manner of their selection, the patients interviewed cannot be called a representative sample, but they constitute an almost total enumeration of eligible patients at four research institutions. The Committee believes that the picture emerging from these interviews accurately portrays the process of patient involvement at VA hospitals with large research programs and many investigators. The Committee recognizes that there may well be contradictory evidence, especially from hospitals with small programs, isolated from a well-developed research milieu.

Investigator Study

As a corollary to the patient interviews, a mail questionnaire sought information from VA principal investigators about various aspects of the informed consent process as they executed it and their experiences with the review of research protocols by human studies committees. It also asked

about patient refusals to participate in research, dropouts from studies, and study designs. Investigators were asked about the benefits and disadvantages of the HSC review and the informed consent process, as well as what they thought were the best ways to inform patients and secure their cooperation.

Questionnaires were sent to all 40 investigators whose research had been identified as meeting the criteria outlined before. Although some investigators were conducting more than one research project at the same time, they filled out a questionnaire referring to only one of these projects. Thirty of the investigators who returned completed questionnaires were responsible for all but one of the studies (and all but two patients) who were interviewed.

Most of the comments about the patient sample also applied to the set of investigator responses obtained. Although the investigator sample was not statistically representative, the committee found no evidence to suggest systematic bias or selectivity in the information received from this source.

Analysis of Consent Forms

The procedure for obtaining informed consent has been in flux. In 1970, the VA issued guidelines* specifying that each station would "establish, within its Research and Education Committee, a Subcommittee on Human Studies and arrange for any investigator desiring to use drugs and/or procedures for

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* January 2, 1970 policy statement added to VA Department of Medicine and Surgery (DM&S), Manual M-3, Research and Education in Medicine, Part I, Revised April 2, 1962.

investigational purposes to submit his proposal for review by such subcommittee." The investigator was instructed to:

1. Fully inform the patient concerning the study and the planned use of drugs and/or procedures in the investigation, including possible adverse reactions.

2. Secure consent of the patient, by signature, on VA Form 10-1086, part 1.

3. Secure the consent of the patient's next of kin or guardian (in circumstances enumerated).

The Form 10-1086, used before 1975, is a standard form certifying that the patient has been informed of "the nature and purpose of the drug and/or procedure and the pertinent potential complications." It did not require the statement of purpose, procedure, risks or benefits of the individual research study, although a brief description was occasionally added.

Following the example of the Department of Health, Education and Welfare, more detailed guidelines were issued by the VA on March 10, 1975* "to bring Human Studies Subcommittees to present standards and to clarify VA's measures for protection of human rights and safety during clinical investigation."

The guidelines of March 10, 1975 stated that "informed consent usually should be obtained in writing and the written material, signed by the subject or a guardian, should be complete enough to reflect the information given as well as any limitation placed on the consent by the subject or guardian."

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* VA DM&S Interim Issue, 10-75-8, March 10, 1975.

Consent also could be obtained orally with a detailed note inserted in the patient's chart or in the investigator's records that reported the conversation, including all disclosures, the consent, and any limitations on consent. In either case, "the interview should be witnessed by a third party who signs the form or note with the subject and the investigator."

Subsequently* Form 10-1086 was revised and required that an investigator prepare a separate document containing information about each individual study. Since that time, the practice of obtaining informed consent has changed considerably. However, studies that began before the issuance of the new guidelines often have continued to use the old Form 10-1086.

Consent forms for the projects the Committee studied were both the old and new types. The new individualized forms were used in 40 of the 50 research projects included in the patient study. These varied in length, complexity and technicality, as well as completeness or coverage of the required information. The consent forms were classified according to the amount of information given on treatment and the amount of information given on patients' rights. Finally, a standardized measure of the level of reading difficulty was applied to the 40 individualized new forms in use on the research projects surveyed.

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* VA DM&S Circular, 10-75-121, June 19, 1975.

RESULTS

The interviewer who questioned patients introduced herself as part of a study "to find out more about the kinds of medical treatment [patients] are receiving." This bland explanation was chosen to avoid suggesting to the respondent that his participation in research was the occasion for his being interviewed. The first question patients were asked was whether or not they were participating in a research study. Their responses were puzzling, because informed consent procedures were required for all projects, all projects had been reviewed by HSC's, and consent forms signed by the patient himself were a part of the record for each patient interviewed. Nevertheless, 27.7% of the patients interviewed were not aware that they were taking part in a medical research study. This result was similar to Gray's finding that 39% of the patients interviewed had participated in a labor-induction experiment without knowing it, "even though all procedural requirements for obtaining clearance for the project and informed consent from the subjects were followed."* Robinson and Merav+ obtained parallel results in a study of 20 patients who had undergone open-heart surgery. Before the operation, their physicians had explained the procedure, its risks and potential benefits and

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* Bradford Gray. Human Subjects in Medical Experimentation: A Sociological Study of the Conduct and Regulation of Clinical Research, (New York: John Wiley & Sons, 1975), p. 139. See also pp. 128-129.

+ Robinson, G. and Merav, A. "Informed Consent: Recall by Patients Tested Post-Operatively," Paper presented at 12th Annual Meeting, Society of Thoracic Surgeons, Washington, D.C., January 26-28, 1976.

answered patients' questions. The surgeons had even recorded the entire interview (with the patient's permission). When these patients were reinterviewed, not only did most fail to remember most of the information given on that occasion, but some even denied having had such a discussion. However, these interviews took place sometimes as much as six months after the preoperative discussion.

The fallibility of human memory is notorious, especially when an individual is under stress. When anxiety is high--as it is likely to be just before surgery--the amount of forgetting appears to be extraordinary. Yet the figure of 27% "unaware" (of their participation in research) is disturbing, given the evidence that consent procedures had been followed for all patients. These unaware patients merit further attention and will be discussed later, but first the analysis will focus on the 112 patients in the sample who recognized and acknowledged their participation in research.

Patients' Reasons for Participating in Research

When the aware patients were asked for their reasons for taking part in research, most of them gave more than one answer, as Table 6-5 shows. The most popular response was that the treatment provided in the research project would have a beneficial effect on their health, for instance, "help me to get better." Almost three-quarters of the patients spontaneously mentioned this reason in their free responses. Thirty-two percent of patients gave an altruistic reason instead or in addition to a "selfish" one. They wished to help humankind, to repay a debt to society, or to the VA. One patient answered, "To repay the VA for this fine treatment they've given me." About 16% gave

TABLE 6-5

Reasons for Participation in Research

	Free Answer[a]			Stimulated Recall		
	No. of Mentions	Percent of Reasons	Percent of Patients	No. of Mentions	Percent of Reasons	Percent of Patients
Make me better, try a new approach, help me recover	82	51.8	73.2	83	22.7	74.1
Doctor asked me to, or wanted me to	14	8.8	12.5	32	8.7	28.5
Help humanity, medical science, pay debt to society	36	22.7	32.1	93	25.4	83.0
Curiosity	18	11.3	16.0			
Financial benefits	4	2.5	3.57	24	6.5	21.4
Wanted this treatment (instead of another, e.g., avoid operation)	4	2.5	3.57	45	12.3	40.1
Wanted a particular doctor				25	6.8	22.3
Get better care				32	8.7	28.5
Other people urged				28	7.6	25.0
Longer hospital stay				3	0.8	2.67
Total number of reasons	158			365		
Total number of patients	112			112		

[a] "Free answer" is the spontaneous reply to the open-ended question, "Why was it, you decided to take part in the study?" "Stimulated recall" comprises the reasons chosen by respondent from a list of possible reasons read aloud to him by the interviewer. Each reason mentioned by a patient is counted. Many patients gave more than one reason.

personal curiosity as a reason, and only about 9% reported that they took part "because a doctor asked me to." A tiny fraction (2%) said they preferred the investigatory treatment over having an operation, and only another 2% spontaneously mentioned financial benefits. When given a list of possible reasons for participating, however, 21% of the aware patients answered "yes" in regard to whether "being in the study helps me financially." For most, this was because of the free care received,* for example:

> I'm not able to work. I'm not able to buy medication.
>
> Well, it would help, what with the cost of medications and the cost of lost work and the doctor's charges that we save by coming here.
>
> I couldn't possibly afford the care I am getting now.
>
> If you had to go to private physicians, you have to pay for prescriptions. Here it's all free and only one stop.

A few said they benefited because they were paid for each clinical visit or for taking tests (usually in the drug projects).

No respondents spontaneously mentioned the possibility of receiving better care as a reason for taking part in research, but when recall was stimulated by the list of possible reasons about 9% replied that this purpose had entered into their decision to participate. Similarly, the expectation of benefiting from a longer hospital stay, the desire to be cared for by a particular physician (the investigator), and the influence of other people's urging

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* Of course, whether in a research study or not, all VA patients receive free care.

them to take part were not mentioned spontaneously by interviewed patients, but came out in response to the more directive question. The last reason on the list--"other people felt I should participate"--is noteworthy in that "other people" turned out to be spouses, relatives, friends, and other patients. Doctors and the hospital personnel were named only infrequently as advocates of participation in research.

Patients' Refusal to Participate in Research

Investigators were asked how many patients had been asked to participate in research and how many of these had refused. Less than 20% of all projects had more than 4 refusals, although a few had as many as 20 out of 30. (See Table 6-6). Obviously, the patient interview did not obtain responses from those who had refused the invitation to participate in research. Data on refusals was obtained from the investigator questionnaire.

The high refusals in certain studies usually can be explained on the basis of the type of study. The two highest refusal rates were for studies that involved either alcoholics or drug addicts. Two other studies involved more risk than most of the other projects--the use of immunosuppressant drugs and a surgical procedure with a high mortality rate. Another study had a high refusal rate perhaps because it involved unorthodox treatment (biofeedback) and considerable inconvenience for the patient. According to the investigator, patients objected to the amount of time required and the inconvenience of getting back and forth for outpatient visits. They also believed that the behavioral treatment was ineffective and only medication could help them. Reasons for refusals in the sixth study are not as easily under-

TABLE 6-6

Number of Patients Invited to Participate Compared to Number Refusing Invitation

Refusals		
High	Low	No Refusals[a]
15 of 75	1 of 15	0 of 80
6 of 25	1 of 25	0 of 30
8 of 48	3 of 15	0 of 33
20 of 30	2 of 98	0 of 5
129 of 200	2 of 46	0 of 30
25 of 60	2 of 15	0 of 20
	2 of 18	0 of 44
	4 of 20	0 of 6
	2 of 20	0 of 6
		0 of 10
		0 of 30
		0 of 20
		0 of 9
		0 of 12
		0 of 12

[a] Projects with less than five patients invited to join were not coded.

stood. According to the investigator, patients did not want to stay for follow-up or participate in any study.

Patients' Understanding of the Research Study

To test what patients actually knew about the nature of the research in which they were engaged would have been an exceedingly complex task, given the various research projects, and the descriptions of them in the research protocols. Thus, the inquiry was not designed to match patient knowledge with the details of the project. Instead two general questions were asked: one in regard to the purpose of the research and the other in regard to the patient's part in the study, as well as several questions concerning the research design.

Three-fourths of the aware patients were able to identify the principal investigator (or a co-investigator) as the person "in charge of the study." Another 10% appeared to know the doctor in charge, but were unable to give his name. The remainder either did not know who was in charge or incorrectly identified other hospital personnel as being "in charge."

Just how clear an understanding the patient had of the purpose of the study and his role in it was not always easy to determine from the respondent's free answers. Two approaches were taken to rating the patient responses. First, the answer to the question, "What is the purpose of the research?" was evaluated separately for each patient by three coders who took into account such components of the response as whether the patient was aware that a drug, a procedure or kind of treatment was being tested on himself and on others, whether he identified it, and how accurately he described it. Each

patient's answers to each of these questions were scaled from "full understanding" to "none" (including "misconception" and "information could not be evaluated"), producing the distribution shown in Table 6-7.

Since meager answers were often given to each of the questions separately, and the answers taken together seemed to indicate better understanding than the answers taken singly, it was decided to try a more comprehensive scoring scheme. Using his answers to the questions about the purpose of the research, the patient's role in it, and why the patient joined the study, the patient's understanding of the "purpose of the research" was scored by two coders who used the following scheme. If the patient's answers mentioned any one of the following items, one point was scored:

- The organ system or illness with which research is concerned.
- That a medication or treatment is a part of the research. (For instance, if the patient said that his role was "to take the medicine," he received one point.)
- The locus of medication or treatment.
- The specific purpose (or action on the body) of medication or treatment whether treatment itself is mentioned or not (for instance, "lower uric acid level in my blood").
- Understanding of the connection between points 3 and 4.
- The name or names of medication or treatment.
- Awareness of experimental aspects of research--mention of testing, new medicines, etc.
- Awareness of experimental design, use of placebo, randomization, etc. (not applicable to every project).

TABLE 6-7

Patients' Understanding of the Purpose of the Research

Level of Understanding	Number	Percent
Full	11	9.8
Fair	36	32.2
Minimal	43	38.4
None	22	19.6
	112	100.0

There was a reasonable degree of correspondence between the results of the two rating schemes, as shown in Table 6-8. By either scoring schemes, at least 20% or more of the patients had very little or no idea of what the research was about. Only 10-12% gave a reasonably complete and lucid account of the purpose or nature of the research, whereas the rest fell somewhere in the middle.

Regardless of scheme, these ratings provided only an approximation of patient understanding, especially since the questioning did not probe deeply and may very well not have elicited everything the patient actually knew. Furthermore, comparisons were difficult because the objectives and procedures in some studies were far easier to understand than those in others.

Some idea of what patients understood can be conveyed by describing their responses. The poorly informed were those who answered simply, "I don't know," or replied, "Just that it's supposed to help me," or "I wouldn't know--he explained it but I've forgotten." This category also includes those with only a vague idea of the nature of the research. These patients generally stated what it is they were being treated for in the research study but gave little indication of knowledge about the experimental drug or treatment. One patient said,

> I don't know [the purpose]. It's heart research. That's all I can tell you. [My role is to] just be myself and be hooked up to their machinery and take medications.

Another responded:

> To help future patients who have a history of ulcers. ... At present I have a duodenal ulcer.

TABLE 6-8

Patients' Understanding of the Purpose of the Research

Level of Understanding from "Purpose" Question	Total Score Based on Three Questions: Points 0-2	3-4	5-6	7-8	Total
Full	-	1	2	8	11
Fair	4	13	13	5	35
Minimal	7	26	11	-	44
None	17	5	-	-	22
TOTAL	28	45	26	13	112

The only other information he gave was that he took three medications.

A second group of patients had a minimal understanding of the nature of the research, and a somewhat more specific idea of the experimental drug or treatment as related to their particular illness. One patient responded:

> Type of medication for the elimination of cholesterol or blockages of the heart.

A patient with a fair understanding said the purpose of the research was to:

> Heal sores up in the quickest time possible. To see if salve will work on bed sores as on burns.

He did not mention the use of a placebo, however, or name the drug. Another patient in this group who said he had a leg injury said the purpose of the study was

> [to test] an experimental medicine to see if they can kill the pain ... Every day they will try a different type of medicine. Start 7:00 in the morning and check every hour. If no relief they will go back to original medication.

This is an accurate description of the experimental design, although the patient did not mention use of a placebo.

Finally, a patient in the best informed (or most articulate) group gave this exceptionally complete answer:

> [The purpose of the study is] for the epileptic drug ____ [names correctly]. It is being used in Europe and Japan and is being tested here to see if it qualifies as an epileptic treatment. [The purpose is to] try to find what its effects are and if it will be acceptable in the U.S. I take the proper amount at prescribed intervals and come to the hospital once a week or every other week for the blood and urine tests to see what the drug's level is in my body and to see if it's made any difference in my seizures and tremors.

Another patient in this group correctly described a randomized study design.

> The _____ [names correctly the drugs involved] study [is to] see if this medication affects the occlusion rate in blood platelets which

> brings about angina pectoris. One-third takes placebo, one-third [one drug], and one-third the combination of [one drug] and [the other drug].

Only a handful of patients spontaneously offered any explanation of the reasons for randomization or the use of a placebo when it would have been applicable. Of those patients who knew they were in research, however, about two-thirds were aware to some degree of the experimental aspects of the study--that a new drug was being used or that some procedure was being tested. Even a few of those with minimal understanding of the study were aware of the experimental design in a general way.

Several questions in the survey probed specifically into the patient's understanding of the study design. Question 35 asked the patient whether the study involved "some patients getting one kind of treatment and some another." As Table 6-9 shows, 34 of the patients in complex designs and 4 in uniform designs answered correctly. Of the 34, 16 gave clear explanations of the study design. The consent forms for these three studies varied in the degree to which the study design was explained. One gave a complete explanation, one a partial explanation, and one no explanation at all. Perhaps the patients in this last study were thoroughly informed orally.

If not all patients seemed fully informed about the nature of the research, most of the aware patients appeared to understand the medical procecures to which they would be exposed in treatment. In response to an open-ended question, 121 patients named 361 medical procedures (diagnostic tests and treatments) that they were undergoing, an average of about 3 items each. Eighty percent recalled that the doctor or nurse who discussed the research with them described these procedures.

TABLE 6-9

Participants' Comprehension of Study Designs

"Does The Study Involve Some Patients Getting One Kind of Treatment and Some Another?"

	Number of Patients			
	Yes	No	Don't Know	Total
Designs with differential treatment	34[a]	29	32	95
Designs with simple (uniform) treatment	7	4[a]	6	17
	41	33	38	112

[a] Correct answer

Consent Procedures

Patients' perceptions. Most of the patients aware of participating in a research project gave a clear account of the process by which they became involved and gave their consent to be subjects of research.

In 65% of the cases, patients reported that the invitation to participate in research had been extended by the principal investigator or a co-investigator. A physician other than the investigators themselves queried 15% of the patients; another 15% reported that other hospital personnel invited them to participate. About 5% of patients interviewed said they had not been invited to participate but had decided to take part in the study on their own initiative. Some 95% said that the study was explained to them and 78% thought that it was one of the investigators who told the patient what would be done in the project.

Some 67% of the respondents said that an explanation of the study was read to them and only about 5% could not recall whether that happened or not. Sixty-three percent reported they were given a description of the study to read themselves.

In the matter of securing consent, 95% of patients who were aware of being in research reported that they did sign a form granting permission to involve them; and 80% of them said that an investigator obtained the signature.

Principal investigators' descriptions. Investigators' responses accorded well with those of the patients in regard to how the procedures were carried out. Three-fourths of the 37* principal investigators who responded to the

*The responses of all 37 investigators who returned questionnaires were used in the analyses whether they had patients who were interviewed or not.

questionnaire said that they themselves were responsible for obtaining consent from patients by asking them to participate, explaining the study to them, and obtaining their signatures, although several shared the responsibility with a co-investigator or others. Twenty of the 37 responses indicated that a co-investigator either shared the responsibility or was wholly responsible. Sometimes parts of the procedure were shared with others--the resident in charge of the patient, another physician, or some other person. For instance, someone other than an investigator on the study asked patients to participate in 10 cases, explained the study to patients in 13 cases, or got the signature in 14 cases. Table 6-10 summarizes this information. Only 12 investigators said that they did not delegate any part of the procedure.

The most frequent reason given for delegating authority was that it was more appropriate for someone else to handle this procedure (because of familiarity with the technical aspects of the study or closeness of association with patients). However, there were four investigators who said that lack of time was the reason and four who said there were too many patients on the study for one person to handle all the details.

Time given to explaining the study varied. About half (12) of the investigators who said they were the ones who explained the study said they spent 15 minutes or less on the task, 9 spent 15-30 minutes, and 3 spent over 30 minutes.

Thirty of the investigators said that there was a written description included in or with the consent form, 27 reported giving the patient a written description to read, 12 said they read a description to the patient, and 35

TABLE 6-10

Responsibility for Obtaining Informed Consent[a,b]

Person Responsible	Asking Patient To Participate	Explaining Study	Obtaining Patient's Signature
Principal investigator	26	26	24
Co-investigator	20	24	21
Physician responsible for patient, other than co-investigator	2	4	3
Resident in charge of patient	6	4	5
Other	2	5	6

[a] Numbers do not add up to 37 in each column because more than one answer was often checked by each investigator.

[b] The responses of all investigators, whether or not they had patients in the patient interview study, were included.

said they described the research orally. Most investigators thought a combination of techniques was the most effective way of communicating with the patients. When asked what were the most important points they covered in describing the study to the patients, 19 investigators said they discussed the nature of the study, the study objectives, and the methodology (12 specifically mentioned randomization and double-blind features of the study); 12 said they discussed the role of the patient; and 16 discussed risks and complications. Eighteen investigators reported withholding information about their research. Of these, 16 said that information in regard to type of treatment or medication was withheld so as not to distort patient response. Thus it appears from the accounts of aware patients and investigators that the prescribed process of obtaining informed consent was being followed in virtually all instances.

A curious exception to this generalization was the report by many patients that the person who obtained their signature on the consent form was unaccompanied. The most recent regulations (presumably in effect when patient interviews were conducted) require that the consent interview be witnessed by a third party. Yet only one-third of patients who said they signed the form remembered that such a third party was present. Nearly half the patients said that no one was present but the person securing their signatures, and 18% could not remember. Several explanations are possible: that patients simply did not remember the presence of the third party because their whole attention was focused on the transaction with the investigator or his substitute; that no witness was present because the investigator was operating under the

formerly correct assumption that none was needed; or that investigators tend to overlook this regulation.

Patient Satisfaction

Despite these omissions, the patients' views of the results of the process for obtaining informed consent appeared to be wholly or substantially positive. Ninety-four percent of those who knew they were in a research study said that they were given enough time to think about whether they should consent or not; 90% said they had enough information to decide what to do; 88% said that no one "urged or encouraged" them to participate; and more than half of the small number who did feel some pressure to participate reported that it came from a relative. Roughly 6% said that doctors or nurses urged the patient to consent to research participation.

Most patients neither consulted someone (other than a member of the investigating team) nor wanted to talk with anyone else before deciding to participate. Among those who did talk to other people before making their decision, most sought the opinion of spouses, other patients, relatives, and friends. It was comparatively rare for a prospective participant to talk about his decision with another doctor, nurse or other hospital employee. Only 5% wanted more consultation than they were able to get.

Similarly, there was little evidence that patients were afraid of the consequences of refusal to participate in a research study. Patients were asked, "If you had decided not to be in the study, what would have happened? Would you have been taken care of at this hospital anyway or would you have had to go somewhere else?" Ninety percent replied that they would have been

able to remain at the same hospital and be cared for; 78% thought that their care would have remained as good. Furthermore, 95% of the respondents said they felt free to refuse research participation and knew that it was purely voluntary. Six patients out of 112 did not feel free to say "no" to participation, but only 3 gave reasons. One said,

> I think I was mistaken, except that I used to be in the Army, and in the Army, there is no such thing as saying "no." In the hospital, it is about the same.

Another only said,

> Just how I feel,

and the third gave this ambiguous answer:

> I didn't feel free to say no, but I'm not the type of person to be blackjacked or coerced into something. So, in a way, I did feel free to say no, since it was my decision.

Eighty percent of those who were interviewed knew that they could drop out of the study at any time although they had agreed to take part. In short, there was no evidence of coercion and every reason to believe that almost all patients entered research studies voluntarily and freely.

Except for a few projects, actual dropouts were very few on those projects about which investigators were questioned. Table 6-11 is a classification of research projects into high, low, and no dropout categories.

The rate of dropouts was usually a function of the type of study. Three of the six studies with high dropouts were alcoholism or drug studies (the same ones that had high refusal rates) and as noted earlier, these involve two categories of patients who are unreliable in keeping appointments and following treatment regimens. Two studies with high dropout rates involved considerable inconvenience for the patient, and another required the patient to wear an uncomfortable device.

TABLE 6-11

Number of Patients Invited to Participate in Study Compared to Number Who Dropped Out

Dropouts		
High	Low	No Dropouts[a]
15 of 22	3 of 33	0 of 15
3 of 4	3 of 30	0 of 25
10 of 44	2 of 20	0 of 80
19 of 200	2 of 15	0 of 30
30 of 60	4 of 98	0 of 5
4 of 12	2 of 30	0 of 25
	2 of 12	0 of 6
		0 of 6
		0 of 48
		0 of 46
		0 of 20
		0 of 15
		0 of 9
		0 of 18
		0 of 20
		0 of 20
		0 of 10
		0 of 30

[a] Projects in this column with less than five patients invited to join were not coded.

It was unlikely that patients were seduced into research participation by exaggerated promises of relief from the pains or discomfort of their illness. Only 29% responded affirmatively to the question, "When you were asked to take part in the study, was it your understanding that any of the treatment you would be having would make you feel better; for instance, take away pain?"

Generally speaking, patients who knew they were taking part in research studies reported that they were prepared for their experiences with treatment. Seventy-two percent said that the information they received before starting treatment prepared them "very well" for the experience and 25% replied "fairly well." Only 3% were unprepared for what had happened to them. About half of the patients reported that the pain or discomfort they experienced from treatment was about what they expected, and 39% said it had been not as bad as they expected. Eleven percent were unpleasantly surprised. Responding to a question on possible side effects from treatment, 73% of the patients recalled having been told before they began treatment that they might experience "slight" or "moderate" side effects and 70% said they had experienced such effects. Ten percent of those who expected side effects found them to be greater than they had anticipated. More than 70% of the patients aware of their participation in research studies said they would be willing to take part in another study. Only about 8% would be unwilling to do so.

Investigators' Attitudes

Attitudes of the investigators toward the informed consent procedures were largely positive. Most (34 out of 37) considered the procedure appropriate and thought their research had actually benefited as a result. Thirty-one thought the procedures had benefited the patients. Those who said their research had benefited gave a variety of reasons. Nine out of 20 presented arguments related to the doctor-patient relationship--that the procedures increased cooperation from patients, improved rapport with patients, and encouraged the patient's confidence in the physician. Reasons given for patient benefit were somewhat similar. Ten investigators said that patient knowledge and understanding of their own health problems had been increased and five others believed that the potential for misunderstanding had been reduced.

In contrast, seven investigators reported that their research had been impeded "somewhat," and two reported it "a great deal" impeded. Several said the main impediments arose from the necessity to spend time preparing adequate consent forms and protocols for presentation to human studies committees as well as revising them to meet their suggestions. One respondent commented that the screening and counseling required for his particular study had caused some patients to seek treatment elsewhere. Several mentioned that

patients did not like to be randomized or receive placebo treatments. Some investigators said that patients did not understand experimental design, and explanation of these matters made patients "wary." Some investigators felt that the procedures also worked to the disadvantage of the patients themselves in that they tended to worry them, and that some were deprived of beneficial drugs or treatment as a result.

Most of the investigator's comments about the review process were positive. (See Table 6-12). Only two of the 37 investigators did not consider the "judgments or recommendations of the human use subcommittee [to be] appropriate." Most (34) said that the committees were beneficial in protecting the rights and welfare of human subjects and 21 said they improved the quality of scientific research at their institutions.

Although few investigators felt the informed consent requirements had impeded research, more extensive criticism was directed at the human studies review process itself. Seventeen investigators said the review process had interfered with the independent conduct of research to some extent and three others said to a great extent. Nine said the procedure had interfered to some extent with the doctor-patient relationship, and 26 said the review process was unnecessarily burdensome and time-consuming. The complaints of these investigators focused on what they considered undue delay in review and on pettifogging or niggling changes such as, "replace the word 'doctor' with the word 'physician' in your consent form."

For 15 of the investigators, some modifications had been made in their studies, either as a result of informal discussions or the formal review of

TABLE 6-12

Investigators' Responses to Questions About

Human Studies Committee Review Procedure

Question	Number of Respondents: To A Large Extent	To Some Extent	Not At All
Has review interfered with independent conduct of research?	3	17	17
Has review interfered with doctor-patient relationship?	3	6	28
Is review process unnecessarily burdensome or time consuming?	6	20	11

	Yes	No	No Answer
Is human studies committee review necessary or not?	33	3	1
Do you know any instances of review preventing research?	6	30	1

the HSC. Eleven said that modifications were made in the consent form, but other kinds were also mentioned by one or two investigators in each case: reduction of risk, changes in experimental design, selection of subjects, and procedures for confidentiality and obtaining consent.

The free responses and comments of investigators regarding the consent process and review procedures ranged from highly critical to highly supportive. One critic explained:

> I think full disclosure of risks to experimental subjects is wise for many reasons. I don't think it protects subjects much, however. I have participated in human studies involving over 300 subjects and I recall only one subject who refused to participate because of material contained in the consent form ...
> There is no doubt in my mind that current procedures for obtaining approval for human studies result in an anti-investigator attitude which drives young investigators either into [only] animal research, or out of academic medicine. The result of this loss of young investigators will be further separation of academia from human disease and lost opportunities for reduction of morbidity and mortality...
> I think these losses are a tragedy of enormous dimension, whose effects will be felt for at least a generation.

Another respondent believed:

> The human studies committee has a very important role to see that subjects are well informed, especially when it involves procedures and drugs. They can often help to come up with the right terminology [for] the consent form. The review committee occasionally criticizes without contributing to the protocol, [but] this happens rarely ...
> I personally found the comments of reviewers very helpful.

Only a few investigators reported knowing of any instances in which research had been prevented by the review. They cited some drug studies on patients who were psychotic or otherwise legally incompetent.

Consent Forms

A third source of information about the process of obtaining informed consent was the written consent forms themselves. Forms for 40 research projects were collected and analyzed for their ease or difficulty of comprehension.* The results are presented in Table 6-13, together with a parallel analysis of similar forms used to obtain consent of prisioners participating in clinical trials of investigative drugs. (The prisoner forms were analyzed separately for "purpose," "procedures," and "risks/discomforts." Only the "purpose" score--the most difficult section--is supplied from that study.) According to Flesch's formula, material at the "difficult" or "very difficult" level requires reading ability at the college level for comprehension of the investigator's purpose. This level exceeds the grasp of most VA patients, as only 27% of them have had more than a high school education.

AWARENESS AND UNDERSTANDING OF RESEARCH

When more than one-quarter of the patients who agreed to take part in medical research projects are found to be unaware that they are participating, further analysis is necessary. This section will examine some characteristics of "unaware" patients and their situations and compare some of their responses to the interviewer's questions with the replies of "aware"

*Flesch, R. "A New Readability Yardstick." J. Applied Psychology, 32(3): 221-233, 1948.

TABLE 6-13

Comparison of Reading Ease[a] Scores of Consent Forms in Two Research Populations

	Very Difficult		Difficult		Fairly Difficult		Standard		Fairly Easy		Easy		Very Easy		Total	
Educational Level Required for Comprehension	College Graduate		College		Grade 10–12		Grade 8–9		Grade 7		Grade 6		Grade 5			
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
VA research projects	5	12.5	29	72.5	5	12.5	1	2.5	0	-	0	-	0	-	40	100.0
Drug trials in prisons[b] ("purpose" section only)	9	27	18	55	2	6	3	9	1	3	0	-	0	-	33	100.0

[a] Measured by a standardized formula developed by R. Flesch.

[b] From the preliminary report of a study for the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research: Research in Prisons, Survey Research Center, ISR, University of Michigan, dated 2 April 1976. Courtesy of Dr. Arnold Tannenbaum.

patients.* One possibility that needed to be examined was whether the unaware patient was simply a very poorly informed patient. A hypothesis that deserved scrutiny was whether unawareness was the extreme of a continuum that ran from full understanding of the purpose of research, its design, and the patient's role in it through minimal or no understanding to total ignorance of the fact that one was involved in research at all.

Besides looking into the personal characteristics of unaware patients and poorly informed ones, two other plausible sources of explanation were examined: the investigator and the type of investigation, including its complexity and the demands it made on patients; and the nature of the transaction between investigator and patient for securing informed consent, including various aspects of the invitation to participate.

Responses of Unaware Patients

Patients who said they were "not taking part in a research study" could not be asked about its purpose, their reason for participating, the research design, or some of the details of the consent procedures. Instead, these unaware patients were asked a series of questions about their treatment which paralleled those asked of patients who said they were participating in research (cf. questions 58-81 of the interview). Comparison of these two sets of questions showed similarities and differences in response patterns.

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* The possibility that unawareness is an artifact of the interviewer's manner of asking the question about research participation was ruled out by examining the distribution of unaware patients by interviewer.

The responses of the unaware patients differed very little from those who were aware of being in research studies. Unawares and awares gave similar answers in regard to whether they were informed about their treatment, their satisfaction with information they received about treatment, and their knowledge of the medical procedures they would undergo. Almost 80% of the unawares said that their treatment was explained to them, compared to 95% of the awares who said that the research study was explained. Seventy-seven percent of the unawares said that they signed a form giving their "permission to have this kind of treatment," compared to 95% of awares saying they signed a form. Thus the unawares seemed to recall going through a consent procedure of some kind, but evidently did not connect it with research.

The unaware patients were quite satisfied with the information they received. Eighty percent said they had enough information about their treatment, compared to 90% of the aware patients. Unawares were somewhat less likely to say they got an explanation of their treatment and somewhat more likely to say they would like to have more information about it. About 57% of the unawares said they were "very well" prepared for their treatment experience; 38% said they were "fairly well prepared." Only 5% of the unaware patients said that they were prepared "not very well" or "not well at all." Furthermore, 66% of the unaware patients said they were getting enough information now, compared to 87% of the aware patients. For 75% of the unawares, the outcome of treatment equalled or exceeded their expectations, compared to 88% of the awares.

Both groups of patients showed great knowledge about the medical procedures involved in their treatment; 39 unaware patients mentioned 127 different tests, with 22 of them knowing as many as 3 each. Some of the unaware patients even had considerable knowledge of the rationale for their treatment, including possible side effects and risks. One of the cancer patients said that he

> had surgery in December and am on chemotherapy now. They said that it might or might not work. They didn't mince words. They promised nothing, only that it might make me feel better.

Another cancer patient said that he hoped the chemotherapy treatments would make him feel better. He expected part of the medicine to nauseate him and he knew that a side effect might be loss of hair.

Another said:

> They're using this drug on me. Is it a part of the research study?... Valley fever is what I have.

He knew that the side effects might be nausea and headaches, but he would like to have known more about the "medication and the rest of my body along with the cure."

These comparisons suggest more similarity than difference between the awares and unawares. Perhaps some of the unawares went through a more cursory informed consent procedure, but, if there were inadequacies in the procedure, they seem to have failed to identify the experimental or research character of the treatment, rather than leaving treatment completely unexplained.

Personal characteristics of patients did not shed much light on the difference between the aware and unaware patients. There was some variation between the two groups in education. A higher percentage of the unaware patients (50%) had less than high school education than the aware patients (34%). Blacks and Hispanics together constituted only 21.6% of the sample, and 33% of them were unaware, as opposed to 22% of the whites. A higher percentage of aware patients had incomes under $5,000 (62%) than the unaware group (38%); but many patients were retired or unable to work and the figures given may not always reflect previous status. Unaware patients were spread haphazardly through all age groups.

One characteristic that did seem to make a difference was whether a patient was an outpatient or inpatient. The sample was divided fairly evenly between outpatients (44%) and inpatients (56%). But only 13% of the outpatients were unaware they were in research, compared to 40% of inpatients. Almost 80% of the unawares were inpatients. Research participation on an outpatient basis may have demanded a clearer and more explicit commitment on the part of the research subject, whereas for inpatients, involvement in research was a more casual and less salient part of a larger treatment experience. This possibility is contemplated in the following section.

Involvement of the Patient and Nature of the Research

Many aware and unaware patients were participating in studies that involved no more than a single, simple test requiring only a short time, and perhaps indistinguishable from other tests and procedures that the patient was being put through as part of the overall treatment. For such patients,

the brief intrusion of a procedure labeled "research" might have little or no salience. When patients responded to interviewers' questions about their "treatment," they discussed that treatment as a whole.

One finding supports this interpretation. In sharp contrast to the generally similar responses of awares and unawares, very few of the unaware patients identified the principal investigator or a co-investigator as "the doctor in charge of [their] treatment." Only 9% of the unawares (compared to 58% of the awares) named any investigator; 57% thought it was another doctor. The doctor whom the unawares identified as explaining the treatment was a physician other than the investigator(s) in 57% of the cases. Most of the unawares did not connect their treatment with the activities of an identified investigator, suggesting that some were participating in research that was of marginal significance to their overall treatment.

Some of the unawares were very seriously ill patients for whom participation in research was a relatively minor aspect of the overwhelming problems of sheer survival. For example, a cardiac patient whose involvement in research was limited to a radioisotopic scan for the purpose of assessing cardiac functioning mentioned nothing about the research study, but he seemed quite well informed about his treatment in general. He said his treatment included surgery, medications, and various kinds of tests:

> X-rays, blood samples, many many; numerous, almost daily measurements with machines, heart catheterization, treadmill test. It is painful to have cardiac catheterization ... they push the catheter into the artery and in my case induced a heart attack. [There is risk of] suffering pain and certainly with drugs, the feeling of well being all shot. Any incision could become infected. My right side had much higher blood pressure than the left, so they cut my right arm and caused great pain. I would like to have known more about the technique

> called cardiac catheterization--the statistics of success and failure, the long-range effects. I signed a release to have catheterization done.

A less knowledgeable patient in a cardiovascular study, who was asked whether he was a research subject, replied:

> Nobody asked me to so I don't think I am ... I had a heart attack. They couldn't [explain the study]. I passed out at a grocery store. All I know is that I was brought in and that was it. I was in intensive care.

This patient did not recall signing a consent form, nor did another patient in this study who replied to the interviewer:

> "[An explanation] wasn't necessary because I'd had previous treatment and came into intensive care and you're too sick [for an explanation]."

These cases illustrate an acute dilemma for the physician and a serious issue for the informed consent procedure. Patients in the midst of a life-threatening illness might be psychologically unable to participate fully in the process even if every step of the prescribed procedure is scrupulously and conscientiously carried out. Patients in such situations may give their consent to a research procedure while retaining no awareness that they have done so. A small number of the unawares in the study fell into this category. In one study, six out of seven patients who experienced traumatic myocardial infarction were unaware of their participation in research, and eight out of eleven patients in two cancer studies were unaware of being experimental subjects.

For the bulk of the unawares, the extent of their involvement in research--in terms of time they had to give to research treatment, or convenience--was not different from that of the aware patients. The intensity of

pain and discomfort of treatment was not different for the unawares and awares. A slightly larger proportion of unaware patients found their treatment to be worse than they had expected in terms of pain and side effects. These differences were small and not statistically significant.

There was a tendency for unaware patients to be in studies that were less demanding of the patient's time and effort, that required less complex and extensive testing, or to have been over and done with in a short span of time. (See Table 6-14). Correspondingly, the longer patients participated in the study, the smaller was the proportion of unawares, suggesting that participation was not a distinct act at a specific time for all patients. For some patients, awareness of participation developed gradually. What to the investigator and the observer was the crucial act that made a patient into a participant-signing the consent form and/or beginning the research "treatment"--was perhaps only one step along the route for some patients. This is not hard to understand if, for example, "treatment" was a "control" treatment (no active intervention) or if it began with a period of observation and testing. One possible explanation of awareness involves illness/disorder, or the type of research involved. Accordingly, Table 6-15 was constructed to display the distribution of unaware patients according to illness or disorder and by hospital.

The distribution does not clearly confirm the importance of illness as an explanatory factor. There were some unaware patients in nearly every category, although more than half the unawares were participants in cancer, cardiovascular, and drug addiction research. A possible explanation of the

TABLE 6-14

Awareness of Research Participation by Extent of Patient Involvement

	Amount of Patient Involvement[a]			
	Very Little[b]	Average[c]	A Great Deal[d]	Total
Aware Patients	27	59	26	112
Unaware Patients	19	16	9	44
	46	75	35	156

[a] (N.S.) $\chi^2 = 5.75$; d.f. 2; $p > .05$

[b] Very little involvement

Total time patient is involved in the study, either hospitalized or as outpatient, is not more than about 3 days,
Or clinic visits are infrequent--not more than every 6 months.

[c] Average involvement

Period of hospitalization 8-9 days or longer up to about 3 weeks,
Or frequent clinic visits, once a month to once a week or more for 2-4 months,
Or infrequent clinic visits (every 3-6 months) with extensive testing at time of visits.

[d] Great deal of involvement

17-30 days or more hospitalization on metabolic ward, with extensive testing, restricted diet, etc.,
Or long hospitalization of a month or more,
Or repeated course of chemotherapy as for cancer patients,
Or frequent clinic visits--daily or five times a week over a long period (6-12 months).

TABLE 6-15

Number of Patients Unaware of Research Participation By Hospital and Illness

Type of Disease/Disorder Being Studied	Hospitals A	B	C	D	All Hospitals: Number Unaware	All Hospitals: Total Patients in Studies
Cancer	6 of 9	2 of 2	-	- [a]	8	11
Cardiovascular	0 of 19	-	0 of 2	8 of 20	8	41
Drug addiction	-	0 of 14	9 of 10	-	9	24
Neurologic	1 of 5	0 of 7	4 of 8	0 of 6	5	26
Arthritis	-	-	2 of 4	0 of 2	2	6
Infection	-	-	1 of 16	2 of 6	3	22
Gastrointestinal	0 of 2	-	5 of 8	0 of 7	5	17
Renal	-	-	2 of 2	1 of 2	3	4
Metabolic	1 of 1	-	-	0 of 1	1	2
Obesity	-	-	-	0 of 3	0	3
Unaware Patients	8	2	23	11	44	44
Total Patients in Research	36	23	50	47	44	156

[a] Six out of seven for one study.

unawareness of patients in the first two categories has already been suggested but it seems implausible for the drug addicts. Perhaps unawareness of research participation was part and parcel of a more generally dissociated state, although one drug addiction study out of three had no unaware patients. Because of the small total numbers of patients involved in arthritis, renal and metabolic studies, little significance can be attributed to the high proportions of unawares. This result could be a product of random factors.

There appeaed to be distinct differences in the frequency of unawareness at the several hospitals where patient interviews took place. Less than 5% of the patients at Hospital B were unaware, whereas 46% of those at Hospital C did not know they were in research. This result could not be accounted for by any one research study, as the unaware patients were spread over all but one of the studies. Most of the investigators at Hospital C were still using the unrevised consent form, which provided the patient with a substantially briefer explanation of the research than does the current version.

It is difficult to decide how much responsibility for unawareness should be borne by the individual investigator. Eighteen out of the 31 investigators whose patients were interviewed had at least one unaware patient. Seven of the remaining investigators had taken only three or fewer patients into their studies at the time of interview; as they proceeded to enroll more patients, one or more of them might be expected to have unaware patients. Instilling full awareness of research participation in patients was evidently difficult for most investigators to achieve.

There was one outstanding case in which one investigator with more than 12 subjects had no unawares, although the disorder he was studying was found to have a high proportion of unawares in other projects. This investigator, whose ingenuity and conscientiousness the Committee applauds, had developed a short examination to test his patients' knowledge of the purpose and procedures of his research, as well as its risks, benefits, and their rights. If patients did not pass the examination, the research was explained to them again.

Consent Procedures and Relation to Unawareness

This report has mentioned that unaware patients were somewhat less likely to say that they had enough information about treatment and had given their permission. Perhaps this group did not get as complete and adequate an explanation of the research study as the awares did. Table 6-16 examines this possibility by showing the distribution of patient awareness level over the studies conducted by 31 investigators who completed the investigator questionnaire and had patients who were interviewed. Patients were categorized by the level of understanding of the research they communicated to the interviewer and by the amount of time the investigator reported he had spent explaining the study. The 17 investigators who answered this question were responsible for research involving 84 patients. For this limited group there is a statistically significant tendency ($p = < 0.01$; 2 d.f.) for the unaware patients to be concentrated in the briefest explanation category. Unfortunately, evidence for this conclusion is weak because information for 72 patients was missing from the analysis. Thus, the length of time spent in

TABLE 6-16

Awareness and Level of Patient Understanding By Amount of Time Investigator Spent Explaining Research[a]

Level of Patient's Understanding of Research		Investigator Reported Spending: Less Than 15 Minutes	15 to 30 Minutes	More Than 30 Minutes	Subtotals	Did Not Answer	Total
Aware	Full understanding	5	11	-	16	10	26
	Fair understanding	11	12	3	26	31	57
	Little understanding	11	7	1	19	10	29
Unaware		19	3	1	23	21	44
		46	33	5	84	72	156

Aware Compared to Unaware Patients

	Less Than 15 Minutes	15 to 30 Minutes	More Than 30 Minutes	
Aware	27	30	4	61
Unaware	19	3	1	23
	46	33	5	84

[a] $\chi^2 = 10.27$; d.f. = 2; $p = < 0.01$

explaining the study to the 21 unawares out of the group of 72 is unknown. About 44% of the unawares, for whom there is information, did receive relatively briefer explanations, but not necessarily so brief as to preclude the possibility that the patient could achieve a fair or full understanding of the purpose of the research project, its design, and his role in it. Nearly one-quarter of the aware patients for whom there is evidence had received only a brief explanation yet they did have a fair understanding of the research.

Several other aspects of the consent process might also have borne on awareness. The investigator questionnaire identifies the persons who usually extended the invitation to participate, explained the study to the patient, and obtained his signature on the form. Often, but not always, these were the same individual. Sometimes it was not the principal or co-investigator(s), but the resident in charge or the VA doctor who was primarily responsible for the patient's care. More rarely it was a nurse, an administrative assistant, or secretary. Table 6-17 shows how these various responsibilities were taken or delegated by the investigators whose patients were interviewed. Principal investigators and co-investigators most often took responsibility for all facets of the informed consent process. Because they tended to monopolize the tasks of inviting patients to take part in the study and explaining the study to the patient, it was difficult to get a clear answer to some important procedural questions: did it make any difference in patient awareness whether the patient was invited to participate in the study by the principal or co-investigator or by someone else at the hospital? Similarly, did it make any

TABLE 6-17

Responsibility for Aspects of the Informed Consent Procedure

Person(s) Responsible	Number of Patients[a]		
	Invitation to Participate	Explanation of Research	Procurement of Patient Signature
Principal investigator	86	87	77
Co-investigator	52	70	55
Primary physician	3	11	8
Resident	20	10	11
Other person	9	22	29

[a] Because some respondents indicated that responsibilities were taken by more than one person, the number of patients does not total 156.

difference to patient awareness who explained the study or obtained the patient's signature on the consent form?

Because investigators were not giving a detailed account of how they had managed the consent process for each patient interviewed, the analyses of their replies must be viewed cautiously. In describing how responsibility for various portions of the consent process was assigned, investigators frequently indicated that more than one category of hospital personnel were involved in each step. An investigator may have answered that he alone invited the patient to participate, explained the research and got the patient's signature on the consent form; or that a co-investigator had also assumed responsibility for one or more steps; or that a resident, the physician in charge of the patient's care, or still some other person had shared the responsibility for some or all steps.

A conservative approach to the basic question would be to divide the research projects into two groups: those in which the investigator(s) took exclusive responsibility for the particular step in the consent process, and those in which they shared it. This analysis shows that whereas the identity of the person inviting the patient to participate in research or securing his signature on the consent form made little or no difference in patient awareness, a statistically significant difference emerges when it comes to the matter of who explained the research. When the investigators alone took responsibility for explaining the research project, a significantly smaller number of patients were unaware than would be expected by chance, as noted in Table 6-18.

TABLE 6-18

Number of Patients Classified by Awareness of Research Participation and Identity of Person Explaining Research[a]

Awareness	Research Explained Exclusively by Investigators	Research Explained by Investigators or Other Hospital Personnel	Total
Aware	87	25	112
Unaware	19	25	44

[a] $\chi^2 = 17.26$; d.f. 1; $p = < 0.001$

Despite the limitations of the analyses, the results suggest that when investigators kept responsibility for explaining the research then it was less likely that patients would be unaware of their participation. However, placing exclusive responsibility for the consent procedure in the hands of the investigator was no guarantee of patient awareness. Almost half the unaware patients were dealt with exclusively by investigators.

Two other features of the consent procedure might have had a bearing on patient awareness: the use of a written description of the research in the course of obtaining patient consent and the content of the consent form itself.

Here, too, the clues to increased patient awareness are obscure. Almost all investigators said they explained the research orally to the patient. Giving him a written description of the project did not seem to reduce unawareness--nor did allowing the patient to keep a copy of it. Investigators who read a written description of the research to the patient had a significantly smaller proportion of unaware patients (Table 6-19). Perhaps this finding simply identified the investigators who gave more complete or consistent explanations to patients, or who took the task of explanation more seriously. Lastly, it appears from Table 6-20 that there is a significant relationship between patient awareness and the completeness of the consent form prepared by the investigator. All consent forms were read by an analyst who checked to see which of the following topics or items were included: purpose of research, major procedures to be used, design, risks and benefits, pain or discomfort, patient's right (to refuse participation, drop out,

TABLE 6-19

Number of Aware and Unaware Patients by Investigator's Practice of Reading a Written Description of Research to the Patient

	Number of Patients[a]		
	Aware	Unaware	Total
Reads a written description	37	8	45
Does not read a written description	47	30	77
	84	38	122[b]

[a] $\chi^2 = 5.93$; 1 d.f.; $p < .05$

[b] Four investigators did not answer this question; therefore, the total number of patients does not sum to 156.

TABLE 6-20

Number of Patients Classified by Patient Awareness and Completeness of the Consent Form[a]

	All Items Covered	One Item Missing	Several Items Missing	Most Items Missing	Total Patients
Aware	53	22	24	13	112
Unaware	11	8	5	20	44
	64	30	29	33	156

[a] $\chi^2 = 20.06$; 3 d.f.; $p < .01$. In this particular analysis χ^2 adjusted for small size within cell was used.

receive alternative treatment) and confidentiality. Consent forms were classified according to the number of items included (or missing). The association is quite clear--unaware patients tended to be in studies using less informative, more barren consent forms.

This rather lengthy analysis of the unaware patient seems justified by the importance of the problem and the evident difficulty in avoiding unawareness. Unaware patients were not distinguished by any special personal characteristics; rather, their unawareness seemed to be a product of certain special situations and features of the consent procedure itself. Unawareness seemed to occur in patients who had a very serious illness, who recently began participating, or who were in projects that did not demand much time or attention--especially if embedded in a larger context of treatment in the hospital. Further, unawares were more likely to be found in studies that were explained by somebody other than the investigators, when the practice of reading a description of the research to the patient was not followed, or when the consent form omitted important items of information. The obverse of these conditions does not guarantee that patients will always be aware of research participation but they should help to achieve that goal.

Poorly Informed Patients

In addition to the patients who were unaware of their participation in research, the interviewers encountered a number of patients who did know they were subjects of research but whose understanding of the purpose, design, rationale, details of the experimental treatment, potential medical benefits of the research, etc. was so scanty or so dim as to justify the label "poorly

informed." According to various methods of rating or scoring their responses in the interview, about 20-25% of the patients interviewed fell into this category. Such a proportion might not have been unduly large, given the complexity of some of the studies and the amount of medical knowledge required for adequate comprehension of the investigations. Although there is no satisfactory standard for judging what an adequate level of comprehension ought to be, these poorly informed patients seemed to justify some further scrutiny.

The poorly informed were fully aware that they had agreed to participate in research. They recalled signing the consent form, said they had enough opportunity to think about it before deciding, felt satisfied with the information they were given about treatment, were aware of their rights (to refuse to have other treatment, to drop out at any time) in about the same proportions as the better informed patients.

The poorly informed patients were somewhat more likely to be older men, but the outstanding individual difference--one that is statistically significant--was in education. The poorly informed were much more likely to have had less than a high school education. In this respect they seemed to be qualitatively different from the unawares, who were not found to be less well educated.

In examining the studies in which poorly informed patients were found, it was clear that they did not pile up in the same places as the unawares. Poorly informed patients turned up in slightly more than half the studies but only one study had more than three poorly informed patients (and this one had no unawares), whereas most had only one or two. The life-threatening

illnesses/disorders were not associated with a lesser understanding of research. Degree of patient involvement did not seem to affect comprehension. The poorly informed patients were not unduly represented in the studies at the hospital that had the largest proportion of unaware patients; the number of poorly informed patients in that hospital was smaller than would be expected.

There were some similarities and differences between the unawares and the poorly informed in the way their consent was obtained. The completeness of the consent form was significantly related to the level of patient understanding of the research: the less well informed patients were on studies in which consent forms covered fewer of the items deemed essential for informing the patient. The patient's comprehension of the research was likely to be greater if a written description of it was read aloud to him--again a statistically significant relationship. A written description of the research presented to the patient did not appear to make any difference in understanding. The identity of the person who explained the study did not have the same importance in distinguishing between well and poorly informed patients as it did in explaining unawareness. There was a slight but not significant tendency for well informed patients to get their explanations from the investigators exclusively, and for the poorly informed to have received them from some other hospital personnel.

Thus the small group of patients who were poorly informed about the nature of their research projects were not simply a less ignorant version of the unawares. The outstanding difference between the two groups seemed to be that the poorly informed were less prepared educationally to abosrb the infor-

mation given them during the consent process. Some of the poorly informed patients also seemed to suffer from the cursory or inadequate processes used to obtain their consent.

SUMMARY

This report is based on interviews with almost all of the patients participating in selected research projects at four VA hospitals with large research programs located in three regions of the country, and on responses to a mail questionnaire returned by the investigators whose patients were interviewed. These are not representative samples of the VA system, but they are nearly exhaustive enumerations of four large research hospitals that do not appear atypical in any important respect from other hospitals with large research programs.

Although 27% of the patients interviewed were unaware that they were participating in a research project, most of them said they received enough information about their treatment, gave their permission for it, and felt no compulsion or inducement on the part of investigators, doctors, or other hospital personnel. Most of the patients aware of participating in research knew who the investigator was, recalled the consent process, and could give at least a rudimentary account of the purpose of the research. They said they joined the study because they expected it to benefit their health and because they wanted to be useful to mankind. Most had enough time to make their decision and did not want or need further advice or consultation. It appears from patients' own accounts that the prescribed process of obtaining informed consent except for witnessing of the interview was being followed

in virtually all instances where the patient was aware of his participation.

Special analysis of the unaware patient suggested that a variety of factors might have produced unawareness: using consent forms and explanations of research that were very brief or that failed to cover essential features of research procedures and patient rights; allowing someone other than the investigator to explain the study to the patient; and not following a consistent and systematic explanatory procedure. Patients with grave illnesses were likely to be unaware subjects, particularly if the research procedures were relatively unobtrusive. A small proportion of patients whose understanding of the research was extremely limited may have suffered from a combination of cursory consent procedures exacerbated by their own low level of educational attainment, a state which left them ill prepared to understand complex medical experiments.

The simple lesson to be drawn from these results is that the consent process cannot be a success every time, but certain actions should minimize unawareness of research participation and maximize patient understanding. These goals are more easily realized when a consent form is used that is written in simple language and is complete in its description of the purpose of research, major procedures, benefits, risks, pain or discomfort, the research design; and patient rights, including the voluntary nature of consent, freedom to drop out of the study, assurance of no prejudice to the patient's treatment if he refuses or drops out, the nature of his options, and confidentiality of information. It also seems helpful if the investigator himself explains the research to the patient and extends the invitation to

participate, rather than leaving this responsibility to other doctors or hospital personnel. If the investigator follows a consistent and systematic explanatory procedure (such as reading a description of the research to the patient) that does not rely on the patient's own efforts to assimilate information, then awareness and understanding should increase. It also seems helpful if investigators make efforts to find out how much the patient does understand. Finally, special efforts are needed to get truly informed consent from patients who are undergoing complex treatments for a life-threatening illness, especially if the research procedures themselves are brief, unobtrusive, or not apparently relevant to the patients' recovery. (How far to go in obtaining fully informed consent in such cases is an ethical issue that exceeds the scope of this study.)

CHAPTER 7

EVALUATION OF VA SCIENTIFIC PUBLICATIONS

Although the Committee put much of its effort into making site visits in which a small sample of research projects were inspected at several VA hospitals, it seemed prudent to employ a supplementary approach that would evaluate the entire VA biomedical research program. For this purpose, the Committee developed a study using citation analysis to evaluate the VA's scientific publications. Citation analysis was employed not only to assess the overall productivity of the VA's biomedical research program, but to examine and compare the ways in which characteristics such as degree of affiliation of VA hospitals with medical schools and special program components of the VA affected research productivity.

USING CITATION ANALYSIS TO MEASURE RESEARCH PRODUCTIVITY

Citation analysis as a means of assessing the productivity, impact, quality, or significance* of scientific publications is a relatively new method, and its full range of usefulness, as well as its limitations, remain to be explored. The development of the Science Citation Index (SCI) in 1963 established the basis for a practical method of counting the number of times a given article was cited or referred to in the scientific (journal) literature. Although not the original purpose of accumulating the SCI, citation

*Although "productivity," "impact," "quality," and "significance" all have different meanings, for the purposes of this study, these words are used synonymously to describe what citation analysis measures.

frequency proved to be useful in estimating the impact of a particular body of work, the impact of research conducted by an investigator or group of investigators, and for tracing the lines of influence among scientific fields. The application of citation indexing to the measurement of research productivity is based on the assumption that authors cite articles which have been helpful in their work or on which they based their own articles and research. Under this assumption, citation analysis would be a direct measure of the productivity (impact, quality) of the research of an individual as reflected in his cited publications, and ultimately a measure based on a review and judgment by peers.

Citation frequency adds a useful dimension to the practice of assessing productivity by counting numbers of publications. Publication counting does not indicate the degree to which scientific information is being communicated, whereas citation analysis does. Furthermore, citation frequency as a measure has intuitive appeal, resting as it does on a kind of marketplace notion of value or worth.

Citation analysis has been used in recent years to assess the productivity of individuals, groups of individuals, departments in institutions, entire institutions, and even countries. The National Science Foundation and the National Institutes of Health (NIH) are currently using citation analysis to assess research productivity of institutions and individuals to whom they award grants.

Several studies* have shown clear parallels between peer review assessments of research productivity and citation analysis. The results of citation analysis also correlate highly with other measures of scientific achievement. For example, two-thirds of the scientists elected to the National Academy of Sciences between 1963-1968 were among the 10,000 most frequently cited scientists out of the estimated one million scientist-authors in the world.† All of the 1972 Nobel Prize winners were in the top 0.1% of cited authors. Further analysis of two groups of Nobel Prize winners showed that the group whose citations had been counted before they became Nobel laureates actually had higher citation rates than the group whose citations had been counted after receiving the prize, suggesting that the number of citations reflects the quality of a person's work rather than simply the "visibility" of the person.‡

Critics of citation analysis have argued that this method does not measure scientific productivity because citations to an article may be made for reasons other than the value of the work to the citing author, e.g., negative citations (to point out errors or devalue a piece of work), self

*See Carter, G.M. Peer Review, Citations, and Biomedical Research Policy: NIH Grants to Medical School Faculty. Rand, R-1583-HEW, 1974, and Virgo, J. A Statistical Procedure for Evaluating the Importance of Scientific Papers. Ph.D. Dissertation, December 1974, University of Chicago.

†Garfield, E. Citation Indexing for Studying Science. Nature 227:669-671, 1970.

‡Cole, J.R., and Cole, S. Measuring the Quality of Sociological Research: Problems in the Use of the Science Citation Index. The American Sociologist 6:23-29, 1971.

citations or citations based on the author's eminence.* On balance, the Committee believed that when the analysis was used to evaluate systems or groups rather than individuals there was sufficient evidence or correlations with other measures of scientific quality to be confident about using citation analysis to evaluate the VA research program.

DATA AND METHODS

Sources of Data

Data on frequency of citation were obtained from the Science Citation Index maintained by the Institute for Scientific Information. In this study, research productivity was determined by counting citations per article.† The data were then aggregated to compare different groups of investigators (e.g., NIH intramural and extramural investigators with VA investigators). Citations to an article were only credited to the first author for publications in the VA bibliography to avoid including publications of medical school investigators in which VA investigators were coauthors.‡ As the NIH

*For example, see Moravesik, M.J., and Marugesan, P. Some Results on the Function and Quality of Citations. Social Studies of Science 5:86-92, 1975.

†Although previous studies usually have determined research productivity by counting citations per investigator, this was not feasible in the present study. Cole and Cole found, however, that the results of using citations per article to measure research productivity correlated highly with results using citations per investigator.

‡It was shown in a subsequent analysis that there was no difference between the average number of citations to multiauthored papers in which a VA investigator was first author and the average number of citations to multiauthored papers in which a VA investigator was not the first author. Cole and Cole have also shown that for aggregates of large numbers of investigators the results of using first author citations only versus total citations to all articles by a particular author is only trivially different.

bibliographies listed only publications from NIH-funded projects, all articles from these bibliographies were included when samples were selected. There was very slight overlap between the VA and NIH bibliographies because VA investigators made up a small fraction of NIH extramural grantees.

The journals used were the 921 biomedical and psychology journals indexed in SCI in 1971 and 1972. Citations to articles published in these journals in 1971 and 1972 were counted in 1973 and 1974. The VA bibliography (i.e., all VA articles) was derived from the congressional report, Medical Research in the Veterans Administration (Part II). Abstracts and reviews in review journals were eliminated. About 20% of the VA articles were in journals not indexed by SCI and so could not be evaluated. NIH articles and investigators were identified by using the 1971 and 1972 NIH Annual Bibliography and the FY 1972 and 1973 Research Grants Index and the articles were classified as produced by either the NIH extramural or intramural research programs. For each of the NIH programs 800 articles were randomly selected from the total bibliographies for 1971 and 1972.

Journal Classification

Articles were classified into disciplines and as clinical or nonclinical according to the journals in which they were published. The classification of 921 journals into 41 disciplines and the classification of the discipline as clinical or nonclinical were based on the work of Narin, Pinski, and Gee,*

*Narin, F., Pinski, G., and Gee, H.H. Structure of the Biomedical Literature. Journal of the American Society for Information Science, January-February, 1976.

Pinski, G. Evaluation of Linkage Between Research Publications and NIH Funding. Computer Horizons, Inc., 1975, a subtask of Contract NO1-OD-3-2109.

who mapped the interrelationship of biomedical journals and identified clusters of journals that tended to cross-reference each other. These clusters appeared to represent self-contained areas of interest within the broader area of biomedicine. On this basis, Narin, Pinski, and Gee divided all the biomedical journals indexed in SCI into 50 disciplines. They further subdivided the disciplines by assigning journals to one of four research levels, ranging from clinical to the most fundamental or basic research journal. In the Committee's study this classification was modified by merging some disciplines and by eliminating review journals and journals that contained only abstracts. The whole discipline was classified as clinical or nonclinical based on the Narin, Pinski, and Gee work, but their subdivision of disciplines into four research levels was not used. The specialties used in this study and their classification as clinical or nonclinical disciplines are listed in Appendix F.

Standardization Across Disciplines

Articles vary widely in average number of citations they receive, partly based on the scientific discipline of the article. For example, articles in biochemistry receive an average of 4.2 citations each, whereas articles in dermatology and venereal disease receive an average of only .98 citations each. Narin, Pinski, and Gee showed that basic science articles tended to receive higher average citation counts than clinical articles. Because research programs and groups with different mixes of scientific specialties covering a spectrum from basic to clinical level research were being compared in the Committee's study, it was necessary to standardize

citations to individual articles by specialty. Once standardization was done, citation counts could be merged across levels and disciplines and assessments made of the output of multidisciplinary groups of investigators. Standardization was accomplished by dividing the number of citations to a particular article by the average number of citations per article in the discipline or specialty of the journal.*

Classification of VA Articles

To make comparisons within the VA system, five characteristics were coded for each VA article.†

- Affiliation status: whether the article came from an investigator from a VA hospital strongly affiliated or not strongly affiliated with a medical school. The strength of affiliation of each of the VA hospitals to a medical school during 1969-1971 was determined from discussions with the VA Central Office, Education Office of the

*Standardized citations = $\frac{\text{Number of citations received in 1973 and 1974 x 10 (to an article published in 1971 or 1972)}}{\text{Mean number of citations in 1973 and 1974 to all articles in that specialty published in 1971 and 1972}}$

†Eighty-nine articles (4%) were excluded from the analyses because information was missing for one or other of these codes.

Department of Medicine and Surgery, and from a study by the NRC's VA Care Committee. VA hospitals were classified by strength of affiliation, which is detailed in Appendix F. In the analysis VA hospitals were categorized into two groups: strongly affiliated and not strongly affiliated hospitals.

- Faculty status: whether the author was a member of a medical school faculty or not. The Association of American Medical Colleges Faculty Roster for academic years 1969, 1970, and 1971 were used to identify faculty status. Because all the analyses showed that faculty status had no statistically significant effect, all tables omit faculty status.
- Type of VA program: whether the author was funded through the institutional research or career development programs (CDP). The cooperative studies program could not be analyzed because of the small number of papers produced by this program.
- Authorship status: whether the article was written by a VA sole author, a VA first author with other authors, or by a non-VA first author with a VA investigator as one of the other authors.
- Degree of first author: whether M.D. or Ph.D. (this classification was needed for Study III, in which institutional and career development program investigators were compared).

Data Analysis

In all studies involving comparisons of citation frequency data (i.e., all except Study I) analysis of variance was used to determine the statis-

tical significance of observed differences among the groups of investigators compared. To meet the assumptions of analysis of variance the standardization citation rate was transformed further into its logarithm. The results are presented therefore in the form used for the analysis:

$\log_e$ [standardized citations +1].*

STUDY I: CORRELATION BETWEEN CITATION AND PEER JUDGMENT METHODS OF RANKING JOURNALS

It is generally agreed that there are differences in the quality of various journals, determined in part by the selectivity of the editorial review board in choosing articles for publication. These peer review practices provide for consistent standards and stabilize the scientific quality of a journal at some level. Building upon this commonly held view, a study was designed to compare the ranking of journals by citation analysis with their ranking by peer review. A high degree of similarity in the two rankings would further strengthen the belief that citation analysis was a valid measure of research productivity.

Peer Ranking

Twenty-five expert scientists in each of 24 disciplines were asked to rate journals in their specialty according to the quality of research found in that journal. Seventeen specialties were omitted from this study because

*This transformation was quite effective in stabilizing the variances, a condition that had to be met to use analysis of variance. After transformation the range of variances over 48 subgroups was from 0.93 in a group of 9 articles to 3.16 in a group of 15. For the 24 subgroups with 30 or more articles the range was from 1.57 (N=70) to 3.08 (N=69). The analysis of variance technique is robust enough to tolerate this degree of variation in the variances. The pooled within-cell variance used in the analysis was 2.33.

peer judges were not available; thus 661 of the 921 journals used for the other parts of this study underwent peer review. Table 7-1 sets forth the 24 specialties scrutinized for Study I. In psychology and general and internal medicine, the list of journals was large enough to warrant division into two and three sections, respectively. Twenty-five reviewers were selected for each section.

Each judge was given specific written instructions in a questionnaire (see Appendix F) to explain the judgment procedure and ensure standardization. The peer judges were selected from the National Academy of Sciences Directory, the Institute of Medicine Directory, a list of scientists considered for appointment to the proposed Panel of Consultants for the National Research Council/Assembly of Life Sciences, and American Men and Women of Medical Sciences, 1975 edition. The responses of the judges were combined to rank order the journals in each specialty. Journals that received ratings from fewer than five peer judges were eliminated from the comparison; accordingly, 200 journals were eliminated.

Citation Ranking

The 461 journals which had been ranked by peer judges were also ranked within discipline/specialty by "impact factor." The impact factor is a measure of the relative frequency with which a journal is cited, and was calculated by dividing the total number of citations to a journal in 1973 and 1974 for its 1971 and 1972 publications by the total number of publications appearing in the journal in 1971 and 1972.

TABLE 7-1

Correlation between Rank Ordering of Journals in 24 Biomedical Specialties by Impact Factor and by a Peer Review Process[a]

Specialty	Correlation Coefficient (r_s)	No. of Journals
Allergy, immunology, arthritis, & rheumatology	.82	25
Anatomy & morphology	.10	9
Biochemistry	.88	24
Biophysics	.90	6
Cancer	.68	13
Cardiovascular system	.84	10
Cell biology, cytology, histology, & microscopy	.71	29
Dentistry	.37	17
Embryology	.85	7
Endocrinology & fertility	.63	18
Gastroenterology	.39	14
General & internal medicine	.70	33
Genetics & heredity	.37	28
Hematology	.62	9
Microbiology & virology	.66	22
Neurology & neurosurgery	.57	34
Pathology	.45	12
Pharmacology	.59	28
Physiology	.73	15
Psychiatry	.66	26
Psychology	.68	47
Radiology & nuclear medicine	.31	11
Respiratory system	.94	6
Surgery	.65	18

[a] Other citation methods have been described besides impact factor for ranking biomedical journals, for example, a citation method by which journals in each specialty received "influence weights" (see Narin, Pinski, and Gee). The Committee's analysis showed that "influence weights" ranking of journals and impact factor ranking of journals correlated to approximately the same degree with the ranking of journals by a peer review process.

Comparison of Rankings

In each specialty, the rank ordering of journals by peer review was compared to the rank ordering of journals by impact factor using the Spearman rank correlation coefficient. The median correlation coefficient was .66.* As shown in Table 7-1, the correlation between the two ratings was high in most fields. However, in a few fields the correlation between the peer review and impact factor rankings was not so strong, for which there are several possible explanations. First, there was not always a consensus among peer judges of the relative quality of a journal and the degree of consensus varied among the different specialties. In some fields journals may not be well differentiated in quality and so were not easy to rank order; or peer judges might have had genuine differences of opinion about a journal's quality. Also, judges may have differed in their acquaintance with journals in their discipline. Secondly, there may have been some very real differences between peer judgment and impact factor ratings because of the types of articles that predominate in a journal. For example, case studies and editorials are cited very infrequently and a journal in which they make up the majority of articles would probably fall low on the impact factor ranking although the research articles in that journal might have received high numbers of citations and been rated as high quality by peer judges. If peer judges rated such a journal high because of the quality of the research articles or the usefulness of the editorials and case studies, such a practice would result in a low correlation between the two rankings. In view of these explanations, the level of correlation between peer review and citation

*This correlation is about the same level as found by Carter when she compared the relationship between NIH study citation review and citation counting as evaluation methods.

analysis as measures of quality of research was especially encouraging. The study provided only an indirect validation of the use of citation counts to measure the impact of individual papers, but at a sufficiently satisfactory level for the Committee to feel confident in using the method to address its central purposes:

- to delineate how VA publications fare against publications of other agencies, in this case, NIH; and
- appraise the special aspects within the VA biomedical research program and their relationship to the quality of VA publications.

STUDY II: COMPARISON OF PUBLICATIONS FROM VA AND NIH PROGRAMS

Study II was designed to compare the quality of the VA's research program with that of the intramural and extramural NIH programs. Because of the differences in emphasis between the VA and the NIH in the type of research that they fund it was considered important to look at the nonclinical and clinical specialties separately. A comparison of articles from VA investigators in VA hospitals strongly or not strongly affiliated with a medical school was made and each of these groups was compared with the NIH investigators. For each of these comparisons, the average number of citations per article based on the total number of articles produced by investigators in the group was used for each of the comparisons.*

The results of this study are presented in Table 7-2. Based on random samples of articles from the NIH extramural and intramural programs and the

*Of course, as explained earlier, the citations were standardized and transformed to logarithms for the analysis.

TABLE 7-2

Comparison of VA[a] Publication to Published Research of NIH Investigators

	VA Investigators in Not Strongly Affiliated Hospitals	VA Investigators in Strongly Affiliated Hospitals	NIH Extramural Grantees	NIH Intramural Program
	Average standardized citations[b]	Average standardized citations[b]	Average standardized citations[b]	Average standardized citations[b]
Clinical articles	1.82 ± 0.05 (823 articles)	2.22 ± 0.05 (827 articles)	2.32 ± 0.08 (346 articles)	2.44 ± 0.07 (420 articles)
Nonclinical articles	1.74 ± 0.09 (282 articles)	1.95 ± 0.11 (213 articles)	2.35 ± 0.09 (280 articles)	2.75 ± 0.09 (278 articles)

[a]Approximately 20% of the 1971 and 1972 research articles from VA investigators (as first authors), 18% of the sample of research articles from NIH extramural grantees, and 7% of the sample of research articles from NIH intramural investigators were not published in the 921 journals used in the bibliographic study and thus were not evaluated.

[b]The results are expressed in the form: $\log_e$ [standardized citations +1] ± standard error. The pooled estimate of the within-cell variance was used to compute the standard error.

total number of articles published by VA investigators in 1971 and 1972, it was found that in the nonclinical area NIH intramural investigators published articles of significantly higher impact than NIH extramural investigators, who, in turn, produced articles of significantly higher impact than VA investigators.

In the clinical area the results were not so clear cut. Pairwise comparisons showed a significant difference between the impact of articles produced by NIH intramural investigators and VA investigators, whether in strongly or not strongly affiliated hospitals. However, there was no significant difference between the two NIH programs nor was there a difference between NIH extramural investigators and VA investigators in strongly affiliated hospitals.

Overall, it seemed that it was only in the nonclinical area that the VA was relatively weak compared to NIH investigators. It was encouraging to find that in the clinical disciplines VA investigators in strongly affiliated VA hospitals fared as well as NIH extramural investigators, many of whom were their counterparts in medical schools.*

One factor that partially explain the VA's relative weakness in the nonclinical area may have been the inclusion of the psychology articles.

*An interesting secondary finding of this study was that VA multiauthored publications had a higher impact than sole authored publications. The interpretation of this finding was unclear because a number of different factors could be contributing to produce this effect. As noted, multiauthored publications had the same impact whether or not a VA investigator was the first author. The non-VA authors of multiauthored publications included medical school faculty, housestaff, research fellows, graduate students, etc.

An analysis of VA specialties showed that this discipline was expecially weak in the VA.* As psychology articles accounted for 22% of the VA articles in the nonclinical area, they had a marked effect on the overall productivity of that area.

Although there was no significant difference between strongly and not strongly affiliated hospitals in the nonclinical area where the VA was relatively weak overall, citation rates were significantly higher in strongly affiliated hospitals in the clinical disciplines. Note that the strongly affiliated hospitals accounted for only 18% of the research-funded hospitals and yet produced approximately 50% of the VA's 1971 and 1972 publications. These findings reinforced the Committee's conclusion from the site visits that a strong medical school affiliation was one of the most important factors influencing the quality of research in a VA hospital.

These results, standardized and expressed in terms of logarithms, are difficult to interpret as well as appearing unimpressive. Some sense of the general pattern can be conveyed by using citation frequency data based on raw (nonstandardized) citation counts. For example, 52% of the articles of VA investigators received one or no citations, whereas 36% of the NIH extramural articles and only 31% of the NIH intramural articles received one or less citations. Similarly, at the upper end of the frequency distribution, 2.2% of VA articles received more than 20 citations, whereas 5.3% of the NIH

*In fact, when standardized to take into account the different citation frequencies of different fields in the total biomedical universe, the mean number of citations to psychology articles in the VA was 8.2, compared to 39.7 mean standardized citations for the strongest discipline in the VA: gastroenterology.

extramural and 7.2% of the NIH intramural articles received more than 20 citations each. It must be emphasized that these were nonstandardized citations (so that specialty differences among the groups may have made a great deal of difference) and the distribution combined clinical and nonclinical disciplines (so masking the clinical area where the VA fared better) and strongly and not strongly affiliated VA hospitals. However, the distribution does reflect a more easily interpreted indication of the general trend.

Table 7-3 compares the citation rates of VA and NIH investigators by taking the average number of raw citations to articles in each of five disciplines. Because the variability within each group is large, the results in any one discipline should be regarded with caution. However, when the five disciplines are viewed overall, a general trend is once again apparent: VA investigators tended to get slightly fewer citations on average than NIH extramural investigators who themselves received slightly fewer citations than NIH intramural investigators.

Raw citation count comparisons of the VA and NIH programs revealed the same trends as the standardized and transformed data. They reinforced the assumption that the standardization procedure, used so that data across different fields could be combined, was not itself producing spurious results.

STUDY III: COMPARISON OF THE VA'S INSTITUTIONAL AND CAREER DEVELOPMENT PROGRAMS

Most VA investigators receive institutional research funds, but a small number receive funds from special research programs. The largest of the special research programs is the CDP, and the Committee had been impressed on its site visits by the quality of the research carried out by CDP inves-

TABLE 7-3

Comparison of the Raw Citations to Publications by VA and NIH Investigators in Five Disciplines[a,b]

	VA Investigators	NIH Extramural Grantees	NIH Intramural Program
	Average citations/ article	Average citations/ article	Average citations/ article
Allergy, immunology, arthritis, and rheumatology	4.2 (83 articles)	7.1 (25 articles)	8.8 (61 articles)
Biochemistry and molecular biology	5.9 (131 articles)	7.3 (135 articles)	9.5 (95 articles)
Endocrinology and fertility	5.4 (84 articles)	6.3 (27 articles)	11.2 (19 articles)
General and internal medicine	3.9 (464 articles)	5.6 (60 articles)	5.8 (84 articles)
Pharmacology	3.8 (81 articles)	3.9 (22 articles)	9.5 (95 articles)

[a]For the analyses shown in other tables biochemistry and molecular biology was classified as a nonclinical discipline; general and internal medicine, pharmacology, endocrinology and fertility, and allergy, immunology, arthritis and rheumatology were classified as clinical disciplines.

[b]Because of the appreciable variability within each group, the results in any one discipline should be viewed with caution, although the table does indicate a general trend overall.

tigators. It was decided to compare the institutional program and the CDP by using citation analysis. Because each of the CDP levels is different from the others, ranging from training positions to fully established investigators, each level was compared with the institutional investigators separately. Also, because almost all investigators in the CDP were M.D.'s, only M.D.'s were used in the comparison.

The results of the analysis are presented in Table 7-4. Although there appeared to be some differences among the groups in the nonclinical disciplines, the number of articles in each group was so small that even if there were quite large differences they would not be detected by the analysis. In the clinical disciplines the group of clinical investigators (CI's) produced research of significantly higher impact than the institutional investigators. The results also suggested that the senior medical investigators (SMI's) produced higher quality research than institutional investigators although the difference was not statistically significant. Again, the high variability within the groups and the very small number of articles in the SMI group made even quite large real differences difficult to detect. There is some justification for thinking that the SMI group did produce very high quality research as the highest raw (nonstandardized) citations in the VA were received by SMI's. One clinical article written by an SMI received 58 citations in the two year period of the study, and one nonclinical article received 45 citations (both these articles were excluded from the analysis because the author was one of the few Ph.D.'s in the CDP group. Those numbers of citations are especially great considering that only half of the

TABLE 7-4

Comparison between Publications from Investigators

Receiving Institutional Research Funds and CDP Investigators[a]

	Senior Medical Investigators	Medical Investigators	Clinical Investigators	Research Associates	Investigators Receiving Institutional Research Funds
	Average standardized citations[b]	Average standardized citations[b]	Average standardized citations[b]	Average standardized citations[b]	Average standardized citations[b]
Clinical articles	2.70 ± 0.38 (16 articles)	2.01 ± 0.21 (51 articles)	2.76 ± 0.18 (72 articles)	2.28 ± 0.14 (117 articles)	2.08 ± 0.06 (758 articles)
Nonclinical articles	(1 article only)	2.86 ± 0.38 (16 articles)	2.20 ± 0.35 (19 articles)	2.27 ± 0.33 (21 articles)	2.22 ± 0.17 (79 articles)

[a] Only M.D.'s were used in this analysis because most CDP investigators were M.D.'s.

[b] The results are presented in the form: $\log_e$ [standardized citations +1] ± standard error. The pooled estimate of the within-cell variance was used to compute the standard error.

scientific articles published in journals indexed by SCI are ever cited, and those that are only receive an average of 1.7 citations a year.

Again, the results of the analysis tended to confirm the Committee's findings from site visits that the CDP was a high quality program and that the CI and SMI groups were particularly outstanding.

SUMMARY

Citation analysis provided a useful means for the Committee to evaluate the VA's research program through its scientific publications, and, in particular, allowed a systemwide comparison of VA research with other biomedical research programs to be made. The results broadly confirmed the Committee's impressions from site visits: that, as the VA program does not compare favorably with the NIH programs particularly in the nonclinical disciplines, all research proposals should be evaluated by merit review boards; that strength of affiliation with a medical school is an important factor in the quality of research in a VA hospital; and that the career development program is of high quality.

The correlation between rankings of journals by peer review and by citation analysis does not directly validate the use of citation counts to measure the impact of individual papers. However, the impact of a journal is based on the citations to individual papers in that journal, and the correlation with peer judgments does support the use of citation counting as a tool for assessing research productivity.

CHAPTER 8

DISCUSSION

OBJECTIVES OF BIOMEDICAL RESEARCH IN VA HOSPITALS

VA hospitals have an overriding and primary objective--to provide care to eligible veterans. Research and education in these clinical settings, therefore, should support this objective. The quality of biomedical research is not necessarily related to its relevance to clinical problems, but only research of high quality is worth supporting. Mediocre research of seeming relevance to a current clinical problem is unlikely to lead to improved patient care. However, scientifically excellent research may provide information and understanding of no immediate applicability or apparent relevance to presently perceived problems or needs, but that research may become crucial once more pieces of the puzzle have been identified. Ideally, clinical research should be both of high quality and relevant to clinical problems. Relevance alone, however, cannot justify the support of mediocre research.

Research should take advantage of the opportunities provided in the setting where it is done. This does not necessarily imply that only research of an applied nature should be carried out in the VA. Although the special opportunities in the VA should be utilized fully, an exclusive concentration on either basic or applied science is not recommended. The research to be

supported should be determined primarily by the extent of knowledge in the particular scientific area. In deciding how VA resources best can be used to contribute to solving a problem, it will be necessary to take into account research programs in other agencies.

Special care is needed in the placement of basic scientists in VA hospitals. Such scientists not only can make direct contributions to knowledge, but under appropriate circumstances may serve as important sources of expertise for clinical investigators. Basic scientists are most likely to be resource persons exercising beneficial effect upon the research program when they coexist and interact with a substantial group of clinical investigators.

To provide the direction needed to ensure the best possible use of VA research opportunities, an advisory council should be established to recommend priority areas, scope and major policies for VA research and research training programs to the assistant chief medical director for R&D. The council should report to the chief medical director and recommendations for appointment to the council should be made by him. The council should be composed of persons from outside the VA, including distinguished physicians, scientists and lay persons knowledgeable about health care or research. The tasks of the council would be to identify programs or areas of research which should be emphasized or enlarged and those which should be reduced or terminated. The council should review special programs and should set standards for merit review boards. In recommending priorities for research in the VA and in planning research strategies, the advisory council should note the

importance of the research for the VA mission, but it should also take into account the availability of qualified investigators, facilities, technical support and the feasibility of the general approach in the area being considered.

To provide a model for what might be done by the proposed advisory council, a member of the Committee undertook to develop a strategy for a centrally organized research program on behavioral disorders. It is clear that the VA has a major commitment to the treatment and therefore to research in behavioral disorders (mental illness, alcoholism, drug abuse, psychosomatic disease, aphasia, and others). The arena of relevant research is a broad one, ranging from basic psychophysiologic inquiry to clinical trials of psychotropic drugs. Although some important exceptions exist, the treatment of behavioral disorders is far from effective and the research base is limited and fragile. But even the small amount of psychiatric research conducted so far has had a strong impact on patient care, notably through the development of medications for treating mental disorders. Investigation into the possibility of more extensive outpatient treatment is one step; a deeper understanding is needed of the psychopharmacology of treatments for schizophrenia and depression; and at a more fundamental research level, the neuropsychology of stroke and the neurobiology of alcohol must be studied. The current VA research effort in behavioral science is not strong. Even in an area of traditional strength--cooperative studies--it is unlikely that first-class work will rise spontaneously and widely throughout the system. There is a pressing need for increased attention to behavioral research, the

development of strategies for upgrading behavioral research, improvement of training, and establishment of a closer working relationship between behavioral research and training. To that end, specific suggestions have been developed, which together with a more fully rounded rationale for the strategy, are presented in Appendix G.

The Committee has not attempted to identify all the research areas appropriate to the health needs of veterans and its exposition of potential VA commitment to behavioral research is simply an illustration--although the Committee believes the example represents a significant need. Other areas of at least equal importance to veterans--aging, rehabilitation of patients with neurologic, skeletal, and muscular disorders, and other chronic problems--also may need special strategies. As its first task, the advisory council should identify areas to which special attention should be paid by the VA and recommend the types of research programs that should be developed. Although the particular illustration emphasized the need for a centrally organized program, the advisory council should recognize the importance of research initiated by individual investigators in its research planning.

In summary, the objectives of the VA's research program should be to support research and scientists of the highest quality in areas of biomedical science related to the health problems and improved care for veteran patients. This research should include both basic and applied science determined by the extent of knowledge in the scientific area. To direct the program towards these objectives, the Committee recommends:

A. An advisory council should be established to recommend the priority areas, scope, and major policies for VA research and research training programs. Members of this council should be persons from outside the VA.

POLICIES, ORGANIZATION AND MANAGEMENT

The policies, organization and management of the VA's research activity are complex. The relationship of research to the mission of the VA, and the importance of research support for the development and maintenance of a climate of clinical inquiry stimulating to high-quality patient care need to be considered when developing policies. The VA Central Office should commit itself to establishing reasonable stability in policy, organization, and management and funding of research activities. In the past, abrupt and incomprehensible changes have caused needless confusion and decreased the morale and efforts of VA scientists. In addition, the lack of clear policy on a number of issues has led to a confused variety of practices. Research policies should be clearly spelled out and uniformly implemented across the system. This section discusses a number of recommendations made by the Committee concerning research policies.

Funding of Research

When considering the importance of supporting high-quality research in VA hospitals and the complexities of managing research activities, several questions arise: Is central merit review of all individual research programs needed? Would central merit review of the overall research program in each VA hospital be sufficient? Or should distribution of funds for research within a given institution be the sole prerogative of a local research

committee or the associate chief of staff?

Current practice gives each hospital considerable control over the allocation of research resources. However, this flexibility has been used at some VA hospitals to support inferior research, often for the purpose of retaining staff whose primary value to the hospital is patient care or administration. The Committee believes then, that to ensure the highest possible quality in the research program, all projects should be reviewed by panels of experts appointed or approved by the Central Office. (These panels could be similar to or include the presently constituted merit review boards.)

Such panels should assess the quality of proposals that fall within the program priorities identified by the advisory council. Other factors to be considered would be the research resources available in terms of expertise, facilities, materials, and the degree of integration with other research effort. In addition, the degree to which a research effort's use of space, effect on personnel, and allocation of funds infringes on patient care must be considered.

At present, approval and funding of research programs after merit review at the VA Central Office does not assure that the particular program will be correspondingly supported at the local VA hospital. Furthermore, even if a research proposal has been disapproved by an expert review panel at VA Central Office, current policy permits its support by funds allocated at the local station. This procedure should be discontinued and decisions following merit review by expert panels at VA Central Office should be honored and implemented as far as it is possible within the program's financial means. When applica-

tions are disapproved, the individual investigator and the local station should be informed as to the basis of disapproval and be allowed to resubmit without prejudice.

Each hospital also will require discretionary funds for administration and common resources, as well as some funds for program innovation and the initial support of new investigators. There should be some correspondence between the size of the discretionary funds and the support received by the hospital for merit-reviewed programs. Discretionary funds should not support projects that have been disapproved in merit review.

Universal merit review should result in research programs of high quality, and it may be appropriate that investigators devote larger amounts of their time to research than is now possible in most hospitals. The amount of time will depend on the individual investigator, but it should be specified in the research application. If approved, the investigator should be freed from some of his clinical duties so that he is able to spend more time on research. Hospital directors should be allowed to justify additional staff positions on that basis.

Although the VA should have a strong intramural research program, it should also be recognized that the resources of the VA cannot fully support the potential research opportunities offered by VA hospitals. Therefore, VA investigators should be encouraged to seek funds outside the VA system to enlarge their research programs, but only with the full knowledge and approval of their VA research committee. At present, staff of VA hospitals awarded monies by the NIH or other non-VA sources often have these funds

administered by the affiliated medical school or university. This practice exists for several reasons, including avoidance of additional burdens for the VA hospitals' administrative staffs; flexibility of fund utilization through the medical school; avoidance of federal administrative encumbrances; and perhaps more importantly, prevention of research technicians accruing civil service tenure. The practice of having an affiliated medical school administer non-VA research funds for the VA hospital's staff may be convenient, but it has left certain issues unexamined. Some of these issues should be tackled directly as, for example, the problem of civil service tenure for support personnel discussed below.

In considering overhead costs, little is to be gained by precisely identifying the hospital services and costs that indirectly support both VA and non-VA research efforts, although the demands placed upon the hospital by research programs should be recognized. For example, when nursing, supply, radiology, laboratory or other hospital services are to be used extensively to support research activities, methods should be developed to provide the additional funds and personnel needed to avoid compromising the patient care programs while meeting the needs of research. The Committee did not give this problem the attention it deserves, but the drain on patient care services should be studied further and policies should be developed to resolve the difficulties that have arisen in some VA hospitals.

Health professionals in VA hospitals such as nurses, radiologists, and pathologists may be affected by the research programs, even if they are not the principal or actively participating investigators. So that these groups

may be adequately informed about research and its demands on their services, they should be invited to share in the deliberations of the hospital's research committee. In some instances, it may be appropriate to appoint them as full voting members of that committee. The Committee is convinced of these groups' interest in research, particularly as it involves veteran patients and the care provided by VA hospitals. Their participation in the deliberations and membership of the research committee would help to sensitize VA investigators to the impact of their research on patients and the hospital's services.

Personnel for Research

The Committee was impressed with the two general problems concerning personnel. One was the difficulty in attracting and retaining a larger number of high-quality investigators. The other was the inability or reluctance to take necessary steps to eliminate investigators of low caliber from the system.

The first problem is attributable to the failure to establish a climate which nurtures the development and growth of worthwhile research programs. Even more essential would be relaxation of regimented practices such as clock-punching and enforced regularization of working hours. Although these practices were not examined on site visits, several Committee members with experience in the VA pointed out the morale problems that such practices bring about. Professionals find these trivial practices annoying, restrictive, and demeaning. Investigators should be judged by their product rather than such artificial measures.

The Committee's recommendation that all projects should be merit-reviewed and only high-quality research supported should partially alleviate the problem of unproductive investigators. The investigator whose primary occupation is patient care poses little problem because he can transfer his activities into patient care. The VA should take steps to eliminate other unproductive investigators. The retention of such investigators has a negative influence on the environment because they do not contribute the intellectual stimulation and technical expertise necessary to high-quality research programs.

When research projects end or are not deemed worthy of further support, dealing with the support personnel is difficult, because many of them have civil service tenure. Technicians' skills are specialized: often they are not transferable to other research programs yet these transfers have to be made. The Committee recommends two approaches in dealing with this problem. The ceiling on the numbers of term employees allowed in the VA has been lifted and such appointments should be instituted more widely for research support personnel. Retraining of technicians with civil service tenure should be encouraged to equip them for new projects or for transfer into hospitals' clinical laboratories. Many investigators are frustrated with the present situation and the provision of suitably trained technicians would help retain high-quality investigators.

Evaluation of Research

The VA Central Office now does not have the staff, expert advice, or funds to establish methods for ongoing evaluation of research in VA hospitals.

Such activities are critical to the success of the research program and more resources should be provided to the Central Office.

Some programs may require periodic evaluations; other programs should be scrutinized on a more continuous basis. An example of the former might be the program on centers for the aging, which will need several years before its success can be evaluated. The VA's research bibliography, however, might need more regular and frequent evaluation. The information acquired in such evaluations is crucial to the proposed advisory council if it is to function successfully.

For such evaluations, reports to the VA Central Office must describe accurately and fully the research support (including non-VA funds) and productivity in a VA hospital. The reporting systems in the VA research program are inadequate for effective managerial decision making or for providing useful information about the VA's program to interested external bodies. Although the annual reporting system and the medical research information system were recently combined--which removed much duplication--a management study of the research information system should be undertaken. This study should identify the types of information required for decision making, develop a more uniform and definitive reporting system, and further eliminate duplication.

Because the written report each hospital submits to the VA Central Office may not truly reflect the quality or pertinence of the research to the VA, more complete methods of review are required. Outside experts, acceptable to or identified by the VA Central Office, should visit VA hospitals periodi-

cally to evaluate the quality of research, the qualifications of investigators, and the adequacy or effectiveness of management of research funds, including both discretionary funds and support provided by the VA Central Office after merit review. Because VA resources are involved in all research in a VA hospital, this review would be applicable to all research efforts regardless of funding source.

The Cooperative Studies Program

The VA is uniquely qualified to undertake high-quality cooperative studies. It has a large patient population that is under one management, and this facilitates adherence to a uniform protocol. The patient population is more stable than those cared for at most large university centers, which permits truly random assignment of patients and more adequate follow-up. The accomplishments of the VA Cooperative Studies Program have fostered a sense of pride in many of the staff that has led to a degree of willingness to participate in cooperative studies that is not found elsewhere

When the Committee reviewed current studies under the cooperative program, it became concerned with the method of identifying and planning them. Most of the proposals originate with one or more investigators at a single VA hospital and are reviewed at the Central Office for feasibility and relevance to the VA mission. This procedure does not appear to take maximal advantage of the resources and opportunities available. Rather, it would seem profitable to establish a mechanism for the central identification of important clinical problems that are best addressed by cooperative studies. We have in mind the establishment of panels of scientists, from within or

without the VA, that would meet periodically to perform that function. We also believe that increased central activity in the planning and monitoring of studies by the CSP evaluating committee would improve the utilization of resources. One important task that this could accomplish is that of ensuring effective linkage between the clinical aspects of a study and the appropriate science base.

The Committee recommends:

A. All research programs supported by the VA should be reviewed regularly for merit by merit review boards. These panels should be comprised primarily of scientists who are not salaried by the VA.

B. Research should be funded in accordance with the recommendations of these merit review panels as far as it is possible within the financial means of the VA Central Office.

C. Programs disapproved by merit review panels should not be funded except for phaseout support. However, investigators should be informed as to the reasons for the disapproval and allowed to resubmit without prejudice.

D. Merit review panels should assess the research setting at the particular VA hospital when evaluating research programs, because environment is important in assuring high-quality investigation.

E. Discretionary funds should be allocated to a VA hospital to provide for research administration, common resources, and the support of exploratory or pilot projects, as well as the initial support of new investigators' research. These funds should not be used for the support of disapproved projects.

F. VA Central Office should examine the management of non-VA research funds awarded for research carried out in VA hospitals and take measures to ensure that appropriate support is provided for VA resources and facilities.

G. The impact of research programs on patient care services (e.g., clinical laboratory, nursing, radiology, supply, and engineering) should be recognized. If these services require expansion to shoulder extra work imposed by research, additional resources should be provided.

H. VA health professionals from the services just described should share in the deliberations of the hospital's research committee, especially if they are expected to carry out research procedures.

I. Evaluative methods should be developed by the VA Central Office to gauge the quality of the VA's research effort and its relevance to the VA mission. Evaluations should signal management difficulties and program needs. Policy changes recommended by the advisory council should be based on these evaluations.

J. Additional staff and resources will be required at the VA Central Office to implement the foregoing recommendations.

RECRUITMENT AND RETENTION OF STAFF FOR PATIENT CARE

The process of affiliating VA hospitals with medical schools to upgrade patient care after World War II brought a vigorous, academically oriented staff into many VA hospitals. The period of recruitment coincided with the rapid expansion of medical schools and medical centers along with a rapid growth of federal (particularly NIH) funds for research. By the 1960's, the improved academic environment, the rapidly expanding research programs, and

the higher salaries offered to medical school staff had placed VA hospitals in a less competitive position for recruitment. These events encouraged new VA-medical school affiliations and the strengthening of already existing ones. The opportunity for VA staff to hold academic rank improved the recruitment rate of medical and scientific personnel in affiliated VA hospitals and the expanding VA budget for research was utilized to aid in recruitment and retention of senior staff. Although the budget for VA research was not large when compared with that of the NIH--the other major grant-awarding agency--during the same period, it represented an in-house source of funds for support of research by VA staff. Between 1965-1975 in particular, the research budget represented an opportunity to provide newly recruited and more senior staff access to research funds that usually were not subject to the type of open competition and external peer review associated with applications for NIH funds. For this reason, VA research funds were an important recruitment incentive.

The current procedures within the VA system for application for research funds are detailed in Chapter 2. Considerable local control exists in the allocation of research funds and local needs influence the decision to support a research proposal. Someone who provides an important and needed clinical or administrative service (e.g., anesthesiologist, cardiologist) to a VA hospital has a good chance of being awarded research funds on grounds other than merit of the research proposal. The perpetuation of such practice could lead and may have led to diminished contributions of biomedical research towards resolving important issues related to health problems of veterans;

but more importantly, perpetuating this practice limits the opportunity to develop new areas of research by competent, young, medical investigators.

The major purpose of initiating the VA research programs was to provide an environment at VA hospitals that would ensure better health care as a result of new knowledge developed by careful and thoughtful research. It is doubtful that it was ever intended that research funds would be used primarily to recruit or retain a staff member who was providing clinical services only. The VA Central Office staff recently have stated that use of research funds for recruitment and retention of VA hospitals' staff should not have as high a priority as quality of the research supported and the relevance of the research to the needs of veterans. The Committee commends and supports this change in emphasis and although a VA hospital benefits from having "fluid" research funds to help recruit new staff members capable of doing research, such funds should be used during the early development of research activities rather than for retaining clinical staff.

The recent enactment and implementation of Public Law 94-123, providing increased pay to eligible physicians and dentists in VA hospitals is an important step in the retention and recruitment of VA hospital staff. The improved salary scale may minimize the need to use research funds as a means of retaining staff. Finally, the Committee repeats that one of the most important determinants in the recruitment and retention of meritorious staff is an environment in which individuals are judged according to their efforts and not on their conformity to regulation. The VA should make every effort to encourage such an environment.

The Committee recommends:

A. Research funds should be provided as a recruitment incentive only to clinical and biomedical investigators expected to produce high quality research.

B. Continuing research support should be provided only for investigators when their research is of high quality. Research funds should not be used to retain staff or reward clinical skills and contributions.

RESEARCH CAREER DEVELOPMENT

The patients receiving care provide opportunities for the trained physician to identify previously unrecognized clinical problems, characterize and understand patients and their illnesses, and investigate disease and methods of care. The interaction of physicians, clinical investigators, and basic scientists in these settings provides an environment for effective research training and research career development. Physicians can enhance the quality of their work, clinical investigators can relate their scientific work to important clinical problems, and basic scientists can provide the expertise important for research of the highest quality. Individuals receiving research training in such an environment can acquire the knowledge and develop the scientific talent and skills necessary to contribute effectively to increased understanding of important medical problems. More immediately, the importance of young, inquiring minds to a continuing research program is obvious and especially needed when the scientific problem is difficult or intractable, as are many of the disorders that make up the bulk of VA hospital admissions. VA hospitals with productive senior clinical investigators and scientists,

particularly those actively affiliated with medical schools, are well equipped to provide research training and should be encouraged to do so.

Some VA hospitals with extensive research programs have few, if any, investigators in the career development program (CDP) in either the training or senior investigator levels. Other VA hospitals with smaller but vigorous research programs and close affiliations with medical schools committed to research have a greater commitment to the program. The essential ingredients to effective research training and career development in VA hospitals are related to the vitality of the ongoing research programs and the degree of interaction between the VA hospital staff and the medical school faculty. It is improbable that any VA hospital, by itself, could provide the number and variety of senior investigators as well as the scientific expertise needed for the most favorable environment for research training and career development. The Committee believes that CDP awards should be provided preferentially to qualified persons in VA hospitals closely affiliated with medical schools where both the VA hospital and the medical school are actively involved in research and research training.

The VA patient population presents many medical problems which, although seen elsewhere in medical practice, are especially abundant among veterans: alcoholism, serious psychiatric disorders, spinal cord injuries, degenerative diseases associated with aging, etc. The need for effective treatments for these diseases is matched by their intractability and the need for scientific research about their etiology and pathogenesis. That additional research attention should be paid to such problems is unquestioned. What is not clear

is whether investigators in the CDP are devoting their attention primarily to them. Research could certainly be encouraged by locating these investigators' laboratories in the VA hospital, and by stipulating that preceptors are suitably qualified VA staff investigators.

It may be appropriate to develop or expand research training programs within or outside the CDP as particular research needs or problems are identified; scientists can be trained to tackle particular problems, the research opportunities offered in the VA can be exploited, and problems of special importance to veterans can be investigated. However, the CDP should be used to recruit and train junior investigators only if more senior investigators are available to develop a high-quality training program in the particular research area.

The VA research training program could be justified on the grounds that it is effective in retaining research scientists in the VA system. Data indicate that 40% of the highly selected, merit-reviewed group of research associates and clinical investigators in the CDP do remain within the system. A moment's reflection, however, suggests that this is too narrow a view. A policy objective should be to recruit researchers who retain an active investigatory interest in problems especially relevant to VA patients. Where and under what auspices they subsequently conduct their research is of lesser import, although their retention in the VA system might expedite the application of knowledge. On the whole, the Committee considers this last condition a marginal gain because of the wide and rapid transmission of biomedical discoveries.

The Committee recommends:

A. Career development awards should be provided preferentially to qualified persons in VA hospitals with a closely affiliated medical school where both institutions have highly productive research programs.

B. Recipients of career development awards should have laboratories in the VA hospital, and qualified VA hospital staff investigators should serve as their preceptors.

C. The policy of review and selection of all career development program awardees by a non-VA committee should be continued.

INFLUENCE OF RESEARCH ON PATIENT CARE

The Committee did not evaluate the quality of patient care in VA hospitals. They drew on the findings of the NAS/NRC Committee on Health Care Resources in the VA (VA Care Committee). The association between quality of patient care and an active research program (as judged by the funds they received) was observed on the VA Care Committee's site visits. Some of the data have been summarized in Table 8-1. Each of the three major bed sections--medicine, surgery, and psychiatry--in each of the 27 site-visited hospitals was rated as outstanding, adequate, or inadequate. The table illustrates that the outstanding services are found in hospitals with sizable research programs. Although not shown here, five of the seven hospitals receiving more than $1 million in research funds had at least one outstanding service. Only two other hospitals in the site visit sample were rated outstanding on any service. None of the services in hospitals with more than $1 million were judged to be inadequate. Almost all inadequate services were found in hospi-

TABLE 8-1

Quality of Care in Medical, Surgical and Psychiatric Services in Hospitals Site-Visited by the VA Care Committee[a]

FY 1976 Level of Research Funding	No. of Hospitals in this Level	Total No. of Services Assessed[b]	No. of Outstanding Services	No. of Adequate Services	No. of Inadequate Services
$ 1,000,000	7	21	7	14	None
$ 300,000 - 1,000,000	7	19	4	14	1
$ 300,000	8	21	None	17	4
None	5	10	None	5	5
TOTAL	27	71	11	50	10

[a] Data from the VA Care Committee (to be released winter, 1976).

[b] Note that not all hospitals had all three services.

tals with very small research programs or none at all.

The table shows association only and does not imply that research alone improves the quality of patient care. It is the total environment which counts. The closeness of the affiliation, the presence of trainees, the quality of staff, and an active research program are all conditions that influence the quality of care. The quality of the staff itself is also strongly influenced by a number of factors, including geographic location of the hospital. Research alone cannot bring about high-quality patient care and should not be expected to do so. However, the Committee believes that research is an important and integral part of an environment where patient care is of high quality.

To understand why research is important to such an environment, it is necessary to understand what comprises medical care. To treat patients requires an ability to deal effectively with doubt and uncertainty and make decisions based upon an understanding of probabilities. Physicians must deal with patients with various manifestations of illness, ranging from minor complaints to serious problems. Accurate diagnosis is not a routine matter, and the correct diagnosis is not necessarily the most obvious one. Similarly, treatment is not routine; it must be individualized and based on sound foundations. The clinician must not only note immediate events but also must pay attention to all phenomena or events indicating changes in the patient's medical condition and way of life. As in research, care of patients provides intellectual challenges and requires planning and evaluation. Despite the major scientific advances, much of medical practice is an art instead of a

science, an art built upon and not a substitute for knowledge.

Medical knowledge and practice are constantly changing. Diseases have become pinpointed as biochemical and physiologic processes rather than merely nosologic entities. Diagnostic processes and the treatment of disease have become increasingly sophisticated and complex, often with the potential of causing harm as well as resolving disease. Recent scientific and technologic advances have created new problems, requiring that physicians have the most current knowledge, understanding and skill to do the best job possible. They must understand the potentially injurious effects of diagnostic and therapeutic procedures to avoid unnecessary risk and maximize benefits.

Thus the best medical care usually is found where there is the least routine or reflex reaction, and the most inquiry, originality, and insight. Biomedical research has a potentially favorable effect on the quality of care in the VA because it encourages such an environment and attracts clinicians with inquisitive and critical minds. Such clinicians often wish to do research, and they should be encouraged in it; however, research should not necessarily be expected of every clinician. The Committee also recognizes the value of an expert clinician and those who prefer to develop their talents in clinical work also should be appropriately rewarded. At present, VA physicians may be awarded research funds for purposes of prestige, and the results are often mediocre at best. Research should not prevent the clinician from taking care of patients. No formula exists that can be expected to fit every clinician, every research project, or every institution. An environment with an active interest in the study of disease, however, is the one in which

medical care will be the most precise, the most effective and in the best interests of the patients.

The Committee recommends:

A. Because poor quality care cannot be improved simply by adding a research program to a hospital, research funds should not be provided primarily with this intent.

MEDICAL SCHOOL AFFILIATION

The Committee's review and evaluation of research and training in the VA convincingly showed that affiliation with medical schools is one of the most important factors associated with the quality and magnitude of the research enterprise in VA hospitals. If they have a research program at all, VA hospitals unaffiliated with established medical schools uniformly have fewer, less productive, and less meritorious research programs and investigators. With few exceptions, the closer the geographic and operational relationship between a VA hospital and a medical school. the more meritorious is the research and the more qualified are the investigators in the hospital. However, merely a strong interdependency between the school and the VA hospital will not bring about high-quality research in the VA. It is also necessary that the medical school itself have a strong research orientation. The quality of the research effort at the affiliated medical school strongly and directly affects the quality of the corresponding VA hospital's program.

The degree of interdependency between VA hospitals and affiliated medical schools varies widely. There may be complete, partial, or no integration of the VA hospital into the medical school's (or its individual departments)

training programs. Some medical schools do not distinguish the university staff from the VA hospital's staff, even to the point of equalizing salaries by supplements to the salaries of VA hospital staff, and by providing VA staff with academic fringe benefits. Other medical schools provide few or no benefits to the staff of an affiliated VA hospital, and gradations exist between these extremes. Some medical schools fully involve their non-VA staff in patient care programs of the VA hospitals to ensure that the quality and character of patient care is comparable with that of the university hospital. Agreements have been made between VA hospitals and university hospitals to share resources and facilities. Some medical schools play a dominant role in recruiting VA clinical and scientific staff, whereas others are very casual about the matter. Some university health centers extend similarly close affiliations between dental schools, nursing schools, and programs in hospital administration, health systems or operations research, or animal care and the VA hospital. Finally, some schools of medicine carry on strong, extensive, and varied research programs, whereas the staffs of others devote most of their time to teaching and patient care. Where the affiliated school has an investment in biomedical research, the VA hospital's research program is likely to benefit scientifically from the relationship.

Although most VA hospitals with a close and interdependent affiliation with a medical school are located in close geographic proximity to the medical center, the Committee observed several institutions where separation of the VA hospital and medical school by a few miles did not seem to deter the quality of the relationship. But VA hospitals separated by considerable distance

from the affiliated medical school frequently have poorly integrated and coordinated programs, and the quality and size of the research in these VA hospitals is judged to be generally less meritorious.

A few VA hospitals, particularly those in large metropolitan areas where two or more medical schools are located, may have affiliations with more than one medical school. Under these circumstances, one medical school may become dominant and develop a closer relationship with the VA hospital than the other. When this does not develop, the strength and effectiveness of the relationship with either school is often weakened, and the patient care, education, and research programs in the VA hospital may not be stimulated.

A dean's committee composed of representatives from the medical school faculty and VA hospital staff is responsible for coordinating the relationships and programs between the medical school and VA hospital. In some instances, these committees assume a very positive role in furthering the interests of the medical school and VA hospital; in others the relationship appears to be perfunctory. Under either circumstance, the necessary relationships between a VA hospital and a medical school are largely the responsibility of the medical school department chairmen and the corresponding chiefs of service at the VA hospital. The interest and motivation of these groups are major determinants of the effectiveness of the affiliation between the VA hospital and the medical school. Other measures can be taken to strengthen the relationship. For example, if a VA hospital's professional staff actively participate in recruiting chairmen of medical school departments, and medical school faculty participate in recruiting chiefs of staff, associate chiefs of

staff, and chiefs of service at VA hospitals, the sense of mutual responsibility will increase and deepen.

Many of the staff of VA hospitals affiliated with medical schools have accepted and remain in positions in the VA hospitals because of the medical school's involvement in their recruitment and support. The Committee was impressed with the higher quality of the VA staff and their research programs that was associated with a strong affiliation between the medical school and the VA hospital. The participation of the medical school in strengthening the staff of some affiliated VA hospitals had established the VA hospital as a stronger environment for patient care, education, and research than in the university hospital itself. Some medical schools have made a VA hospital into the major teaching and research base for their academic programs.

Although the relationships between VA hospitals and medical schools are usually ones of balanced and mutual advantage, the VA Central Office nonetheless needs to develop means of monitoring the effectiveness of these affiliations to ascertain that the needs of the VA are being met and not exploited in the interest of the medical school. Affiliations between a medical school and a VA hospital should be continued where they are strong and viable, strengthened where they are weak or merely formal, or, if they cannot be strengthened, abandoned. The availability of VA research funds has been an inducement in encouraging medical schools to develop strong relationships with VA hospitals and enhance the patient care, education, and research programs in these hospitals. In research programming, however, the VA Central Office should evaluate the capacity of the affiliated school to provide scientific support, set

high standards, and offer collaborative opportunities to VA research staff. If the school cannot carry out these responsibilities, the wisdom of providing a research budget to the affiliated VA hospital is questionable. It may be reasonable to continue an affiliation on the grounds that the medical school faculty, through training, supervision and consultation, sustain high-quality patient care; but this asset is not itself a justification for research support. Although a strong affiliation should be required ordinarily as a basis for research support, sometimes research support and training may be provided to unaffiliated or weakly affiliated hospitals when particular research needs of the VA can be met best by involving these hospitals and clinics in investigative work. However, support should be given only when such research programs are initiated, monitored, and directed by the VA Central Office, or by cooperative studies centers, or when the staff of an affiliated VA hospital develop and direct research programs in unaffiliated hospitals to meet specific scientific objectives.

The Committee recommends:

A. A strong affiliation between a VA hospital and a medical school with demonstrated interest and competence in biomedical research ordinarily should be required as a basis for a research program at that hospital.

B. Except in unusual circumstances, research programs should not be instituted or maintained at VA hospitals unaffiliated with medical schools

unless the program in these hospitals is centrally initiated and directed.

C. The VA Central Office should develop means for evaluating and monitoring the strength and quality of an affiliation between a VA hospital and a medical school.

D. On the basis of this evaluation, affiliations between medical schools and VA hospitals should be continued or established only when this arrangement is deemed to be mutually supportive.

INFLUENCE OF RESEARCH ON PATIENT WELFARE: WAYS TO ENSURE PROTECTION OF HUMAN SUBJECTS

The search for "a better solution" is so characteristic of intelligent human action that most of us take for granted the legitimacy of inquiry, exploration, trial-and-error, and the testing of hypotheses against the hard facts of experience. The process of scientific inquiry culminates in the controlled clinical trial or experiment. The word "experiment" requires further specification, for in everyday discourse "experimentation" has come to mean almost any kind of trial of a novel (to the experimenter) action, substance, or procedure.

In its most restricted meaning, "experimentation" denotes a scientific procedure designed to test an explanation under carefully controlled conditions. The design of experiments requires ruling out accidental variation, unintentional bias, and other false explanations. This usually necessitates "randomization,"--in the case of clinical research this is a procedure that

sometimes appears unfair or unethical, because some individuals may seem to be bearing an unfair burden (e.g., of a possibly ineffective treatment). Because it is unknown which patient would benefit more from which treatment or whether any patient would benefit at all from the experimental treatment compared to the control, random assignment is both fair and necessary. A comparison under carefully designed conditions is needed to allow the experimenter to rule out plausible alternative explanations, and determine as well as possible that the experimental treatment or procedure is better than (or no better than) the conventional one.

When a physician is responsible for investigations involving patients, his concern about the patient is the most important factor in protecting the patients' rights and welfare. Other safeguards than a physician's concern are necessary, however, when patients are involved in research that cannot be interpreted as part of their ordinary care, to ensure that they are protected from exploitation and excessive risk. These safeguards include the requirement that each patient be fully informed about the research, voluntarily agreed to participate, and be free to withdraw from the research at any time. In addition, human studies committees (HSC) are required to review and approve the procedure for obtaining informed consent and protecting the patient's rights and safety. These safeguards serve to expand the physician-investigator's awareness and sense of responsibility for the patients who are experimental subjects, and increase patient familiarity with the research in which he may or may not agree to be involved.

It is often difficult to obtain fully informed consent from a patient who might be involved in experimentation, but it is a goal that should be sought by the physician. Patients often accede to requests made by their physician on the basis of trust, and HSC's must see that the procedure itself protects patients from unintended hazards as well as from thoughtlessness, careless ness, or haste in explaining an experimental treatment.

When the Committee began its work (in 1974), the VA was revamping its procedures to protect human subjects in research projects. On some of the early site visits, it appeared that these newer, more restrictive guidelines had not been disseminated or put into operation at some hospitals. The Committee was concerned about the adequacy of procedures then employed in protecting and obtaining consent to research participation from VA hospital patients. Its concern was reinforced by the interest of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, which had begun to look into the special problems of dependent persons, that is, children, prisoners, and other institutional inmates whose freedom of choice to participate in research might be limited. Because many veteran patients are dependent on the VA hospital system for their care, and because the commission had explicitly decided not to visit VA hospitals, the Committee undertook a special study of patient involvement in research (reported in Chapter 6 and Appendix E). Most patients interviewed were aware of their participation in research and said that the project and their part in it had been explained to them; stated that they had not been subjected to pressure, persuasion, or inducement to participate; said that they had enough

time to make their decision to participate; and had been given enough information about the research. A minority of patients (27%) who were not explicitly aware that they were in a research study nonetheless replied that their treatment had been explained to them, their questions answered, and that they had signed a consent form. Although the reasons for their unawareness remain a puzzle, a distinct possibility exists that the concentration of unaware patients in one of the four hospitals studied was a function of some faultiness in the way consent was obtained, but it is not clear just what the defect, if any, was.

Investigators found the human studies review beneficial, although many complained that the review process itself was time consuming. Most thought that this type of review has been beneficial to patients and a substantial number thought it has even had scientific benefits for research.

In short, the current procedures for involving VA patients in research appeared to be working effectively in the hospitals studies to protect patient interests. While this conclusion is generally reassuring, it must be kept in mind that the sample was drawn from patients in four strongly affiliated VA hospitals with large clinical research programs located in metropolitan areas. However, one rural, unaffiliated hospital in the site visit sample had no procedures for the protection of human subjects of research in effect and its staff was not aware that there were guidelines to be followed. The Committee believes that prudence requires continued attention to the area of human studies and the operation of review committees. Some recommendations of a procedural nature have been developed by the Committee to aid the VA in im-

proving patient protection further.

This Committee has reviewed the guidelines developed by the Department of Health, Education and Welfare to the protection of human subjects and found them to be appropriate for VA hospitals. To provide for the special needs of VA patients, the Committee has recommended some additional guidelines and procedures.

Each VA hospital should develop its own HSC, separate from that of its affiliated medical school or university. Veteran patients often use VA hospitals as their only available source of medical care, an obligatory relationship different from that of patients cared for in university hospitals where optional sources of care are obtainable in other settings.

The HSC of a VA hospital is constituted as a subcommittee of the research committee. The Committee considers the responsibilities of the HSC to be separate and different from those of the research committee and believes HSC membership should be distinct. A research committee may approve of the merit and scientific justification of a proposal for human experimentation, but questions of ethics or safety may cause the HSC to reject the research because it threatens patients' welfare or rights.* If the membership of the two committees and their responsibilities are not clearly separated, the independ-

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* In judging the propriety of medical research projects, HSC's should take into account the scientific and medical benefits to be derived as well as the protection of the individual patient.

ence of this dual review for separate purposes is jeopardized. The HSC of a VA hospital should be responsive to the research committee, but it should report to the hospital director and/or the chief of staff. No member of the research committee should be a member, although other physicians or scientists should be appointed to the HSC. It would be appropriate for health professionals other than physicians (e.g., a nurse or social worker from the VA hospital) to serve as a member of the HSC. If the Committee's recommendation for increased lay membership is implemented the HSC would be composed mainly of concerned lay members of the community. It is also recommended that the majority of the HSC should not be employed by the VA. Because of the HSC's independence, methods should be established by the VA Central Office to provide investigators the opportunity to appeal decisions by the HSC.

The HSC's for cooperative studies support centers are composed exclusively of persons not in the health or biomedical research professions. Although consultants may be used by these HSC's, at least one clinican or investigator not affiliated with the VA should serve on these committees. There should be closer coordination between the support centers' HSC's and the participating VA hospitals' HSC's in reviewing, evaluating, and monitoring cooperative studies.

HSC's should establish procedures for checking if a study complies with the guidelines for protecting patients. They should also assure that experimental subjects have available opportunities for expressing grievances arising from their involvement in research. Sometimes the principal investigator asks patients to participate in research studies or the staff or physicians not responsible for the research will solicit subjects. The Committee believes

that, under most circumstances, investigators themselves should carry out this responsibility. The individuals responsible for informing the patient about and seeking his consent to participate in research should be clearly specified in every research proposal before it may be approved by a HSC.

The VA Central Office should provide methods to familiarize HSC's of VA hospitals with their responsibilities and operational procedures by arranging for the chairmen of these committees to discuss issues, problems, objectives, and procedures to ensure that patients' rights are protected.

Finally, HSC's and principal investigators in the VA hospitals have a deep responsibility to provide information about the objectives, goals, and purposes of human experimentation, and increase awareness of the safeguards provided to protect patient welfare and rights. Patients, as well as the public at large, usually recognize that research with human subjects is necessary, motivated by a concern for improving health and medical care, and performed with deep concern for the welfare and rights of individual patients. Wider discussion of human experimentation with participants and the public is necessary to involve those who participate in, support, and contribute to research.

The Committee believes that carefully designed and conducted experiments offer one of the best protections to subjects of research. In addition, to protect patients' welfare the Committee recommends:

A. The VA should continue to accept the guidelines of the Department of Health, Education and Welfare as the basis for assuring protection of veteran patients who are subjects of experiments.

In addition,

B. Each VA hospital should have its own human studies committee separate

from that of its affiliated medical school.

C. The membership of the human studies committee should not overlap with that of the research committee and it should have representation of both lay and professional people.

D. Human studies committees in VA hospitals should establish a procedure for monitoring compliance with the guidelines for the protection of veteran patients.

E. VA hospitals should establish a grievance procedure for experimental subjects.

APPENDIX A

VIEWS AND PERSPECTIVES OF THE VA RESEARCH PROGRAM FROM OUTSIDE AGENCIES AND VA STAFF

The Committee's first activity was to identify the issues it should address in its study, which was accomplished by requesting written opinions from or meeting many individuals and groups who were acquainted with the VA's research program. This appendix summarizes the views and opinions the Committee received during two meetings and in over 40 letters.

INDIVIDUALS AND GROUPS

The first meeting was concerned with the rationale for a VA research program and the major policies within it. The Committee discussed these issues with the following VA staff and individuals representing agencies outside the VA that influence its research program:*

Dr. Lawrence Foye, Deputy Chief Medical Director

Dr. Thomas Newcomb, Assistant Chief Medical Director for R&D

Dr. Marguerite Hays, Director of Medical Research Service

Dr. Marc J. Musser, former Chief Medical Director

Mr. Donald Derman, Veterans Affairs Division, Office of Management and Budget

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* Because the Committee promised these individuals and groups that their responses would be treated confidentially, no sources of information are identified in the text.

Dr. John Sherman, Vice President, Association of American Medical Colleges

Dr. Lionel Bernstein, Office of the Assistant Secretary of Health, Department of Health, Education and Welfare

Ms. Louise Ringwalt, Professional Staff Member, Subcommittee on Human Resources, United States Senate

The Committee also received written responses on these same topics from 24 individuals, including VA hospital directors, chiefs of staff, associate chiefs of staff for research, chiefs of medicine or surgery, senior medical investigators, and deans and department chairmen of medical schools affiliated with VA hospitals.

The second meeting focused more on the effects of research on individual patients and on the quality of care in VA hospitals. The Committee discussed these issues with nurses, social workers, and hospital directors from within the VA. Representatives of veterans service organizations, including the Veterans of Foreign Wars, American Legion, and the Paralyzed Veterans of America, testified before the Committee. Finally, Dr. Thomas Chalmers, M.D., President, Mt. Sinai Medical Center, and Samuel Gorovitz, Ph.D., Chairman, Department of Philosophy, University of Maryland, discussed the ethics of human experimentation in research. As with the first topics, the Committee had the benefit of written responses from many other individuals. Twenty VA nurses, social workers, and hospital directors, and the Disabled American Veterans responded to the Committee's request for opinions on the effects of research on individual patients and on patient care in general.

JUSTIFICATION FOR A VA RESEARCH PROGRAM

Everyone who wrote or talked to the Committee felt that the research program was justified. The consensus that research was improving the quality of health care for veterans and capitalizing on the unique resources of the VA was surprising to the Committee. The improvement of health care was attributed, in large part, to the presence of research programs in a hospital, which helped to attract and retain clinical staff as well as those involved in research. In addition, many respondents noted VA achievements in medical sciences that had resulted from the research program.

There was virtually unanimous agreement on the rationale for direct support of biomedical research by the VA. This support was seen as important for ensuring research into the special health needs of VA patients. Degenerative diseases, addictive diseases, mental disorders, spinal cord injury, renal failure, and the problems associated with prosthetic and orthotic needs occur with higher incidence among VA patients than in the general public. These problems traditionally have been afforded low priority in the research programs of other agencies. Intramural support for research was deemed important in keeping VA research relevant and supportive of the VA patient-care mission. One group advocated better coordination among federal agencies to avoid excessive duplication of effort.

Another argument for VA-sponsored research programs was that much VA research, either because of its clinical or collaborative nature, was thought

not to be as attractive to NIH as single investigator research of a more basic nature. The NIH tends to accord this sort of research low priority despite the support it deserves because of its necessity to patient care. The VA Central Office stressed that the intramural program also supports the investigator rather than the project. Supporting the individual allows his research interests to evolve and change; money is not abruptly terminated if a project is not completed within a specified period of time. This stability in funding was considered to be a strong factor in retaining physician-investigators within the VA system.

FOCUS

Everyone agreed that a national policy was needed to define the areas of research in which the VA should be involved. Both VA Central Office and local hospital staff felt the consequences of not having such a policy. Several hospital directors suggested that the Central Office should provide more guidance for the emphasis and direction that a research program should take.

Some VA hospital staff advocated that VA patient problems should be the foundation of all research, whereas others felt that basic research not immediately related to VA problems also was necessary. Several groups arguing on behalf of veterans insisted that VA patient problems should be emphasized, noting in particular research needs in prosthetics and orthotics.

The VA's unique ability to carry out large-scale cooperative clinical trials and the many advances achieved from these studies was cited with admiration by almost everyone who testified. Many VA hospital staff members

wrote that this resource was underexploited and that cooperative studies should receive more emphasis in the future. It was acknowledged that the large system under a single management with a large and relatively stable patient population was well suited to longitudinal, follow-up, and epidemiologic research as well as cooperative studies.

Another issue noted by both VA hospital and the Central Office staff concerned the role of the basic scientist in the VA. They stated that support of the Ph.D. scientist was sometimes hard to justify because his direct contact with patient care would be marginal. However, the importance of basic science expertise in rounding out a clinical team was recognized by many of the staff. Again, the necessity for a clear policy on this point was emphasized.

LEVEL OF SUPPORT

The level of support provided by the VA for its medical research was considered by VA hospital staff to be less than ideal. VA Central Office staff pointed out that the research commitment of the VA Department of Medicine and Surgery was 2.4% of its patient care budget. This amount compared unfavorably with the percentage of funds expended on research by other federal agencies engaged in health-related activities, and it was even lower when compared to the private sector, where pharmaceutic companies commit about 10% of their budgets to research.

The research budget may be somewhat larger than is apparent because most investigators' salaries and many resources available for research are charged to patient care budgets. Some VA hospital staff considered this use

of patient care resources to be improper and felt that research was not paying its way. Others felt that since the research program was itself a resource for patient care, it was appropriate that patient care services provided support for research.

POLICIES FOR FUNDING RESEARCH

Administrative policies and ways of allocating funds have fluctuated widely over the years in association with changes in the top administration at the Central Office. The need for policies stable enough to withstand changes in personnel was emphasized by the present VA leadership.

Opinions varied regarding policies of administration and allocation of funds among the people testifying. Several persons within and outside the VA felt that funding should be based primarily on the scientific merit of the proposal. They favored a central review process to ensure review by persons with the necessary expertise, who would exercise uniform standards of judgment. Another group composed principally of VA staff supported the present system, that is, a mixture of central and local peer review with most funding decisions made by local hospital officials once their appropriation from Central Office is received. This system allows an investigator's contribution to the hospital's patient care mission as well as the scientific merit of his research to be taken into account.

RESEARCH SPACE

Many of the VA hospital staff brought up the problem of finding adequate space for research. In some VA hospitals, the lack of research space was especially frustrating for hospital directors attempting to expand their research programs in conjunction with recruitment efforts. The moratorium on

funds for construction and renovation for research facilities had aggravated this problem. Perhaps because of the general shortage of space, a number of hospital staff noted that research was taking up valuable space that could be used for patient care.

In other hospitals, respondents felt the research space was isolated so much that there was little potential for investigators to interact with patient care activities. Hospital staff strongly disapproved of locating a VA investigator in laboratory space in the affiliated medical school whether he had clinical duties or not, because it isolated him from VA patient care activities.

RESEARCH AND ITS RELATION TO THE QUALITY OF PATIENT CARE

Improved health care was attributed to the ability of the research program to attract and retain high-quality staff interested in pursuing research and education along with the practice of medicine. Such staff were given credit for improving the intellectual atmosphere at the hospital, so that more and better staff chose to work and train there. The importance of research funds for recruiting competent staff was accepted as an article of faith by almost everyone. However, one group wanted specific evidence in support of this use of funds and it was interested in the percentage of research dollars used as a recruitment and retention device. Others rejoined that it would be difficult to determine this fraction because of the many other interrelated factors. For example, VA staff at hospitals strongly affiliated with medical schools can obtain faculty appointments accompanied by considerable salary supplementations; these hospitals are also the ones with

large research programs. Several individuals believed that a research program in a weakly or unaffiliated hospital would not attract the high-caliber clinicians need to upgrade the quality of patient care because of the deficient academic setting. Therefore, some VA hospital staff felt that research dollars invested in an unaffiliated hospital were wasted.

Problems resulting from the presence of biomedical research primarily were attributed to the diversion of patient care resources for research purposes. Several hospital directors and nurses noted that physician involvement in research sometimes occurs at the expense of patient care activities. Nurses themselves often are required to conduct many procedures on research patients in addition to their routine workload, at times to the detriment of these routine activities. For this reason, chiefs of nursing expressed a desire to be included on research committees whenever nursing services would be required in research, so that they could plan their work better or let investigators know when the extra work would be too burdensome.

THE INDIVIDUAL PATIENT

VA hospital staff members and the veterans service organizations' representatives commented that many patients entering VA hospitals with vigorous research programs had fears about being treated like "guinea pigs." Many patients construed routine clinical practice to be research, and the observation was made that, in any case, the line between research and patient care is very fine. Much of patient care could be considered "unstructured" research; as such, it could be argued that treatment should require informed consent as much as structured research. The service organizations felt

that it was as important to inform patients about decisions regarding their medical care as about their participation in research.

Patient participation in what was clearly understood to be structured, approved research was considered acceptable by all the people interviewed as long as appropriate safeguards existed. One person argued, however, that the present distribution of risks and benefits from any biomedical research involving humans is unjust. Members of the lower socioeconomic classes are preferentially conscripted for research and this same group usually has the lowest health status. Referring more specifically to VA patients, he noted that it was possible the patient might be forced to participate in research. The patient seeking VA care usually cannot afford care in the private sector. If offered a research protocol, a patient might feel that he had no choice of an alternative treatment. Others concurred, citing examples of patients who perceived that they had to accept the research protocol or receive no care. Because one informant felt the patient population was a captive one, he emphasized the need for patient advocates in VA hospitals.

It became apparent that no mechanism existed to monitor whether or not research involving patients was being carried out in strict adherence to the protocols approved by the human studies and research committees. Social workers stated that they had never been involved in witnessing the receipt of informed consent. Nurses indicated that usually they were not well enough informed about the purposes and risks of an experiment to know whether patients' rights were being infringed upon or denied.

The representatives of the veterans organizations suggested that the enthusiasm of patient subjects would be increased if the results of their participation were explained to them fully. Chief nurses expressed a similar view for nurses assisting with the protocols.

One hospital director noted that "guinea pigs" fears may be alleviated if the general aims and purposes of research were explained more to the veteran constituency which the VA serves. Finally, one participant commented that it was desirable for scientists to explain research to the general public much more, and scientists themselves need to understand the fears the public harbors because of unfortunate incidents that have occurred.

SUMMARY

All of the groups that testified strongly supported the VA biomedical research program. Some problems were identified, but the consensus was that they were vastly outweighed by the benefits derived. The issues and problems brought to the Committee's attention during these meetings became integral parts of this study.

APPENDIX B

CONSULTANTS TO THE COMMITTEE

John D. Baxter, M.D., University of California at San Francisco, School of Medicine
Gordon L. Brownell, Ph.D., Massachusetts General Hospital
J. Michael Criley, M.D., University of California at Los Angeles, School of Medicine
Lawrence S. Cohen, M.D., Yale University School of Medicine
Darrell D. Fanestil, M.D., University of California at San Diego, School of Medicine
S. Julian Gibbs, D.D.S., Ph.D., Vanderbilt University, School of Medicine
Vay Liang W. Go, M.D., Mayo Medical School
Thomas A. Gonda, M.D., Stanford University School of Medicine
John C. Harvey, M.D., Georgetown University School of Medicine
James W. Kilman, M.D., Ohio State College of Medicine
Joel Kleinman, Ph.D., National Center for Health Statistics, Rockville
Robert Leinbach, M.D., Massachusetts General Hospital
Charles B. Mullins, M.D., University of Texas Health Science Center
Charles E. Poletti, M.D., Massachusetts General Hospital
George A. Porter, M.D., University of Oregon Medical School
Richard E. Rieselbach, M.D., University of Wisconsin Medical School
Morris Schambelan, M.D., San Francisco General Hospital
Lewis M. Schiffer, M.D., Allegheny General Hospital, Pittsburgh
Stuart F. Seides, M.D., Georgetown University School of Medicine
Anthony J. Sliwinski, M.D., Georgetown University School of Medicine
Merton F. Utter, Ph.D., Case Western Reserve University School of Medicine
John H. Vaughan, M.D., Scripps Clinic and Research Foundation
James H. Warram, M.D., Harvard School of Public Health
Benson R. Wilcox, M.D., University of North Carolina School of Medicine
Andrew Winokur, M.D., University of Pennsylvania School of Medicine
Emmanuel Wolinsky, M.D., Metropolitan General Hospital, Cleveland
Samuel A. Wells, M.D., M.D., Duke University Medical Center
John H. Yardley, M.D., Johns Hopkins Hospital

APPENDIX C

CONTRIBUTIONS OF VA RESEARCH PROGRAM TO AMERICA'S HEALTH

(as identified by the VA Central Office)

I. Work Recognized by National Awards	AWARD
1976 Morton I. Grossman, M.D., Ph.D., Senior Medical Investigator, VA Wadsworth Hospital Center, Los Angeles, Calif. For broadening medical understanding of peptic ulcer, pancreatic insufficiency, and gastrointestinal hormones.	Modern Medicine Magazine 1976 Awards for Distinguished Achievement
1975 Paul Heller, M.D., Senior Medical Investigator, Chicago, Ill. (WS) VAH. For his work in immunology, enzymology, and metabolism. He investigated the mechanism of immunologic deficiency in multiple myeloma.	William S. Middleton Award*
1975 William H. Oldendorf, M.D. VAH, Los Angeles, Calif. For his work on computerized tomography, which allows cross-sectional planes of the brain to be photographed.	Albert Lasker Award for Medical Research
1974 Madge Skelly, Ph.D., Chief of Audiology and Speech Pathology, VAH, St. Louis, Mo. For her clinical research in which she innovated and perfected treatments such as compensatory speech for those whose tongues have been excised; gestural language for the speechless, and kinetic communication for the blind patient who is also deaf.	Federal Woman's Award

* Highest nonor given by VA to its research investigators. Awarded yearly since 1960. Group composed of non-VA medical and education specialists makes final recommendation on this award.

1973	Ludwik Gross, M.D., Senior Medical Investigator, and Chief, Cancer Research Unit, VAH, Bronx, N.Y. For his original discovery of leukemia and cancer-inducing viruses in animals.	William S. Middleton Award
1972	Kenneth Sterling, M.D., Chief of the Protein Research Laboratory, VAH, Bronx, N.Y. For his outstanding accomplishments in hematologic and endocrinologic research using the techniques of nuclear medicine.	William S. Middleton Award
1971	Marcus A. Rothschild, M.D., Chief, Nuclear Medicine, VAH, New York, N.Y. For research in liver disease control, mechanisms affecting serum albumin, and the pathophysiologic regulation of liver metabolism.	William S. Middleton Award
1971	Ralph L. Biddy, Chief of Staff, VAH, St. Louis, Mo. For improving and innovating new programs for inpatient treatment in mental health care.	John Shaw Billings Award, Assn. of Military Surgeons of the U.S.
1971	Edward D. Freis, M.D., Senior Medical Investigator, VAH, Washington, D.C. For his research on high blood pressure.	Albert Lasker Award for Medical Research
1970	Andrew V. Schally, Ph.D., Senior Medical Investigator, Chief, Endocrine and Polypeptide Laboratories, VAH, New Orleans, La. For his investigations of the physiology and biochemistry of hypothalamic neuro-hormones.	William S. Middleton Award
1969	Roger H. Unger, M.D., Associate Chief of Staff, VAH, Dallas, Tex. For his conception of the physiology of metabolism of fats and carbohydrates, basic to better therapy for diabetes patients.	William S. Middleton Award

1968	Thomas E. Starzl, M.D., Chief, Surgical Service, VAH, Denver, Colo. For pioneering surgical transplantations of kidneys and livers, and the development of antilymphocyte globulin and other immunosuppressants to suppress the rejection of transplanted organs.	William S. Middleton Award
1967	Leonard T. Skeggs, Ph.D. Biochemist, VAH, Cleveland, Ohio. For automated laboratory test devices and biochemistry of hypertension.	William S. Middleton Award
1966	Leo A. Hollister, M.D. VAH, Palo Alto, Calif. For numerous contributions in the field of therapeutic drugs for mental illness.	William S. Middleton Award
1965	Lucien B. Guze, M.D., and George M. Kalmanson, M.D., VA Center, Los Angeles, Calif. For discerning the host-parasite relationship in chronic, infectious kidney disease.	William S. Middleton Award
1964	Robert O. Becker, M.D., Chief Orthopedic Section, VAH, Syracuse, N.Y., For demonstrating that an electrical control system can be used to stimulate the regeneration of tissue in mammals.	William S. Middleton Award
1963	Stanley Ulick, M.D. VAH, Bronx, N.Y. For his discoveries in the chemistry and metabolism of mineral corticoid hormones.	William S. Middleton Award
1962	Leslie Zieve, M.D., and William C. Vogel, Biochemist, VAH, Minneapolis, Minn. For studies of phospholipids and phospholipases.	William S. Middleton Award

1961	Hubert A. Pipberger, M.D., Chief, VA Research Center for Cardiovascular Data Processing, VAH, Washington, D.C. Pioneer in computer interpretation of electrocardiograms.	William S. Middleton Award
1960	Solomon A. Berson, M.D. (dec.) Chief, Radioisotope Service, and Senior Medical Investigator and Rosalyn Yalow, Ph.D., Chief, Nuclear Medicine Service and Senior Medical Investigator, VAH, Bronx, N.Y. Development of radioimmunoassay technique, an invaluable tool for detecting and measuring tiny amounts of biologic substances, revolutionizing the science of endocrinology.	William S. Middleton Award

II. Other Work of Significance

A. Senior Medical Investigators (not included above)

1) Research on smoking and lung cancer; on emphysema and cardiovascular sequelae found after long-term cigarette smoking in man and after exposure of animals. Oscar Auerbach, M.D., VAH, East Orange, N.J.

2) Research on the nature of the brain-mind adaptation of the individual to drastically altered or stressful environments. The perception and processing of information in man and the psychophysiology of sleep disorders and of sensory and perceptual isolation are two specific studies. Jay Shurley, M.D., VAH, Oklahoma City, Okla.

3) Research on the normal and disordered physiology of the thyroid gland and its hormones. Sidney Ingbar, M.D., VAH, San Francisco, Calif.

B. Cooperative Studies Research

A number of investigators (3-50) in VA Hospitals (2-19) are involved in each study.

1) Establishment of effectiveness of chemotherapy of tuberculosis and of optimal therapeutic regimens.

2) Hypertension - demonstration of the fact that antihypertensive therapy greatly reduces the risk of crippling or fatal strokes in men with diastolic blood pressures of 115-130 mm mercury, and subsequently the demonstration of the efficacy of such treatment for men with diastolics ranging from as low as 90-114 mm mercury.

3) Schizophrenia - establishment of the efficacy of the phenothiazines in the management of schizophrenia and determination of optimal therapeutic regimens.

4) Demonstration of efficacy of nitroprusside treatment in acute myocardial infarction.

5) Pioneering work in cardiac catheterization.

6) Demonstration that X-ray treatment prior to operation for rectal cancer increases a patient's chance of surviving for a longer period of time.

C. Other Biomedical Research

1) Design of the krypton-81m generator with two colleagues from Argonne National Laboratories. This device allows biologic application of the harmless radioisotope in the visualization of blood circulation, replacing the use of the sometimes harmful radio-opaque dyes. Ervin Kaplan, M.D., VAH, Hines, Ill.

2) Development of a new theory of micturition, application of which has led to sphincter relaxation and voiding of the neurogenic bladder. In the past, complications of the neurogenic bladder have caused many deaths among paraplegics. Robert J. Krane, M.D., Carl A. Olsson, M.D., VAH, Boston, Mass.

D. Prosthetics Research

1) Fitting of a bilateral arm amputee with a unique arm and control system developed at Colorado State University. This device permits independent control of three motions (gripping, wrist rotation, and elbow flexion).

2) A prototype electric wheelchair enabling quadriplegics to stand erect and move about in the erect position. Improved models being fabricated for clinical testing.

3) The Mauch hydraulic ankle is ready for limited field testing. Preliminary tests have shown major advantages for ascending and descending hills and ramps, and for walking on rough ground.

E. Health Services Research

1) The completion of a "pre-admission psychiatric assessment unit," which immediately supplies the results of comprehensive psychiatric, psychological, social, and physical screening tests made when the patient applies for care. This complex of information assists the physician in deciding whether to admit the patient.

2) A system for transmitting electroencephalograms by telephone has been found to be effective.

APPENDIX D

STANDARD PROCEDURES AND FORMS USED ON SITE VISITS

I. SAMPLING PROCEDURES FOR SITE VISITS

A. Sampling the VA Institutions

VA institutions were ranked in descending order of funds received from the VA for research.

- Hospitals appearing in the VA Care Committee sample for their cohort study were omitted.
- Outpatient clinics were not included in the ranking. Although it was considered important to look at one of them, for purposes of convenience only the clinic that was geographically closest to a hospital in the sample was visited.
- VA hospitals receiving less than $40,000 in research funds were excluded. Thus 22 hospitals were excluded, but the total of their research funds is less than 1% of the VA's institutional research funds.
- San Francisco (already visited) and San Juan were omitted.

This left 84 institutions, of which 12 were to be visited (a 1 in 7 sample).

The 84 institutions were divided into three equal groups:

- those with large research funds; $2.6 million to about $1 million;
- $1 million to about $300,000; and
- less than $300,000

Each group was then divided into four subgroups based on geographic location. The resulting 12 groups are shown in Table D-1.

In each of the 12 groups, one hospital was picked by the following procedure: The names were written on cards; the cards in the group were shuffled and one picked at random.

Research programs were stratified by size to make sure that the sample would have equal proportions of hospitals with large, medium and small research programs.

Stratification by geographic location was employed to give nationwide spread to the hospitals visited, and for convenience in making the site visits. The stratification allowed higher-, medium-, and lower-funded research programs to be seen in each region, but the stratification was not for the purpose of making comparisons among regions. The geographic regions were not well-defined--boundaries were "adjusted" to allow equal groupings.

Stratification was not done according to affiliation strength because it correlates so highly with research funds.

B. Selecting Investigators within Institutions

1. Cooperative Studies

   All components of cooperative studies appearing in the sample of 12 hospitals were evaluated.

2. Career Development Program (CDP)

   CDP investigators were purposefully picked so that investigators in all levels of the program would be seen by the end of the site visits.

TABLE D-1

VA Hospitals from Which Random Choices for Site Visits Were Drawn

	Large Research Programs	Medium Research Programs	Small Research Programs
	Washington	Syracuse	Brockton
	Boston	Albany	Northport
	West Haven	East Orange	Wilmington
Northeast	Philadelphia	Buffalo	White River Junction
	Bronx	Brooklyn	Togus
	Cleveland	Bedford	Montrose
	Chicago (Westside)	Newington	Bath
	Hines		
	Oklahoma City	Ann Arbor	Danville
	Kansas City	Cincinnati	Dayton
Midwest	St. Louis	Allen Park	Huntington
	Iowa City	Pittsburgh	Clarksburg
	Wood	Louisville	Coatesville
	Nashville	Lexington	Des Moines
		Martinsburg	Oteen
	Miami		
	Houston	Augusta	Jackson
	Birmingham	Richmond	Columbia, S.C.
South	Gainesville	Atlanta	Tuskegee
	Memphis	Tampa	Hampton
	North Little Rock	Charleston	Tuscaloosa
	Dallas	Perry Point	Biloxi
		Baltimore	Lake City
	Los Angeles (Wadsworth)		
	Sepulveda	Albuquerque	Martinez
West	Palo Alto	Tucson	Livermore
	Salt Lake City	Omaha	Temple
	San Diego	Columbia, Mo.	Leavenworth
	Seattle	Chicago (Research)	Topeka
	Denver	Downey	St. Cloud
		Indianapolis	Muskogee

The number of investigators selected to represent each level was proportionate to the total number of investigators in that level.

3. Investigators Receiving Institutional Funds*

It was decided that 40% of the investigators in each institution was the most that could be evaluated. However, if this sample size resulted in less than three investigators from an institution, then three investigators were selected. If a hospital had less than three investigators, all investigators were included in the sample. It should be noted that principal investigators rather than projects were sampled. When investigators had more than one project, their funding reported was the total for all their projects.

Selection of investigators within an institution was carried out by ranking investigators according to the total of their funding over the last three years. The rank was then divided into groups so that when one investigator was chosen from each group (by shuffling and randomly picking cards), a 40% sample resulted. Where selected investigators could not be present for the site visit, another investigator was selected from within the same group.

The sample guarantees that lower and higher financed projects were included in each hospital and throughout the system.

---

* All CDP investigators were left out of this group although they might be receiving institutional funds.

II. CHECKLIST OF ISSUES TO BE COVERED ON THE SITE VISIT

A. Issues to be Discussed with Administrative Staff and Individual Investigators

Information should be gathered from as many sources as possible; in some cases, it will be more suitable for individual members of the team to explore issues in depth on a one-to-one basis.

1. Role of research in the VA, especially in that institution
   a. As it affects the scientific milieu
   b. As it affects affiliation arrangement
   c. As it affects the availability of sophisticated diagnostic and therapeutic procedures
2. Handling of fund allocation
   a. Is there a policy of holding back money to give to new or younger investigators?
   b. Is there any policy regarding the number of projects sent in for merit review?
   c. Are investigators given what has been recommended in the merit review?
   d. Are investigators encouraged to seek money from outside agencies?
3. Effects of local policies on the quality of the research program
   a. How adequate is the local peer review?
   b. What are the views of administrative staff and individual investigators about Central Office policies and management?

c. How is the allocation of space handled and is the space for research adequate?

d. Is relevance to the VA mission stressed in the research program and if so, how?

e. What are the affiliation agreements and what impact do they have on the research program?

f. What impact does research have on patient care facilities?

g. What impact does research have on staff time? Are there any policies to allow time for investigators to carry out research?

h. What are the activities of the human studies committees? What are their attitudes toward discharging their responsibilities?

B. Evaluation of the Research

1. For each individual investigator evaluated, information should be gathered on

a. The importance of the research problem and the information sought

b. The adequacy of the experimental design

c. The feasibility and suitability of the methods used

d. Originality

e. Training, experience and other characteristics that determine how well the investigator can carry out the project

f. The adequacy of the facilities and other resources (e.g., co-workers) that aid the investigator in carrying out the project

g. The adequacy of the budget

h. The presence of proper safeguards if human subjects are being used

i. The compliance with acceptable ethical standards if animals are

being used in the project

The above information should be used to give a 1-5 rating to the investigators' work (since one investigator may be involved in several projects, he should be given one overall rating for all his work).

2. Other products of research

Information should be sought from the investigator himself and the administrative staff of the hospital on the following issues:

a. Does the investigator have influence on other people; e.g., residents and if so, does his research contribute to this influence? That is, is his research helping to set up a scientific milieu in the hospital?

b. Whatever the scientific quality of the work, is research of importance to the investigator? Is it at least helping him to keep abreast of the literature and to be open to scientific innovation?

c. How important was research in recruiting the investigator to the VA?

3. Evaluation of career development program (CDP)

In addition to assessing the scientific merit of CDP investigators' projects, the team should explore views about the CDP with administrative staff and investigators in the program.

4. Evaluation of the cooperative studies program (CSP)

a. Evaluate the scientific quality of the cooperative studies as seen in this particular hospital

b. Question investigators participating in cooperative studies about their participation

(1) Are they happy with the way it is being managed?

(2) What personal rewards do they find in being involved in a cooperative study?

(3) What reasons would they give for not participating again?

5. Tour of the facilities

a. Is space for research suitable for the hospital's programs?

b. Are common resources adequate and well managed?

III. AGENDA FOR SITE VISITS

Evening Before Visit:	Site team meets at hotel to finalize agenda and orient *ad hoc* team members
First Day	
8:30-8:45 AM	Introductory Remarks Site Team Chairman Hospital Director (All hospital staff to be interviewed during the site visit are encouraged to attend; the Committee's study and purpose of visit are described)
8:45-9:45 AM	Discussion with Chief of Staff Chief of Medicine Chief of Surgery Chief of Psychiatry
9:45-10:30 AM	Discussion with Chairman of Research Committee Associate Chief of Staff for Research
10:30-11:30 AM	Discussion with medical school representatives including Chairmen of Departments of Medicine, Surgery, and Psychiatry and/or Dean's Representative to Research Committee

11:30-12:30 PM	Lunch - Site team only
12:30-1:30 PM	Tour of research laboratories and facilities

In the afternoon the site team divides into two groups, as described below.

Group A continues interviews as follows:

1:30-2:30 PM	Discussion with Chiefs of Service with which research interacts, including Nursing, Radiology, Clinical Laboratory, Social Work, Engineering, and Supply Services
2:30-3:30 PM	Discussion with members of Human Studies Committee In some institutions one site team member meets with representatives of veterans service organizations

Group B begins interviews and evaluations of individual investigators as follows:

a. Each interview is scheduled for 45 minutes

b. Usually two site team members with the appropriate scientific expertise interview each investigator

c. 40% of investigators receiving institutional funds are interviewed.

In addition, CDP investigators and all principal investigators involved in cooperative studies in that hospital are interviewed.

End of First Day

Site team meets together. Opportunity for further discussion with any of hospital staff.

Second Day

In hospitals with large research programs, project evaluations continue. Final executive session of the site team at the end of the day.

Evening of Final Day

Team meets together to prepare report.

IV. COVER LETTER AND QUESTIONNAIRE MAILED TO INVESTIGATORS

NATIONAL RESEARCH COUNCIL
ASSEMBLY OF LIFE SCIENCES

2101 Constitution Avenue Washington, D. C. 20418

DIVISION OF MEDICAL SCIENCES
COMMITTEE ON BIOMEDICAL RESEARCH
IN THE VETERANS ADMINISTRATION

MEMORANDUM

TO: Research Investigators

FROM: Leighton E. Cluff, M.D., Chairman, Committee on Biomedical Research in the Veterans Administration

SUBJECT: Questionnaire to Research Investigators

As you know by now, your project has been selected at random for review when the National Academy of Sciences Committee on Biomedical Research in the VA, visits the VA Hospital. In addition to discussing your scientific endeavors, the site team members are interested in your views and perspectives on the VA's research program. To make your discussion with the site team more interesting and useful, we would appreciate your spending a few minutes filling out the attached questionnaire. The information you provide here and in your discussion with the site team will be kept confidential. Please feel free to make any additional comments in answer to the questions in the attached document.

As the site visit will take place in , we should be grateful if you would send your replies to us as soon as possible to give us time to mail them out to the appropriate site team members. The questionnaire should be sent to:

Committee on Biomedical Research in the
Veterans Administration
National Academy of Sciences
2101 Constitution Avenue
Washington, D.C. 20418

We hope that you will be as open and informative as possible, as these views and perspectives will be used by the Committee in making recommendations to the VA about policy issues affecting the overall research program.

NAME: _____

QUESTIONNAIRE TO RESEARCH INVESTIGATORS

1. What funds (in dollars) do you have available to support your research? (Please fill in the following table.)

Source	FY 1975	FY 1976
VA		
NIH		
Other agency (specify)		

2. If you are not receiving outside funds now, have you ever sought outside funds while in the VA?

/__/ YES /__/ NO

(a) When _____

(b) From which agency _____

(c) What was the result _____

_____

3. How many people are associated with your research program? (Please fill in the following table.)

	Collaborating With You	Supported by Your Research Funds
M.D.'s (Medical School)		
M.D.'s (VA Staff)		
Ph.D.'s (Medical School)		
Ph.D.'s (VA Staff)		
Technicians		
Others		

4. What percentage of your time is salaried by the VA? _____

5. What percentage of your time (per week) is devoted to:

   (a) Patient Care _____

   (b) Research _____

   (c) Student and house staff teaching _____

   (d) Administrative matters _____

   (e) Other _____

6. If you have clinical duties, would you like to see a formal policy instituted allowing a specified amount of time for research?

   /__/ YES /__/ NO

7. If you have an academic appointment, what are your academic responsibilities and how many hours per week do you spend on them?

_____

_____

_____

8. What bearing, if any, do your research activities have on your academic appointment?

Makes it possible.

Will help secure promotion.

None

Other: _____

9. What factors influenced your decision to seek employment in the VA system?

_____

_____

_____

10. As compared to other positions you have been in, to what extent does your present situation allow you the opportunity you need to pursue your research efforts effectively?

/___/ VERY WELL /___/ SATISFACTORILY /___/ SOME PROBLEMS

/___/ TOTALLY UNSATISFACTORY

11. If you are not satisfied with your present research situation, what are the reasons?

_____

_____

12. Have you seriously considered leaving the VA in the last three years?

/__/ YES /__/ NO

13. Do you expect to be in the VA three years from now?

/__/ YES /__/ NO

14. If you have considered leaving or anticipate leaving, what opportunities or conditions elsewhere have encouraged you to leave?

_____

_____

_____

15. Assuming that geographic, personal, and other such factors were not involved, would you prefer to pursue your research at:

(a) An institution like NIH /__/

(b) A medical school department /__/

(c) A VA Hospital /__/

(d) Other (specify) _____

16. At present, projects greater than $25,000 are merit-reviewed centrally. Do you think:

(a) All or more proposals should be centrally merit-reviewed /__/

(b) This is an appropriate size of project for central review /__/

(c) Only very large projects (> $100,000) should be centrally reviewed /__/

(d) No projects should be centrally reviewed, they can all be reviewed locally /__/

(check one of the above)

17. Even after merit review, each hospital has considerable flexibility in allocating funds. Please check one of the following:

    (a) This is an appropriate amount of flexibility /__/

    (b) The hospital should have complete flexibility /__/

    (c) The hospital should have to allocate funds as recommended by the merit review /__/

18. Are you satisfied with your local Research Committee at this time?

    /__/ YES /__/ NO

    If you answered "NO" please give your reasons:

    _____

    _____

19. Should investigators seek funds outside of the VA?

    /__/ YES /__/ NO

20. In what way do you see your research efforts as a contribution to the VA mission?

    _____

    _____

21. In its allocation of research funds, should Central Office place more or less emphasis on relevance to the VA mission?

    /__/ MORE /__/ LESS /__/ ABOUT RIGHT

22. Would the VA interest in high-quality research be best served if research were pursued on a full-time basis by those best qualified?

    /__/ YES /__/ NO

23. Would the patient care mission be best served if clinical care were provided on a full-time basis by those best qualified? /__/ YES /__/ NO

APPENDIX E

ADDENDA TO THE STUDY OF PATIENT INVOLVEMENT IN RESEARCH

I. PATIENT QUESTIONNAIRE

OMB No.: 130-S-75011
Approval Expires: July, 1976

STUDY OF PATIENT INVOLVEMENT IN RESEARCH IN VA HOSPITALS
BUREAU OF SOCIAL SCIENCE RESEARCH, INC.
WASHINGTON, D.C. 20036

BSSR Serial No. _____

INTRODUCTION

Hello, I'm _____ from the Bureau of Social Science Research in Washington, D.C. We have been asked by the National Academy of Sciences to interview patients at several hospitals across the country to try to find out more about the various kinds of medical treatment they are receiving. Your name was given to us as someone who is receiving treatment here at _____, and I would like to ask you some questions about that,
(NAME OF HOSPITAL)
if it is all right with you. These questions will not take more than half an hour of your time, and you are free to refuse to answer any that you object to or to drop out once you begin. No one here at the hospital will know what you tell me. Everything you tell me will be confidential, and your name will never be connected with any of the answers you give. If you prefer not to answer, it will not affect your medical care in any way. (IF PATIENT AGREES). I would like to ask you to sign here showing you are willing. The Bureau of Social Science Research requires that I sign my own name at the end of the interview to certify that I will protect all the information.

Patient's Signature: _____

RECORD OF QUALITY CHECKS

Checked by: _____ Date: _____

Checked by: _____ Date: _____ _____

Time at start of interview: _____AM

_____PM

1. Some patients in this hospital (coming to this clinic) are taking part in a medical research study. Are you taking part in a research study?

Yes 0

No (SKIP TO Q. 58) 1

2. How long have you been taking part in this study?

_____ weeks

OR _____ months

3. Who is in charge of the research study?

Knows research doctor's name 0

Appears to know doctor, but not name . . 1

Don't know, Can't recall 2

4. And what is the purpose of the research study as you understand it. That is, why are the doctors doing this study? (PROBE: Is there anything else you can tell me about the study?)

5. And what is your part in the study? What is it that you have to do?

6. Why was it that you decided to take part in the study? (PROBES: What reasons did you give yourself? What things did you think about when you said you would take part?)

7. Now I'm going to read you a list of reasons other people have given for taking part in a medical research project like this. Would you please tell me, for each one, whether it was one of the reasons why you decided to take part in the study.

	Was NOT a reason	Was a reason	Don't recall
a. This was how my doctor wanted it.	0	1	2
b. I had heard about this procedure or treatment and wanted it.	0	1	2
c. It was going to help me feel better or get well sooner.	0	1	2
d. The study is of benefit to medical science and to other patients.	0	1	2
e. I thought I would get better care than I would get otherwise.	0	1	2
f. I had heard about the doctor who's running the study and wanted him for my doctor.	0	1	2
g. Being in the study helps me financially.*			
h. Other people felt I should take part.	0	1	2

IF OTHER PEOPLE FELT I SHOULD TAKE PART:

h-1. What other people do you mean?

_____

i. (ASK ONLY OF INPATIENTS) Being in the study meant I got care in the hospital for a longer time.	0	1	2

---

* IF BEING IN STUDY HELPS FINANCIALLY:
g-1. You mentioned just now that being in the study helps you financially. How is that?

8. Now I would like to talk to you about the time you first were asked to take part in this research study. Who was it that asked you to participate?

Dr. _____ 0
(STUDY DIRECTOR)

Another doctor _____ 1
(NAME, IF PATIENT KNOWS)

A nurse (SKIP TO Q. 10) 2

Some other person (SPECIFY BY ROLE, e.g., HOSPITAL ADMINISTRATOR, ETC. AND THEN SKIP TO Q. 10)

_____ 3

INTERVIEWER: ENTER NAME OF PERSON WHO ASKED PATIENT TO TAKE PART, IN ITEM #4, TAB

9. Is Dr. _____ your own regular doctor?
(ANY DOCTOR NAMED IN Q. 8)

Yes 0

No 1

10. Before your participation in the study began, did someone explain the study to you and tell you what was going to be done?

Yes 0

No (SKIP TO Q. 14) 1

Don't recall (SKIP TO Q. 14) . . 2

IF YES:

11. Who was it that explained the study to you and told you what would be done? (IDENTIFY BY NAME, IF PATIENT KNOWS, AND ROLE)

_____

INTERVIEWER: ENTER NAME OF PERSON WHO EXPLAINED STUDY TO PATIENT, IN ITEM #5, TAB

12. Did any other person on the hospital staff come along with the person who explained the study to you, or was he/she alone?

Another person along 0

Person alone (SKIP TO Q. 14) 1

Don't recall (SKIP TO Q. 14) 2

13. Who was it that came along? (IDENTIFY BY ROLE) _____

_____

14. Before your participation in the study began, did someone read a description of the study to you?

Yes 0

No. 1

Don't recall. . . . 2

15. Before your participation began, were you given a description of the study to read yourself?

Yes 0

No. 1

Don't recall. . . . 2

16. To the best of your recollection, did you sign a form that described the research and gave them permission to involve you in it?

Yes 0

No (SKIP TO Q. 21). 1

Don't recall (SKIP TO Q. 21). . 2

IF YES:

17. Who asked you to sign the form? (IDENTIFY BY NAME, IF PATIENT KNOWS, AND BY ROLE)

_____

18. Was any other person on the hospital staff along with him/her when he/she asked you to sign the form?

Yes 0

No (SKIP TO Q. 20) 1

Don't recall (SKIP TO Q. 20) . . 2

IF YES:

19. Who was it that came along when they asked you to sign the form? (IDENTIFY BY ROLE)

_____

20. Were you given a copy of the form to keep for yourself?

Yes 0

No. 1

Don't recall. . . . 2

21. When you were asked to take part in the study, did you feel you had had enough time to think about it, or would you have liked to have some more time?

Had enough time 0

Would have liked more time. . . . 1

Don't recall. 2

22. Besides the people we have already mentioned, did you talk to anyone else--such as another patient, some other doctor, a nurse, someone in your family, or someone else--before you decided to take part?

Yes 0

No (SKIP TO Q. 24) 1

Don't recall (SKIP TO Q. 24) . . . 2

IF YES:

23. Who was it you talked to before you decided to take part?

_____

24. Was there anyone else you would have liked to have talked to before you decided to take part in the study?

Yes 0

No (SKIP TO Q. 26). 1

Don't recall (SKIP TO Q. 26). . . . 2

IF YES:

25. Who would you have liked to have talked to before you decided?

---

26. At the time you made your decision to take part in the study, did you think you had enough information then to decide or would you have liked to have had more information?

Had enough information (SKIP TO Q. 28) . . . 0

Wanted more information 1

Don't recall (SKIP TO Q. 28). 2

IF WANTED MORE INFORMATION:

27. What would you have liked to know more about? (PROBE: Anything else?)

---

28. At the time you were making up your mind about taking part in the study, did anyone ever urge or encourage you to participate?

Yes 0

No (SKIP TO Q. 30). 1

Don't recall (SKIP TO Q. 30). . . . 2

IF YES:

29. Who was that? Another patient, the doctor in charge of the study, some other doctor, a nurse, someone in your family, or someone else? (CIRCLE ALL THAT APPLY)

Another patient	1
Study doctor.	1
Another doctor.	1
Nurse	1
Family member	1
Someone else (SPECIFY).	
_____	1

30. If you had decided that you did <u>not</u> want to be in the study, what would have happened? Would you have been taken care of at this hospital anyway, or would you have had to go somewhere else?

Remain patient at this hospital . .	0
Go somewhere else.	1
Don't know	2

31. If you had decided <u>not</u> to take part, do you think the care you would have gotten would be as good as the care you are getting now, or do you think it would not have been as good?

As good as the care getting now . .	0
Not as good care	1
Don't know	2

32. At the time you were asked to take part in the study, did you believe it was purely voluntary, that is did you feel free to say no?

Did not feel free to say no. 0

Felt free to say no (SKIP TO Q. 34). . 1

Don't recall (SKIP TO Q. 34) 2

IF DID NOT FEEL FREE TO SAY NO:

33. Why was that?

34. When you talked with _____ that time about joining
(NAME FROM ITEM #4 ON TAB)
the study, or when the study was explained to you was it your understanding that you could drop out of the research study at any time, even if you had already agreed to take part?

No, <u>was not</u> my understanding 0

Yes, <u>was</u> my understanding. 1

Don't recall 2

35. Does this study involve some of the patients getting one kind of treatment and some another. That is, is there anything about the treatment or procedures they are using for you that might be different for some of the other patients in the study?

Yes 0

No (SKIP TO Q. 39). 1

Don't know (SKIP TO Q. 39). 2

IF YES:

36. What would be different?

37. When you were first asked to take part in the study, or when it was explained to you do you remember talking about how they would decide who gets which treatment?

Yes, do remember 0

No, don't remember (SKIP TO Q. 39) . 1

IF YES, REMEMBERS:

38. How would they decide who gets which treatment?

39. Now I would like to ask you some specific things you may have talked about with _____ at the time when he/she asked you
(NAME FROM ITEM #4 ON TAB)
to take part in the study. Did you talk about what they would be doing in the study--what kinds of procedures or treatment they would use?

Yes 0

No. 1

Don't recall. 2

40. What sorts of treatment or procedures are they using for you? As I mention each kind of treatment or procedure, would you tell me whether or not it is included for you. (CIRCLE ALL THAT APPLY)

Surgery 1

X-ray or radiation therapy for your illness 1

Special medicines or drugs 1

Tests to find out more about your illness, such as X-rays blood samples, biopsies (that is, tissue samples) measurements with machines (like measuring your heart rate with an EKG machine), catheterization, or any kind of test to find out more about what you have 1

IF TESTS:

41. What tests are those?

42. Is there any other kind of treatment or procedures that you are having that I haven't mentioned?

Yes 0

No (SKIP TO Q. 44) 1

IF YES:

43. What is that?

44. When you were asked to take part in the study, was it your understanding that any of the treatment you would be having would make you feel better, for instance, take away pain?

Yes 0

No (SKIP TO Q. 47). 1

Don't recall (SKIP TO Q. 47). 2

IF YES:

45. What part of the treatment was it that would make you feel better?

46. What has been your experience so far? Have the results of the _____ _____ been the same as you expected, better
(PATIENT'S WORDS FROM Q. 45)
than you expected, or not as good as you expected?

Same as expected 0

Better than expected 1

Not as good as expected 2

47. When you were asked to take part in the study, was it your understanding that any of the treatment you would be having would be painful or unpleasant?

Yes 0

No (SKIP TO Q. 49). 1

Don't recall (SKIP TO Q. 49). . 2

IF YES:

48. What part of your treatment did you understand would be painful or unpleasant?

49. How would you describe your actual treatment so far? Has it been not at all painful or unpleasant, a little bit painful or unpleasant, or quite painful or unpleasant?

Not at all (SKIP TO Q. 52). . . . 0

A little bit 1

Quite 2

IF A LITTLE BIT OR QUITE PAINFUL OR UNPLEASANT:

50. What part of your treatment so far has been painful or unpleasant?

51. Is the pain or unpleasantness about what you expected at the time you were asked to take part in the study, or is it not as bad as you expected, or is it worse than you expected?

About what was expected 0

Not as bad as expected 1

Worse than expected 2

52. Sometimes certain treatments or procedures have side effects. Back when you were talking to _____ about taking part in the
(NAME FROM ITEM #4 ON TAB)
study, or when it was explained to you was it your understanding that any of the things they would be using for you would have any side effects? That is, would there be no side effects from your treatment, or might there be slight side effects, or might there be moderate or more serious side effects?

No side effects (SKIP TO Q. 54) . . . 0

Slight side effects . . . . . .

Moderate or more serious side effects. 2

Don't recall (SKIP TO Q. 54) 3

IF SIDE EFFECTS:

53. What side effects did you understand these might be?

54. Have you experienced any side effects?

Yes 0

No (SKIP TO Q. 56) . . 1

55. Is that what you expected, or are the side effects less than you expected, or are they more than you expected?

What expected 0

Less than expected. 1

More than expected 2

56. Some treatment or procedures have possible risks of complications of some kind. Was it your understanding that any of the things you said they are using for you might have any risks of complications? That is did you understand that there would be no known risk, that there might be slight risk, or that there could be some more serious risks?

No known risks (SKIP TO Q. 82) . . . 0

Might be slight risks 1

Could be more serious risks 2

Con't recall, don't know (SKIP TO Q. 82) 3

IF RISKS:

57. What risks did you understand there would be?

INTERVIEWER: NOW SKIP TO QUESTION 82

FOR PATIENTS NOT AWARE OF BEING IN A RESEARCH STUDY

58. Would you please tell me, then, who is the doctor in charge of your treatment?

---

59. Before you started having the treatment you are having now, did someone explain the kind of treatment to you?

Yes 0

No (SKIP TO Q. 63) 1

Don't recall (SKIP TO Q. 63) . 2

IF YES:

60. Who was it that explained it to you? (IDENTIFY BY NAME, IF PATIENT KNOWS, AND BY ROLE, IF POSSIBLE)

_____

61. At the time your treatment was explained to you, did you feel you got to know enough about it then, or would you have liked to know more?

Knew enough (SKIP TO Q. 63) 0

Would like to have known more . . . 1

Don't recall (SKIP TO Q. 63) . . . 2

IF WOULD LIKE TO HAVE KNOWN MORE:

62. What sorts of things would you have liked to know more about then? (PROBE: Anything else?)

63. Before you started having the treatment you are having now, did you sign a form that gave your permission to have this kind of treatment?

Yes 0

No. 1

Don't recall. 2

64. What sort of treatment or procedures are they using for you? As I mention each kind of treatment or procedure, would you tell me whether or not it is being used for you? (CIRCLE ALL THAT APPLY)

Surgery (SKIP TO Q. 66) 1

X-ray or radiation therapy for your illness (SKIP TO Q. 66) . 1

Special medicines or drugs (SKIP TO Q. 66). 1

Test to find out more about your illness such as X-rays, blood samples, biopsies (that is, tissue samples), measurements with machines (like measuring your heart rate with an EKG machine), catheterization, or any kind of test to find out more about what you have 1

IF TESTS:

65. What test are those?

66. Is there any other kind of treatment or procedures that you are having that I haven't mentioned?

Yes 0

No (SKIP TO Q. 68). . . 1

IF YES:

67. What is that?

68. Before you started these treatments was it your understanding that any of the treatments you would be having would make you feel better, for instance, take away pain?

Yes 0

No (SKIP TO Q. 71). 1

Don't recall (SKIP TO Q. 71). . 2

IF YES:

69. What part of the treatment was it that would make you feel better?

70. What has been your experience so far? Have the results of the _____ _____ been the same as you expected, better than you expected, or not as good as you expected?
(PATIENT'S WORDS FROM Q. 69)

Same as expected 0

Better than expected 1

Not as good as expected 2

Don't know, didn't expect 3

71. Before you started your treatment, was it your understanding that any of the treatment you would be having would be painful or unpleasant?

Yes 0

No (SKIP TO Q. 73) 1

Don't recall (SKIP TO Q. 73) . . 2

IF YES:

72. What part of your treatment did you understand would be painful or unpleasant?

73. How would you describe your actual treatment so far? Has it been <u>not at all</u> painful or unpleasant, <u>a little bit</u> painful or unpleasant, or <u>quite</u> painful or unpleasant?

Not at all (SKIP TO Q. 76) . . . 0

A little bit 1

Quite 2

IF A LITTLE BIT OR QUITE PAINFUL OR UNPLEASANT:

74. What part of the treatment so far has been painful or unpleasant?

75. Is the pain or unpleasantness <u>about what you expected</u> before you started the treatment, or is it <u>not as bad as you expected</u>, or is it <u>worse than you expected</u>?

About what was expected 0

Not as bad as expected 1

Worse than expected 2

Don't know, didn't expect 3

76. Sometimes certain treatments or procedures have side effects. Before you started the treatment you are having now was it your understanding that any of the things they would be using for you would have any side effects? That is, would there be no side effects, from your treatment, or might there be slight side effects, or might there be moderate or more serious side effects?

No side effects (SKIP TO Q. 78) 0

Slight side effects 1

Moderate or more serious side effects . . 2

Don't know, don't recall (SKIP TO Q. 78). 3

IF SIDE EFFECTS:

77. What side effects did you understand there might be?

78. Have you experienced any side effects?

Yes 0

No (SKIP TO Q. 80). 1

79. Is that what you expected, or are the side effects less than you expected, or are they more than you expected?

What expected 0

Less than expected. 1

More than expected 2

Don't know, didn't expect 3

80. Some treatment or procedures have possible risks of complications of some kind. Was it your understanding that any of the things you said they are using for you might have any risks of complications? That is, did you understand that there would be no known risks, that there might be slight risks, or that there could be some more serious risks?

No known risks (SKIP TO Q. 82) 0

Might be slight risks 1

Could be more serious risks. 2

Don't know, don't recall (SKIP TO Q. 82) 3

IF RISKS:

81. What risks did you understand these would be?

FOR ALL PATIENTS

82. On the whole, would you say the information you got before you started your treatment prepared you very well, fairly well, not very well, or not well at all for the experience?

Very well 0

Fairly well 1

Not very well 2

Not well at all 3

83. Now, a couple of questions about how it's going for you. Are you getting as much information now as you would like about your medical progress?

Yes, getting enough 0

No, not getting enough. 1

Can't say 2

84. Is there anyone else here at the hospital besides the doctors and the nurses to whom you can go to talk about your medical care?

Yes 0

No (SKIP TO Q. 86). 1

Don't know (SKIP TO Q. 86). . 2

IF YES:

85. Who is that (PROBE: What is his/her title?)

_____

ASK QUESTION 86A OF PATIENTS WHO ARE AWARE OF BEING IN A RESEARCH STUDY. ASK QUESTION 86B OF PATIENTS NOT AWARE OF BEING IN RESEARCH.

86A All-in-all, how willing would you be to take part in a research study again? Would you say you would be very willing, somewhat willing, not very willing, or not willing at all?

Very willing 0

Somewhat willing 1

Not very willing 2

Not willing at all 3

Don't know 4

86B At the beginning of this interview you said you were not involved in a research study. Would you be willing to take part in a medical research study?

Yes 0

No. 1

Don't know 2

87. Now I need to ask you just a few more questions for our tabulation purposes, and then we'll be through.

How old were you on your last birthday? _____

88. What was the last grade of regular school you completed, not counting specialized schools like trade or business schools? (CIRCLE APPROPRIATE NUMBER)

Elementary	High School	College
0 1 2 3 4 5 6 7 8	9 10 11 12	13 14 15 16 17 +

89. FOR INPATIENTS: What was the last kind of work you did before you were hospitalized? (IF MILITARY: What was your military specialty?) (IF RETIRED: What was your last occupation before you retired?)

_____

_____

FOR OUTPATIENTS: What kind of work do you do? (IF MILITARY: What was your military specialty?) (IF RETIRED: What was your last occupation before you retired?) (IF UNEMPLOYED: What did you do before you became unemployed?)

_____

_____

90. In which of these general groups did your total family income fall last year, before deductions and from all sources? (HAND RESPONDENT CARD) Just read me the letter.

a. Below $5,000 0

b. $5,000-7,999 1

c. $8,000-9,999 2

d. $10,000-14,999 3

e. $15,000-19,999 4

f. $20,000-24,999 5

g. $25,000-or more 6

h. Don't know 7

i. Refused. 8

91. Just one last question. Did anyone tell you that we would be asking you these questions?

Yes 0

No 1

Don't recall. 2

THAT IS THE END OF THE INTERVIEW. THANK YOU VERY MUCH.

****

INTERVIEWER: CODE, DO NOT ASK.

92. Respondent ethnicity. (CODE ONE ONLY)

Hispanic 0

White. 1

Black 2

Other. 3

Time of completion: _____AM

_____PM

I affirm this to be a true and faithful record of the interview conducted with the respondent who was selected according to this study's specifications; that I will divulge no information from this interview to any one other than authorized BSSR employees; that I have followed the "interviewer instructions" for this study and the principles of BSSR's Policy for the Protection of Human Subjects.

_____

INTERVIEWER'S SIGNATURE

WORKSHEET

1. Hospital _____

2. Research Director's Name _____

3. Patient is:

   Inpatient 0

   Outpatient 1

4. Person who first asked R. to take part in study (Q. 8) _____

   _____

5. Person who explained study (Q. 11) _____

6. (Approximate) date patient signed consent form _____

II. LETTER AND QUESTIONNAIRE MAILED TO INVESTIGATORS

NATIONAL RESEARCH COUNCIL
ASSEMBLY OF LIFE SCIENCES
2101 Constitution Avenue Washington D C 20418

DIVISION OF MEDICAL SCIENCES
COMMITTEE ON BIOMEDICAL RESEARCH
IN THE VETERANS ADMINISTRATION

Dear Dr. _____:

I am writing in regard to the National Academy of Sciences study on "Patient Involvement in Research in Veterans Administration Hospitals," a part of our over-all study on "Biomedical Research in the Veterans Administration." This study was requested by and is being supported by the Veterans Administration.

First, let me thank you on behalf of the National Academy Committee on Biomedical Research in the Veterans Administration, the National Academy staff, and the Bureau of Social Science Research, our subcontractor for this study, for your considerable help so far. Without the willing cooperation of the research investigators, our study would not have been possible.

Given the importance of biomedical research and its continued public support as an essential element in the provision of quality medical care and given the current national concern in regard to the question of human experimentation, our Committee deemed it essential to address the question of patient involvement in research. As one of the first attempts to look at how patients actually perceive their participation in research, this study should be useful in providing some data where there has been little before. We are also interested in the opinions of investigators themselves on this subject.

We would therefore now like to make one further request of you--that you fill out the enclosed questionnaire and return it in the stamped, self-addressed envelope, also enclosed, to the Bureau of Social Science Research. Questions are included in regard to the procedure of obtaining informed consent, your views on these procedures, and your views on the process of review by the Human Use Subcommittee. The results of our data analysis will be generalized; your answers will be entirely confidential; and our report will not connect any of the data collected with a particular investigator, project, or

hospital.

We are asking that you answer questions in regard to only one of your studies, the title of which is inserted on the face sheet. As soon as your reply is recorded by the BSSR, the face sheet will be removed and destroyed.

We would appreciate your returning the questionnaire within 8 days of receipt.

Again, with thanks for your cooperation.

Sincerely yours,

Leighton E. Cluff, M.D.
Chairman

Enclosure

E-26

March 1976

STUDY OF PATIENT INVOLVEMENT IN RESEARCH IN VA HOSPITALS
BUREAU OF SOCIAL SCIENCE RESEARCH, INC.
WASHINGTON, D.C. 20036

INVESTIGATOR QUESTIONNAIRE

This questionnaire is designed to obtain information about Investigator participation in the Informed Consent Process.

As indicated in the enclosed letter, all information you furnish will be held in strict confidence and will be reported in statistical aggregates or in general statements only.

Filling out the questionnaire will take less than thirty minutes of your time. Most questions can be answered by circling the appropriate code number. In some instances you will be asked to supply a brief written response.

Please feel free to make comments relating to the scope of the questionnaire, the patient consent process and to the Human Use Subcommittee procedures which are not herein addressed.

Thank you for your time and consideration.

BSSR: 473-02

I.D.# _____

OBTAINING PATIENT PARTICIPATION

1. First of all, assuming the consent process has three parts, WHO is responsible in this project for each part?
(PLEASE CIRCLE ALL THAT APPLY.)

Person Responsible	Three Parts of the Consent Process: Asking the Patient to Participate	Explaining Study to Patient	Obtaining Patient's Signature
Yourself	1	1	1
Co-investigator(s)	1	1	1
Physician responsible for patient, other than co-investigator	1	1	1
Resident in charge of patient	1	1	1
Other (PLEASE SPECIFY)	1	1	1

2. If you yourself explain the study to patients, approximately how much time do you spend with the average patient?
(CIRCLE CORRECT CODE)

15 minutes or less . . 0

16 - 30 minutes. . . . 1

Over 30 minutes. . . . 2

3. If some parts of the consent procedure, or the consent procedure for some of the patients is handled by someone other than yourself, why do you delegate this task?

Does not apply, I handle it myself . . . 0

Does apply, for the following reasons. . 1

_____

_____

4. About how many patients altogether have been asked to take part in this project?

Number asked _____

5. How many of these patients have refused to participate? (IF NONE, INDICATE WITH '0' AND SKIP TO QUESTION 6.)

Number refused _____

5A. For what reasons have these patients refused to participate in this project?

_____

_____

_____

6. How many patients have dropped out of this project? (IF NONE, NOTE '0' AND SKIP TO QUESTION 7.)

Number dropped out _____

6A. For what reasons have these patients dropped out of this project?

_____

_____

_____

THE CONSENT PROCEDURE

IN ANSWERING THE FOLLOWING QUESTIONS, PLEASE DESCRIBE PROCEDURE CURRENTLY USED (OR PROCEDURE WHICH WAS USED WITH PATIENT MOST RECENTLY ADMITTED TO STUDY).

7. Is there a written description of the research included in or with the consent form? (PLEASE CIRCLE THE CORRECT CODE NUMBER.)

Yes . . . 0

No. . . . 1

8. When the study is explained to the patient, please indicate, for each of the following, whether or not it is used.
(CIRCLE ONE CODE NUMBER FOR EACH STATEMENT.)

	Used	Not Used
A. The patient is given a written description of the research to read	0	1
B. A written description of the research is read to the patient.	0	1
C. The research is described orally to the patient.	0	1

9. Which technique, or which combination of techniques, do you believe is the most effective in making patients understand BOTH the potential benefits and risks of their participation in the research?

_____

_____

_____

_____

10. Is the patient given a copy of the written description to keep?

Yes 0

No. 1

Not applicable (there is no written description) . . 2

11. If you explain the study orally, what are the most important points that you tell the patient about the project?

_____

_____

_____

_____

_____

12. Do you consider any of the requirements (HEW/VA) for obtaining informed consent inappropriate or unnecessary in obtaining consent from patients in this project? (That is, what is told to the patient and how.)

Yes 0

No (SKIP TO Q. 14). . . 1

13. Can you explain what kinds of things are inappropriate or unnecessary and why? (PLEASE USE LAST SHEET IF MORE SPACE IS REQUIRED.)

_____

_____

_____

_____

14. Does the DESIGN of this study entail the withholding from subjects of information about the following:
(PLEASE CIRCLE ONE CODE FOR EACH ITEM.)

		Yes	No
A.	Purpose of the study	0	1
B.	Purpose of specific procedures	0	1
C.	Recording or filming	0	1
D.	Risks or discomforts	0	1
E.	Benefits or absence of benefits	0	1
F.	Which treatment or medication the individual patient will receive (e.g., as in a randomized design).	0	1
G.	Other aspects	0	1

IF OTHER ASPECTS, PLEASE SPECIFY.

_____

_____

IF ALL ITEMS IN QUESTION 12 WERE CIRCLED NO, SKIP TO QUESTION 16. IF ANY ITEM WAS CIRCLED YES, PLEASE CONTINUE.

15. Is information withheld . . .	Yes	No
A. Because full disclosure would frighten subjects	0	1
B. Because full disclosure might confuse subjects	0	1
C. To encourage participation in research . .	0	1
D. Because full disclosure would distort patient response	0	1
E. For other methodological reasons	0	1
F. For other reasons	0	1

IF OTHER REASONS, PLEASE SPECIFY

_____

_____

16. In your experience, to what extent has the procedure for obtaining informed consent IMPEDED your research? (CIRCLE APPROPRIATE CODE.)

Not at all (SKIP TO Q. 18) . . .	0
Somewhat	1
To a large extent	2

17. If you feel your research HAS been impeded, please describe in what way it has been impeded.

_____

_____

_____

18. To what extent has the procedure for obtaining informed consent BENEFITED your research?

To a large extent 0

Somewhat 1

Not at all (SKIP TO Q. 20) 2

19. If you feel your research HAS benefited, please describe in what way it has benefited.

_____

_____

_____

20. To what extent would you say the procedure for obtaining informed consent has BENEFITED patients?

To a large extent. 0

Somewhat 1

Not at all (SKIP TO Q. 22) 2

21. If you feel the patients HAVE benefited, please describe in what way patients have benefited.

_____

_____

_____

22. In your opinion, to what extent has the procedure for obtaining informed consent worked to the DISADVANTAGE of patients?

To a large extent. 0

Somewhat 1

Not at all (SKIP TO Q. 24) . . 2

23. If you believe the procedure for obtaining informed consent HAS worked to the disadvantage of patients, please describe in what way it has worked to the disadvantage of patients.

_____

_____

_____

THE REVIEW PROCESS

THE NEXT SET OF QUESTIONS HAS TO DO WITH THE REVIEW OF YOUR RESEARCH FOR COMPLIANCE WITH THE REQUIREMENTS FOR PROTECTING HUMAN SUBJECTS.

24. First of all, did you have any discussions concerning this research with the Human Use Subcommittee or its members PRIOR TO the formal review?

Yes 0

No (SKIP TO Q. 26). . . 1

25. IF YES, did you make any modifications based on these informal discussions?

Yes 0

No 1

26. During the formal review procedure by the Human Use Subcommittee, were you required to make any revisions or modifications concerning the use of human subjects as a result of the committee review?

Yes 0

No (SKIP TO Q. 28) . . 1

27. IF YES, were modifications made in:

		Yes	No
A.	The consent form	0	1
B.	The procedures for obtaining consent	0	1
C.	Confidentiality procedures	0	1
D.	Reduction of risk.	0	1
E.	The scientific design	0	1
F.	The selection of subjects	0	1

28. Altogether, do you consider the judgments or recommendations of the Human Use Subcommittee appropriate?

Yes (SKIP TO Q. 30) 0

No 1

29. IF NO, why do you feel this way?

_____

_____

30. In general, to what extent do you feel that the Human Use Subcommittee in this hospital has had beneficial effects in protecting the rights and welfare of Human subjects?

Beneficial to a large extent. 0

Beneficial to some degree 1

Not at all beneficial (SKIP TO Q. 32) . . 2

31. If you feel there have been beneficial effects, what are these?

_____

_____

_____

32. In general, to what extent do you feel that the Human Use Subcommittee here has had beneficial effects on the quality of scientific research conducted at this institution?

Beneficial to a large extent. 0

Beneficial to some degree 1

Not at all beneficial (SKIP TO Q. 34). 2

33. If you feel there have been beneficial effects, what are these?

_____

_____

_____

THE REVIEW COMMITTEE PROCEDURE

34. Do you think the review committee procedure is necessary or unnecessary to insure the protection of human subjects?

Necessary 0

Unnecessary 1

35. To what extent do you feel that the review procedure interferes with an investigator's independent conduct of his research?

To a large extent. . . . 0

To some extent 1

Not at all 2

36. To what extent do you feel that the review procedure interferes with the doctor-patient relationship?

To a large extent. 0

To some extent 1

Not at all 2

37. To what extent do you feel that the review process is unnecessarily burdensome or time consuming for individual investigators?

To a large extent . . . 0

To some extent 1

Not at all 2

38. Do you know of any instances at this institution in which studies in your field have been prevented because of the review procedure?

Yes 0

No (SKIP TO Q. 40). 1

39. IF YES, what kinds of studies were they? (Just the general type, we don't want specific names.)

_____

_____

_____

40. Do you receive any financial support for this study from a government agency other than the VA?

Yes 0

No 1

41. Please add any additional comments you would like to make. (USE BACK OF PAGE IF NECESSARY.)

THANK YOU FOR YOUR PARTICIPATION

APPENDIX F

ADDENDA TO THE BIBLIOGRAPHIC STUDY

I. SPECIALTIES OF THE 921 JOURNALS

Clinical	Non-Clinical
General and internal medicine	Physiology
Allergy, immunology, arthritis and rheumatism	Anatomy and morphology
Anesthesiology	Embryology
Cancer	Genetics and heredity
Cardiovascular system	Nutrition and dietetics
Dentistry	Biochemistry and molecular biology
Dermatology and venereal diseases	Biophysics
Endocrinology and fertility	Cell biology, cytology, histology and microscopy
Gastroenterology	Microbiology and virology
Geriatrics	Biomedical engineering
Hematology	Multidisciplinary basic research
Obstetrics and gynecology	Psychology
Neurology and neurosurgery	
Ophthalmology	
Orthopedics	
Otorhinolaryngology	
Pathology	
Pediatrics	
Pharmacology	
Pharmacy	
Psychiatry	
Radiology and nuclear medicine	
Respiratory system	
Surgery	
Tropical medicine and parasitology	
Urology and nephrology	
Veterinary medicine	
Hygiene and public health	
Multidisciplinary clinical research	

II. COVER LETTER AND INSTRUCTIONS TO PARTICIPANTS IN PEER REVIEW ANALYSIS

NATIONAL RESEARCH COUNCIL
ASSEMBLY OF LIFE SCIENCES
2101 Constitution Avenue Washington, D. C 20418

DIVISION OF MEDICAL SCIENCES
COMMITTEE ON BIOMEDICAL RESEARCH
IN THE VETERANS ADMINISTRATION

OMB: #130-S76001
Approval: Expires 1-19-77

QUESTIONNAIRE

Dear Dr.

The National Academy of Sciences is currently engaged in a study to evaluate the quality of biomedical research in the Veterans Administration.

As part of this study we are seeking an evaluation of biomedical journals by a peer judgment process.

Therefore, we are asking Members of the National Academy of Sciences, Institute of Medicine and other eminent scientists to rate journals in their specialty area.

Enclosed is a list of journals which we have assigned to the specialty field of _____.

The entire process should not take more than 30 minutes.

It would be appreciated if the completed Rating Sheet could be returned within a couple of days.

Your ratings will be held in strictest confidence.

Sincerely,

Leighton E. Cluff, M.D.
Chairman

Enclosure

INSTRUCTIONS

1. On the enclosed list of journals, please rate every one with which you are sufficiently familiar. Assign a rating of "1," "2," or "3," depending on how you evaluate the quality of each journal. Assign a rating of "1" if the journal falls in the highest 25% of journals in its field, "2" if it falls in the middle 50%, or "3" if it falls among the lowest 25% of journals in its field.

For example, if journal ZXY is, in your estimation, among the best in its field, you would probably give it a rating of "1" (Circle 1; see example below). If you consider it merely average, a rating of "2," etc. When you have completed all your ratings, check back to see that you have rated approximately 25% of the journals "1," 25% of the journals "3," and approximately 50% with a rating of "2."

	Top 25%	Middle 50%	Lower 25%
EXAMPLE: Journal ZXY	(1)	2	3

2. If journal is not familiar to you, do not rate it.

3. Base evaluation of a journal primarily on the overall quality of research (clinical and non-clinical) represented by the articles appearing in that journal over the last 4-5 years.

CODE _____

RATING SHEET

Specialty: Anesthesiology

Journals	Top 25% in Field	Middle 50% in Field	Lower 25% in Field
ACTA ANAESTHESIOLOGICA SCANDINAVICA, AND SUPPLEMENTUM	1	2	3
ANAESTHESIA	1	2	3
ANAESTHESIST	1	2	3
ANESTHESIE, ANALGESIE, REANIMATION	1	2	3
ANESTHESIA AND ANALGESIA: CURRENT RESEARCHES	1	2	3
ANESTHESIOLOGY	1	2	3
BRITISH JOURNAL OF ANAESTHESIA	1	2	3
CANADIAN ANAESTHETISTS SOCIETY JOURNAL	1	2	3

III. VA INSTITUTIONS WITH RESEARCH FUNDING AND THE STRENGTH OF THEIR AFFILIATION TO A MEDICAL SCHOOL (1969-1971)

Strong Affiliation	Medium Affiliation	Weak or No Affiliation	
Ann Arbor	Albany	Alexandria	Livermore
Atlanta	Albuquerque	American Lake	Lyons
Augusta	Allen Park	Bath	Manchester
Birmingham	Baltimore	Battle Creek	Marion
Chicago (Research)	Boston	Bay Pines	Martinez
Chicago (Westside)	Bronx	Bedford	Martinsburg
Cincinnati	Brooklyn	Biloxi	Montrose
Denver	Buffalo	Boston OPC	Mountain Home
Durham	Cleveland	Brecksville	Murfreesboro
Gainesville	Dallas	Brockton	Newington
Houston	East Orange	Brooklyn OPC	Northampton
Little Rock	Hines	Butler	Oteen
Los Angeles	Indianapolis	Canandaigua	Perry Point
Madison	Iowa City	Castle Point	Philadelphia OPC
Miami	Jackson	Charleston	Phoenix
Minneapolis	Kansas City	Clarksburg	Pittsburgh (Psychiatric)
New York	Long Beach	Coatesville	Prescott
Oklahoma City	Louisville	Columbia SC	Providence
Palo Alto	Memphis	Danville	Reno
Philadelphia	Nashville	Dayton	Roseburg
Salt Lake City	New Orleans	Des Moines	Saginaw
San Francisco	Northport	Downey	Salem
Seattle	Omaha	Dublin	Sheridan
Tucson	Pittsburgh (General)	Fargo	Shreveport
West Haven	Portland	Fayetteville	Spokane
	Richmond	Fort Howard	St. Cloud
	San Juan	Fort Meade	Temple
	Sepulveda	Fresno	Togus
	St. Louis	Grand Junction	Tomah
	Syracuse	Hampton	Topeka
	Washington	Huntington	Tuscaloosa
	West Roxbury	Jefferson Barracks	Tuskegee
	Wood	Kerrville	Vancouver
		Knoxville	Waco
		Lake City	White River
		Leavenworth	Wichita
		Lebanon	Wilkes-Barre
		Lexington	Wilmington
		Lincoln	

TOTALS

VA Hospital Affiliation with a Medical School	FY 68 & 69 VA Funding (in thousands) Intramural	Extramural	Total	No. of Hospitals	No. of Articles 1971 & 1972
STRONG	41,555	18,186	59,741	25	1,040
MODERATE	36,907	13,457	50,364	33	875
WEAK OR NO (with publications)	12,594	1,243	13,837	53	230
WEAK OR NO (without publications)	923	53	976	24	0

APPENDIX G

BEHAVIORAL RESEARCH IN THE VA

(A suggested model for an advisory council to follow in developing research strategies)

By whatever criterion one may choose, it is clear that the VA has a major commitment to the treatment of behavioral disorders (mental illness, alcoholism, drug abuse, psychosomatic disease, aphasia, and others). Thirty percent of all beds in the VA system are allocated to psychiatric disorders and 35% of admissions to general medical and surgical services have alcohol-related problems. The magnitude of this commitment alone warrants special attention to the research base that underlies treatment. The arena of relevant research is a broad one, ranging from basic psychophysiologic research to clinical trials of drugs for the treatment of schizophrenia and affective disorders. In general, the area is underdeveloped.

BACKGROUND

To comprehend the current situation, it is necessary to recognize how recently the behavioral sciences began to develop a data base and how limited and fragile it still is. The treatment of mental illness may serve as an example. Although a 2% incidence rate for schizophrenia and 3% for disabling depression had long been apparent, before World War II there was little psychiatric or psychological research into the causes and possible cure of these diseases.

The experience of World War II dramatized how important a problem mental illness was. Ten percent (1.85 million) of the otherwise eligible young men

were rejected for military service on psychiatric grounds. Of those who survived psychiatric screening, another 1 million or 10% were hospitalized for psychiatric reasons, and 500,000 received neuropsychiatric discharges. The demonstration of the massive need for treatment services motivated an expansion of training in both psychiatry and clinical psychology. In 1946, the VA began making grants for the training of clinical psychologists. By the middle of the 1950's, clinical psychology programs were established in 60 universities and turned out approximately 150 graduates a year, many of whom entered VA services. Correspondingly, the number of psychiatrists in the United States tripled in size in the 12 years following World War II. Yet these increases did little to develop the research base underlying treatment, for available personnel were needed to help care for the mentally and emotionally disabled.

Expanding the cadre of scientific investigators in the behavioral sciences has proven to be a slow and difficult process. Despite the impressive gains attributable to the career development program of the National Institute of Mental Health (NIMH) and the VA's clinical psychology training program, comparatively few investigators study mental illness. In addition, the funding of mental health research has declined. During the 1950's and early 1960's, the research enterprise of NIMH kept pace with those of its fellow institutes that dealt with general medical and surgical problems. With the development of major service programs under the Community Mental Health Centers Act (1963), the emphasis shifted. The NIMH research budget for FY 1975 was $93 million, significantly less than the $102 million allotted a

decade ago, whereas the total amount budgeted for general medical and surgical research had risen from $.75 billion to over $2 billion in the same 10 year period.

One implication of this vast discrepancy between the allocations of biomedical and behavioral research funding is of special significance to the VA, for it suggests a unique opportunity. Because of the erosion of NIMH's support for behavioral research, a number of investigators are being forced out of active research. Thus, the potential leverage of the VA budget upon behavioral research is great. Even a small increase in VA support of behavioral research could effect changes that could be felt beyond its own programs. Such support could lure larger numbers of competent behavioral researchers to the VA. It is hard to think of any other feasible course of action that could have a more salutary effect or be of greater relevance to the VA's vast commitment to the mentally ill.

ACHIEVEMENTS

Even the small amount of psychiatric research conducted so far in the United States has had an impact upon patient care as significant as that of research in any other field of medicine. For many years before 1955, the number of resident patients in state and county mental hospitals had increased at a rate of 2% per year.

A turning point occurred at the end of 1955, when the patient population reached its peak of 559,000. During that year, chlorpromazine, the first of the effective antipsychotic agents, was introduced nationwide. The following year, for the first time, the number of patients in mental hospitals had not

increased but declined. This decline has continued in each of the succeeding years, and the rate of decrease has accelerated.

As a result of new pharmacologic and psychological approaches (including the antipsychotic drugs), the patient population in state and county mental hospitals had fallen to 193,400 by the end of FY 1975, despite the increase in the population at large. The magnitude of the achievement in reducing the number of hospitalized mentally ill from the 1955 peak of 559,000 is attested to by the calculation that the number hospitalized would now be over 800,000 had the earlier trend continued. This achievement has alleviated a vast amount of human misery; it has also saved vast amounts of money. With mental hospital care now costing $38 a day, the current annual per diem cost alone would have been $11.1 billion compared to its actual $2.7 billion.

The VA was instrumental in developing the treatments responsible for these major gains, and their history should be highlighted because the research was of a kind for which the VA is uniquely suited. For over 10 years, the central neuropsychiatric research laboratory directed a series of large-scale cooperative studies of the phenothiazines. These studies resulted in authoritative reports that form much of the basis for the use of these agents in treating schizophrenia. The reports defined when to use phenothiazines and which ones to administer for particular clinical syndromes; established effective dosage schedules; described the characteristics and treatment of side reactions; and charted the effects of continuous and intermittent usage by chronic patients. These studies eliminated several less potent antipsychotic medications. More recently, similar large-scale cooperative

studies of tricyclic antidepressants and lithium have been carried out, resulting in similarly authoritative conclusions regarding the use of these medications in affective disorders. These studies have made a huge contribution toward reducing the burden of mental illness within and outside the VA. Much more, however, remains to be done.

WHAT NEEDS TO BE DONE

One of the greatest contributions of an enlarged research program could be made through direct studies of the care of mentally ill patients within the VA system. For example, despite the major shift of emphasis in American psychiatry toward outpatient treatment, VA services remain oriented toward inpatient care. A major factor in the burden of care of the mentally ill by the VA is the long (68.8 days) average hospital stay of such patients. Any fruits of research that could reduce this duration of stay would repay many times over the cost of that research. It is conceivable that new practices soon could reduce that duration of stay by a week. It would be difficult to reduce the average stay of general medical and surgical patients so dramatically because it is relatively brief already.

A major shift to outpatient treatment of VA patients should be based upon firm evidence that this shift benefits the veteran. Unequivocal evidence on this point does not exist today, but the VA system is uniquely suited to confirm or refute the benefits of this shift in practice to the advantage not only of veterans, but of all the mentally ill.

The psychopharmacology of treatments for schizophrenia and depression needs to be understood more fully. Twenty years after the introduction of

chlorpromazine and 15 years after the introduction of the tricyclic antidepressants, critical information is still lacking about the relationship between blood levels and the behavior they affect. Even basic information about indications and dosage of newer phenothiazines is unavailable, and still less is known about Clozapine and dibenzoxazepine, two new and potentially very effective antipsychotic agents with chemical structures different from those of the phenothiazines.

To these concerns about treatment must be added the need for basic research on the causes and cures of many behavioral disorders. The neuropsychology of stroke is poorly understood and attempts to help its victims recover intellectual function, articulation, and sensory capacity would benefit from basic research on nervous system activity. The neurobiology of alcohol may have to be understood better before effective treatments for alcoholism can be developed.

CAPACITY TO MEET THE CHALLENGE

Is the research capability of the VA equal to these tasks? The answer must be "not now." Support for research on mental illness is severely limited: only $6.3 million (9% of the research budget) was allocated in FY 1973. Behavioral research personnel occupied only 5% of the places in the career development program in FY 1976; only one behavioral scientist is among the 28 current (July 1976) holders of medical investigator and senior medical investigator awards.

Furthermore, behavioral research has lost ground in one critical respect. The central neuropsychiatric research laboratory has been

disestablished* so that its organizing and directive influence has been lost. As a result, the formerly productive program of cooperative studies of behavioral problems has lost much of its effectiveness. The weaknesses of current VA research in behavioral science make it unlikely that first-class cooperative studies can be expected to arise spontaneously throughout the system. Such studies will require the reestablishment of a strong, centrally organized program.

RECOMMENDATIONS

Despite this gloomy picture, an energetic program can improve behavioral research substantially in the VA. Towards this end the Committee submits five recommendations:

1. Improve liaison at the Central Office between research and development and mental health and behavioral sciences services. One person designated as coordinator of research should have the sole task of mobolizing the resources of both services in the interest of behavioral research. This person should have the responsibility for effecting the substantive recommendations which follow.

2. Establish small, high-quality, four-year research residency training programs in conjunction with outstanding residency training programs at five leading hospitals. Retention of the outstanding graduates of these programs should be encouraged by allocating sufficient research associate positions to

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* To become a cooperative studies support center.

accomodate those who wish to remain in the VA. This training program will require staffing by psychologists and other behavioral scientists whose training has prepared them to carry out research as well as to teach these skills. Such persons already are present at the leading hospitals and would require only supplemental funding to permit diversion of some of their time to the research training program.

The next recommendations deal with three different levels of research: research carried out in large, well-funded programs; research carried out in programs of more modest size and quality; and others.

3. A small number--perhaps five to ten--of excellent psychiatric research programs exist in the VA. All are in the larger hospitals closely affiliated with strong schools of medicine. These programs have strong leaders and a critical mass of investigators, are large and well-funded, and can compete effectively for research grant support from the NIMH. These programs are going well; the VA should maintain the circumstances which are supporting these programs.

4. It is possible to make major improvements in behavioral research at a few hospitals whose research programs now fall between the outstanding ones of the leading hospitals and the poor or absent ones of the unaffiliated hospitals. Funds should be made available to about 10 of these hospitals on a competitive basis to establish "centers of excellence," each headed by a senior psychiatric investigator. They should be assured of sufficient continuity of funding to attract and maintain a critical mass of research