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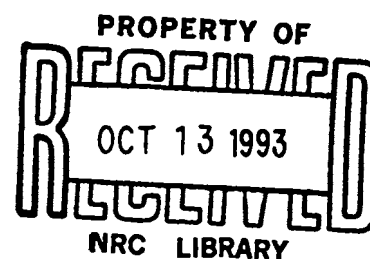
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Intellectual Property Rights in Industry-Sponsored University Research

**A Guide to Alternatives
for Research Agreements**



**GOVERNMENT-UNIVERSITY-INDUSTRY
RESEARCH ROUNDTABLE**

**INDUSTRIAL RESEARCH
INSTITUTE**

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The Government-University-Industry Research Roundtable

The Government-University-Industry Research Roundtable is sponsored by the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. The Research Roundtable was created in 1984 to provide a forum where scientists, engineers, administrators, and policymakers from government, university, and industry can come together on an ongoing basis to explore ways to improve the productivity of the nation's research enterprise. The object is to try to understand issues, to inject imaginative thought into the system, and to provide a setting for discussion and the seeking of common ground. The Roundtable does not make recommendations, nor offer specific advice. It does develop options and bring all interested parties together. The uniqueness of the Roundtable is in the breadth of its membership and in the continuity with which it can address issues.

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Preface

The Government-University-Industry Research Roundtable has a longstanding interest, beginning well before my time as Chairman, in minimizing difficulties associated with the negotiation of research agreements for industry-sponsored research in universities. In 1988, a Roundtable committee, in conjunction with the Industrial Research Institute, developed a set of model agreements to streamline the negotiation process¹. The intent was that these models would decrease the time and effort needed to develop a research agreement, as well as provide a starting point for companies and universities new to negotiating agreements.

In general, the models were well received by the academic and industrial communities.² However, one concern, intellectual property rights, continues to pose significant hurdles to successful negotiation. We have had repeated requests from academic and business officials for further guidance on negotiating intellectual property rights in research agreements. And members of our Roundtable Council, particularly Richard Zare, professor of chemistry at Stanford, have maintained that cooperative relationships will continue to be strained without some improvements in this area. In response, the Roundtable formed a Task Force on Intellectual Property Rights in Industry-Sponsored University Research. The members of the Task Force are listed in Appendix I.

The charge to the Task Force was to identify the contentious issues related to intellectual property rights and develop contract language that makes it easier to negotiate agreements for industry-sponsored university research. The focus of the effort was to clarify issues that cross institutional boundaries when university-industry research agreements are negotiated. In spite of the temptation to deal with several related issues, the Task Force concentrated its efforts on this narrow focus. Therefore, this document does not address other institutional issues that may or should impact how a company or a university approaches negotiations (e.g., issues related to conflict of interest, and incentives and rewards for investigators). Neither did the Task Force address some of the more global questions that arise when discussing university-industry research relationships:

¹**Simplified and Standardized Model Agreements for University-Industry Cooperative Research**, Government-University-Industry Research Roundtable and Industrial Research Institute, 1988.

²**Survey to Assess the Usefulness of Two Model Agreements for University-Industry Cooperative Research**, Government-University-Industry Research Roundtable, 1990

- What principles should guide universities and industries that participate in cooperative research?
- What principles should guide foreign company participation in research endeavors with U.S. universities?
- What principles should guide industry participation in university research endeavors supported by federal funds?

These questions merit full consideration, but were beyond the scope and focus of this project.

I believe that this document will serve its purpose in clarifying the more difficult issues that arise in negotiating intellectual property rights in research agreements. I hope that using this document will enable university and industry research partners to spend less time negotiating contract clauses, and more time addressing what type of cooperative relationships and research projects make sense.

I am also hopeful that the tenor of this document will modify the erroneous perception I have heard from many quarters: that university-industry research relationships will generate substantial revenue for all involved. Experience just does not bear this out. For example, at MIT—viewed by many as the archetype at forging university-industry relationships, gross revenue from all licensing operations is equal to an amount which is less than 2 percent of the university's overall research budget.

University and industry experts on the Task Force emphasize the value of the research rather than the financial gain that might be realized from tangible products of the research. University-industry negotiations and relationships benefit when each party understands the value of the interaction to the other party. Then, the sometimes competing interests of the two parties can be balanced with regard to intellectual property rights, and a "win-win" agreement and relationship can be achieved.

The audiences for this document include officials from universities and industry who seek additional understanding of key intellectual property issues in industry-sponsored university research agreements and ways to deal with those issues. Senior officials from these organizations, who are not routinely involved in negotiating research agreements, may also be able to use this document as a conceptual framework for thinking about how university-industry research arrangements can work effectively. Also, anyone interested or involved in these relationships—

including small businesses and faculty members—might use this document as a primer to learn from those who have had extensive experience in these negotiations.

I am delighted with what the Task Force has accomplished. Led ably by Al Barber, Special Assistant to the Chancellor of UCLA and Associate Member of the Roundtable Council, they carried out a difficult task with remarkable spirit and commitment. Casey Kiernan, Project Director, did an outstanding job of working with Task Force members, individually and collectively, and capturing and knitting together their views to create the scenarios and contract language that are the core of the final document. I hope you find this result of their efforts to be of use.

**Richard F. Celeste
Chairman, Research Roundtable
August 1993**

I. Introduction

During the past decade, research relationships between universities and industry have flourished. A number of structures for such relationships exist. A company may sponsor a specific project involving one or more investigators, or an area of research involving a university department, center, or consortium, with one or more universities participating. Alternatively, several companies may support these structures. A collaborative arrangement, in which both the company and the university are involved in the conduct of the research project, may involve individual investigators—either as a long-term arrangement or a short-term focused project—or it may include a university department, center, or consortium.

Within these structures, universities and industry have a variety of expectations and objectives which motivate industry-sponsored research.

From an industry point of view, research relationships with universities provide a window to new information, knowledge, or different approaches to increase fundamental understanding of technologies which may be of current or future interest to the company. These relationships facilitate the transfer of knowledge from universities that may lead to commercially valuable products or processes. Access to faculty expertise and students provides a pool of candidates for consulting and recruitment.

Universities, for their part, look to these research relationships as a way to enhance the potential development and application of university-based knowledge and discoveries for the public benefit. By working with industry, universities gain access to financial support for research and training; expose academic scientists to industrial approaches to research; and increase understanding of how university research can address industrial concerns. Finally, these research arrangements provide internship and employment opportunities for students.

These industry and university expectations of research relationships fit into the larger, primary objectives of each of these two sectors. Industry focuses on profit and on obligations to stockholders. Universities focus on research, education, and services. Thus, two very different cultures are interacting. Even within these individual cultures, a great deal of diversity exists in terms of objectives, policies, and requirements.

Given the range of possible structures and expectations of university-industry research relationships, it is not surprising that

each relationship may require consideration on a case-by-case basis. Terms to include in a given research agreement will depend on: the structure of the relationship; the stage of investigation relative to commercial application (e.g. basic, applied) and field of research (e.g. biotechnology, electronics, manufacturing); the type of industry (e.g. pharmaceuticals, aerospace); the existing state of knowledge and development (e.g. a newly explored research area, an already highly developed one with patents outstanding); the experience and expectations of the university and industry investigators (e.g. new to industry-sponsored research or "old hands").

Reaching agreement for the conduct of research between two or more partners takes patience, flexibility, and an understanding of each other's objectives. Some relationships have been stalled in the process of negotiation, and some have failed, because of a lack of understanding and accommodation of natural differences in culture and expectations between universities and industry. Frequently, prospective research partners need to get to know each other before a successful agreement can be reached.³

Difficulties in negotiating agreements often are the result of the perception by one party that the other party has unrealistic expectations. The extent to which partners expect to profit financially from the arrangement underlies some of these difficulties. In addition, university and industry expectations regarding diligence in exploiting intellectual property for public benefit may differ. If a commercial product emerges from the sponsored research, all involved stand to gain: the company because it has a tangible result from its investment in a high-risk endeavor; the university because its objectives of making the results of the research available for the public benefit have been realized.

Advanced knowledge, rather than a potential product, is often the most valuable result of industry-sponsored research. The obligation of the sponsor and the university to maximize the public benefit from the research results may, but does not necessarily, require that a product be sold; internal use of the research results by the sponsor may promote public benefit by increasing efficiency and reducing production costs.

³See, for example, **Research Universities as Research Partners: How to Make It Work**, Howard Schneiderman, 1987; and **New Alliances and Partnerships in American Science and Engineering**, Government-University-Industry Research Roundtable, 1986.

The primary value of the relationship is in new knowledge generated by the research that benefits the university, the company, and the public, with the added value of training students to understand industrial R&D problems. If both parties can keep this in mind throughout the negotiation process, potential conflicts may be more easily resolved. All sides win if agreement can be reached.

II. This Document

To minimize difficulties in negotiation, the Government-University-Industry Research Roundtable, in conjunction with the Industrial Research Institute (IRI), established the Task Force on Intellectual Property Rights in Industry-Sponsored University Research Agreements (see Appendix I). The Task Force was directed to provide greater understanding of the framework of university-industry research relationships, given the diversity of attitudes and perceptions; clarify the issues and complexities related to intellectual property rights; identify and describe the key issues that make negotiations difficult; and suggest a "menu" of scenarios and contract language to handle the key issues—all in an attempt to minimize or avoid unnecessary difficulties in the negotiation of industry-sponsored university research agreements.

The Task Force chose to focus its analysis specifically on sponsorship by a single company of a single university investigator project, and collaborative research between an industry scientist and a university investigator. Issues particularly related to the licensing of technology outside of a research agreement (including licenses stemming from government-sponsored research), materials transfer agreements, clinical trials, multiple sponsorship, and consortia were not explicitly addressed.

The Task Force's decision not to address these issues is not intended to minimize their importance. Although many of the issues related to multiple sponsorship and consortia and other types of relationships are the same as those considered here, these types of relationships may pose additional issues which are more complicated by the nature of the relationship. Addressing the unique features of each of these relationships is beyond the scope of this project.

The Task Force conducted its work in meetings, conference calls, and a workshop during which the input, questions, and comments of the broader community were solicited. (See a list of workshop participants in Appendix II.) Input was also sought from the IRI University Relations Committee and the IRI University Research

Relations Directors Network. The result of these deliberations follows.

This document is divided into four sections: (1) ownership of intellectual property; (2) rights to use intellectual property; (3) procedural issues; and (4) special considerations involving copyright. The term "intellectual property," as used in both the ownership and rights to use sections, includes both patents and copyrights.⁴ Special considerations for both types of intellectual property are noted as necessary. Each section presents a discussion of the relevant issues and suggests reasonable ways of dealing with them. Suggestions for specific contract language, where appropriate, have been included in sidebars throughout the text. (A fully integrated contract is not included. The reader is cautioned that the use of the language provided in this document in the sidebars in an actual contract will require redrafting for consistency of terms and approach.)

The scenarios and the contract language described in this document are intended to provide a range of alternatives, a description of issues to consider when choosing those alternatives, and ways of navigating around potentially contentious obstacles. These alternatives may be useful as starting points for negotiating some of the most obvious and potentially difficult intellectual property rights issues.

The scenarios and the contract language neither cover every conceivable issue and problem, nor are they intended to be used as a standard approach. Each issue and approach to handling it must be considered in the context of the unique nature of the relationship and the objectives of both parties in it. The negotiations are part of the "courtship" that is necessary. Up front negotiation enables each party to learn the other's objectives and expectations in order to define a successful relationship.

III. Ownership of Intellectual Property Rights

There are three primary scenarios for the ownership of intellectual property rights: (1) the university owns the intellectual property; (2) the sponsor owns the intellectual property; and (3) the university and sponsor jointly own the intellectual property. As a matter of policy, universities generally require faculty

⁴Intellectual property arising from industry-sponsored university research should not take the form of trade secrets as this form prohibits publication or presentation of research results. Trade secrets require a level of guardianship that universities are not set up to provide, especially a state institution that must comply with a Freedom of Information Act.

members and other employees to assign to the university ownership of inventions arising from research undertaken while employed at the university. Faculty members and other university employees usually sign an employment agreement to this effect. The research agreement may provide assurances to the sponsor that such an agreement has been signed.

University policies vary on whether students, research fellows, or visiting scientists are viewed as "employees" when considering ownership of intellectual property rights. Most universities require students and research fellows to assign such rights to the university if the rights are generated in the performance of the sponsored research. There is more variance, however, among university policies on ownership of intellectual property rights of visiting academic or industry scientists participating in sponsored research.

These policies should be discussed during the negotiation of research agreements in which such personnel will be participating so that both parties know what to expect.⁵

Scenario 1: The university owns the intellectual property

Most universities own inventions conceived or reduced to practice solely by their employees during the conduct of research. In general, sponsors have accepted this position subject to other considerations such as the right to use intellectual property as discussed in Section IV on page 7.

In general, universities also own software generated during the performance of a sponsored research project, if a university scientist or other employee has created the material.

Scenario 2: The sponsor owns the intellectual property

Companies from some industrial sectors take the position that the sponsor has a right to own the intellectual property since it has paid for the research. Under this scenario, the

Contract language for "Faculty members, staff, students, and research fellows"—*Each of University's faculty members, staff, students, and research fellows involved in performing investigations or providing services under this Agreement shall be obligated to University in writing, prior to such involvement, to assign his or her rights to any University Intellectual Property resulting from research under this Agreement.*

Contract language for "The university owns the intellectual property"—*University Intellectual Property" means individually and collectively all inventions, improvements, or discoveries and all works of authorship, excluding articles, dissertations, theses, and books, which are generated solely by one or more employees of University in performance of the research agreement during the Contract Period. All rights and title to University Intellectual Property developed under the research agreement belong to University and are subject to the terms and conditions of this Agreement.*

⁵See, for example, *Ownership of University Inventions*, B. Jean Weidemier, 1992, *Journal of the Association of University Technology Managers*, Volume IV, pages 1-20.

sponsor owns the intellectual property through contract or assignment by the university or the investigators. This scenario may apply, for example, when the sponsor has made a substantial investment in the development of the technology that is the subject of the university's research, when the sponsor is likely to be the only practical user of the resulting inventions, or if the sponsor has provided proprietary information, technology, or material which is the basis of the research.

In cases when the sponsor acquires ownership of a copyright or invention, the university retains a royalty-free right to use the intellectual property for any internal research and teaching purposes, and may retain the right to sublicense to investigators for research and teaching purposes.

Company ownership of intellectual property resulting from federally sponsored research requires the permission of the federal funding agency.⁶

Scenario 3: The university and sponsor jointly own the intellectual property

For intellectual property jointly made by employees of a university and an industrial sponsor, under U.S. law, the parties have joint ownership in and the independent right to exploit the intellectual property, unless otherwise agreed.⁸ If one party wants exclusive rights to jointly-owned intellectual property, that party needs to obtain the other party's rights, by licensing or assignment, as discussed in Section IV., Scenario 3 on page 13.

Contract language for "The sponsor owns the intellectual property"—University shall assign to Sponsor, upon request, all right, title, and interest in University Intellectual Property. No sooner than three months following termination of this Agreement, or any extension thereof, the University shall have the right to request that Sponsor make a final decision regarding such assignment. Sponsor shall then make the decision no later than sixty (60) days after the University's request. Any assignment made by the University to the Sponsor shall include the following conditions:

_____⁷

Contract language for "The university and sponsor jointly own the intellectual property"—"Joint Intellectual Property" means individually and collectively all inventions, improvements, or discoveries and all works of authorship, excluding articles, dissertations, theses, and books, which are generated by one or more employees of University and one or more employees of Sponsor in performance of the research under the Agreement. All rights and title to Joint Intellectual Property belong jointly to University and Sponsor and are subject to the terms and conditions of this Agreement.

⁶35 USC 202 (c)(7)(A); 37 CFR 401.14 (k) Special Provisions for Contracts with Nonprofit Organizations. If the contractor is a nonprofit organization, it agrees that: (1) Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor...

⁷The assignment might include no conditions. Alternatively, some possible terms include: royalty, diligence, reservation of rights, reversion.

⁸For copyrights, and for patents in many foreign countries, the ability to license without accountability to or permission of the other party may be limited.

IV. Rights to Use Intellectual Property Under Different Ownership Scenarios

For the purposes of discussing the rights to use intellectual property, the three scenarios used in the previous section are also used here: (1) the university owns the intellectual property; (2) the sponsor owns the intellectual property; and (3) the university and sponsor jointly own the intellectual property.

Scenario 1: The university owns the intellectual property

Under this scenario, three approaches are described to acquire license rights to use intellectual property. The document then goes on to describe the scope of the license provisions considered within each of these approaches.

A. Approaches

When the university owns the intellectual property, sponsors may wish to acquire license rights to the intellectual property, including the right to use and the right to make derivative works. These rights may be in the form of an option in which the sponsor can elect a future license, or in the form of a grant of a specific license as part of the research agreement, although these are not mutually exclusive. Three approaches for transferring these rights are discussed below: the option for a license; the grant of a license; and the right of first refusal.

Approach 1: Option for a license

The research agreement provides for an option period during which the sponsor has the sole right to elect a license, to be negotiated in good faith. While an invention disclosure or filing of a patent application is of significance, many inventions for which applications are filed are never commercialized. Thus, a sponsor will typically have insufficient information at the time of filing to reach an informed decision on whether to commit to a commercial development under a license agreement. One reason for the university to conclude a license agreement, however, is to commit the sponsor to a

Contract language for "Option for a license"—University hereby grants to Sponsor the exclusive option to elect any of the following licenses:⁹

- i) a non-exclusive, royalty-free license to the University Intellectual Property for any internal research and development purposes*
- ii) a non-exclusive, royalty-free license to the University Intellectual Property without the right to grant sublicenses*
- iii) a non-exclusive, royalty-bearing license to the University Intellectual Property including the right to grant sublicenses*
- iv) an exclusive, royalty-bearing license to the University Intellectual Property in the field of use of _____ including the right to grant sublicenses*
- v) an exclusive, royalty-bearing license to the University Intellectual Property including the right to grant sublicenses*
- vi) an exclusive, royalty-free license to the University Intellectual Property including the right to grant sublicenses*

This option shall extend for _____ [time] from the disclosure of intellectual property to the sponsor, OR filing of a patent application, OR notice of patent allowance, OR issuance of a patent, OR conclusion of the contract period. Terms and conditions of these licenses are to be negotiated in good faith and agreed upon between University and Sponsor.

⁹The sponsor and the university need to discuss which choices are to be included in the research agreement. For example, an exclusive license may negate the need for the grant of a non-exclusive license.

commercialization of the invention. Both parties' interests may be substantially met if they can agree on mutually satisfactory commitment, other than commercialization, during the option period. This commitment may consist of continued funding of the research program, payment of patent costs, internal company development, or other considerations, including further funding tied to a patent application or other milestones.

The beginning and length of the option period varies widely according to the nature of the anticipated intellectual property and the industry involved. In general, universities want a short option period to enable the university to seek a third party licensee in the event that the sponsor is not interested in a license. The sponsor, on the other hand, would prefer a longer option period in which to assess the commercial potential of the intellectual property.

For intellectual property which is a potential product, such as that which may arise from research funded by a pharmaceutical company, the option period generally extends for some period beyond the initial invention disclosure or filing, and may extend beyond the termination of the sponsored research agreement.

In some industries, it takes longer to determine the commercial value of the intellectual property. For example, in many areas of technology, a single patent rarely defines an entire product, in which case, the value of a single patent may not be clear until other patents emerge from a company's patent portfolio. In such cases, an extended option period, perhaps even beyond issuance of a patent, may be appropriate. Intellectual property of these types sometimes arise from research in such industries as petroleum, chemical, and heavy manufacturing, and is typically utilized with other proprietary technologies in actual commercial use.

Approach 2: Grant of a license

In some cases the research agreement grants a specific license to the sponsor to use the intellectual property and describes the extent of the permitted use, as distinguished from an option which grants only the right to obtain a license at a later time, but no present rights. Often the

Contract language for "Grant of a license"—University hereby grants to Sponsor any of the following licenses:'

- i) a non-exclusive, royalty-free license to the University Intellectual Property for any internal research and development purposes***
- ii) a non-exclusive, royalty-free license to the University Intellectual Property without the right to grant sublicenses***
- iii) a non-exclusive, royalty-bearing license to the University Intellectual Property including the right to grant sublicenses***
- iv) an exclusive, royalty-bearing license to the University Intellectual Property in the field of use of _____ including the right to grant sublicenses***
- v) an exclusive, royalty-bearing license to the University Intellectual Property including the right to grant sublicenses***
- vi) an exclusive, royalty-free license to the University Intellectual Property including the right to grant sublicenses***

Terms and conditions of these licenses are to be negotiated in good faith and agreed upon between University and Sponsor.

sponsor obtains a non-exclusive, royalty-free license for internal research and development in the research agreement, though more extensive license rights may also be granted in that agreement.⁹ Some sponsors may be reluctant to fund research without knowing what effect license provisions will have on the availability and cost of the eventual product. So some license provisions may be defined in the research agreement. However, by including an option for a license in the research agreement, negotiation of most license provisions may be deferred until some time after disclosure of the specific intellectual property.

Approach 3: The right of first refusal

In practice, when the sponsor elects to take a license, the parties are almost always able to reach acceptable terms for a license agreement for the intellectual property resulting from the sponsored research. If agreement cannot be reached, mediation or arbitration can sometimes be helpful. Occasionally, in spite of these efforts, agreement still cannot be achieved within the agreed upon time. When this occurs, the university has the right to negotiate with third parties. If the university is able to reach agreement with a third party on more favorable terms than were presented to the sponsor, under the right of first refusal, the sponsor has the right to accept such a license offered to a third party.

The right of first refusal may be acceptable to a university if it is contingent upon the sponsor negotiating a license agreement in good faith during the option negotiation period. Having the right of first refusal may provide the added level of comfort that a sponsor needs to justify the research investment. However, some universities are reluctant to accept the right of first refusal under any circumstances, because the practical effect may be to impede the university's ability to interest a third party in a license. For its part, the sponsor may feel that, in the absence of detailed license terms in the research and option agreement, a right of first refusal is needed to reduce the risk that the university will prematurely initiate negotiations with a third party.

Contract language for "The right of first refusal"—If Sponsor exercises its option, the parties will thereafter negotiate in good faith to conclude a license agreement within ___ [time]. Such negotiations shall take into account factors affecting Sponsor's ability to commercialize the product profitably, including, but not limited to, terms of any third party license which may be necessary for the manufacture, use, and sale of any product relating to the field, size of market, development time and cost, product performance relative to competing products, and whether the invention is covered by a sole or joint patent.

In the event the parties fail to reach a mutually acceptable agreement within the negotiation period, University shall be entitled to negotiate in good faith with one or more third parties a license for any University Intellectual Property and University's interest in any Joint Intellectual Property. However, upon the conclusion of such negotiations and before any license is granted to any such third party on terms more favorable than were offered to Sponsor, University shall offer Sponsor a license on the same terms. If Sponsor is willing to enter into a license with University on such terms, Sponsor shall be granted the license instead of such third party.

B. Scope

Regardless of which of the above approaches to acquiring a license is utilized, consideration of the scope of the license is the same. Below is a discussion of possible provisions to be considered, including provisions for exclusive and non-exclusive licenses, royalty rates, field of use, and inclusion of a full license agreement.

1) Exclusive and non-exclusive license provisions

Exclusive licenses are especially important in some industries, such as pharmaceuticals, biotechnology, and chemicals, whereas they may not be as important to others, such as electronics and automobile manufacturing.

If a technology is of general use or limited value, or if it is a small part of a large system, the sponsor may choose a non-exclusive license. Sponsors often expect non-exclusive rights to inventions resulting from sponsored research to be royalty-free, but companies are generally willing to pay royalties for exclusive rights.

In some industries, pharmaceuticals, for example, if a sponsor is granted a non-exclusive license, the university may have difficulty interesting other licensees. Some potential licensees may not be willing to spend large sums of money developing a product using the intellectual property that the original sponsor chose not to develop, but could subsequently use royalty free or market in an improved form.

If the sponsor elects a non-exclusive, royalty-free license to use the intellectual property solely for research purposes, the university is still able to grant an exclusive license to a third party for commercialization of the intellectual property. If the sponsor takes an exclusive license, the university must retain the right to use the intellectual property in its own research and instructional programs.

2) Royalty provisions

Generally, royalty provisions are not included in research agreements.¹⁰ When they are, the sponsor often will agree to a range of royalty rates, deferring determination of the actual rate. The pre-specification of royalty rate—or a range of rates—does not preclude discussion of other financial considerations during negotiations of the license.

Royalty rates are influenced by a number of factors including the potential market size and profitability of the licensed product, the potential cost of commercialization, the obligation to pay royalties to more than one licensor-holder for the product, the value added to the product by the university invention, and the degree of exclusivity granted by the license. The field of research, type of invention, size of the research project, prior or background rights, stage and type of research being carried out, and the nature of the potential intellectual property, also may affect the rates. Royalty payments may be capped on a cumulative, percentage, or annual basis.

The royalty base will require definition and may be based on: net sales, net earnings, bulk manufacturing costs, number of units, products, processes, value added, and profits. No contract language is provided here for royalty provisions because these and other variables must be considered.

In the case of copyrights, universities may expect companies to pay royalties for using software, for some other types of copyrightable material, and for derivative works if the software is not considered part of the "deliverables" in a sponsored project. (See the definition of derivative works in footnote 15 on page 17.) If royalties are to be paid for derivative works, the basis and extent of this obligation may be further defined in subsequent license agreements or in the initial research agreement depending on the specificity of other intellectual property terms in the agreements and the preference of the parties.

¹⁰Under Title XIII Tax-Exempt Bonds and the House and Senate amendments to it, tax-free status of public bonds may be adversely affected under certain conditions, particularly for pre-negotiated royalty rates with exclusive licenses. Because of its complexity, competent tax advice may be necessary. See the Conference Report to the Tax Reform Act of 1986, II-683ff, especially II-685-6 and II-689.

3) Field of use provisions

Licenses to intellectual property may limit the sponsor's license rights to specific fields of use. The license may allow exclusive or non-exclusive use within specific fields.

In many instances, the sponsor may wish to obtain a license for all fields of use. The university, however, may be concerned about the ability of the sponsor to fully commercialize the licensed product in every possible field of use. In fact, such full development is an ideal rarely realized in practice. Market size, development costs, and other factors often make the development of an invention for particular applications or markets unprofitable. Contract language is generally included that commits the sponsor to use "commercially reasonable efforts" to develop the invention within the field of use. The sponsor may develop certain applications or markets through sublicensing or joint ventures.

For certain types of products, such as pharmaceuticals, a broad field of use may be critical to commercial success. For instance, successful commercialization may ultimately depend on the later discovery of a new medical use for a compound that was not considered commercially valuable during the original negotiations. Alternatively, a drug may have multiple uses that collectively make the product sufficiently profitable to justify undertaking the research. The sponsor may not be willing to gamble resources on a subset of possible applications. At the very least, the sponsor will likely feel that competitors should not benefit, at the sponsor's expense, from the research it has sponsored.

A compromise acceptable to both the university and the sponsor may be to include all fields to which the sponsor will devote "commercially reasonable efforts."

4) Inclusion of full license agreement as an appendix

In many cases both the university and the sponsor are reluctant to negotiate a full license as part of the research agreement because it is time-consuming. However, some sponsors insist on it. When the parties have sufficient information about the probability of intellectual property resulting from the research, as well as its likely commercial value, a full license agreement may be

Contract language for "Field of use provisions"—[See contract language for option for a license and grant of a license on pages 7 and 8, respectively, where fields of use may be specified.]

Contract language for "commercially reasonable efforts"—"Commercially Reasonable Efforts" means efforts and resources commonly used in the _____ (e.g. pharmaceutical) industry for a product at a similar stage in its product life of similar market potential taking into account the establishment of use of the product in the marketplace, the competitiveness of alternative products in the marketplace, the proprietary position of the product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the product and alternative products, and other relevant factors.

appropriate. When included, it is usually as an appendix to the research agreement. This allows the appendix to be easily modified without affecting other provisions of the agreement. Discussion of terms to be included in the full license is beyond the scope of this document.

It should be noted that some states require disclosure upon request of information in research agreements under provisions of their Freedom of Information Act. If a license agreement is appended to the research agreement, it may become publicly available and, therefore, subject to such disclosure.

Scenario 2: The sponsor owns the intellectual property

When the sponsor owns the intellectual property through contract or assignment by the university or the investigators, the university should reserve the right to continue to use the intellectual property for internal, research and teaching purposes, and may retain the right to sublicense to investigators for research and teaching purposes.

Scenario 3: The university and sponsor jointly own the intellectual property

Under this scenario, both parties can use and license the jointly owned intellectual property without obtaining permission from the other party, unless they have signed an agreement to the contrary.¹¹ If the sponsor wants exclusive rights to commercialize jointly-owned intellectual property, the decision to include option and license terms in the research agreement should be made based on the same considerations discussed above in Section IV., Scenario 1.

V. Procedural Issues

A. Delay of Publication

University researchers must be able to publish and make presentations on the results of sponsored research. Sponsors usually obtain the right to review manuscripts prior to submission for publication or oral presentation. This is done

Contract language for "Rights to use when the sponsor owns the intellectual property"—*University reserves for itself a royalty-free, irrevocable license to make and use such University Intellectual Property within the University for internal non-commercial purposes only.*

Contract language for "Delay of publication"—*Sponsor shall be furnished copies of any proposed publication or presentation at least 45 days before submission of such proposed publication or presentation. During that time, Sponsor shall have the right to: (i) review the material for confidential information provided by the sponsor and (ii) assess the patentability of any invention described in the material. If the Sponsor decides that a patent application should be filed, the publication or presentation shall be delayed an additional seventy-five (75) days or until a patent application is filed, whichever is sooner. At Sponsor's request, confidential information provided by Sponsor shall be deleted.*

¹¹As mentioned previously, for copyrights, and for patents in many foreign countries, the ability to license without accountability to or permission of the other party may be limited.

to insure that no confidential information of the sponsor is released and to assess the patentability of any invention described in the material. Commonly, sponsors have 45 days to review the material, and another 30 to 75 days to prepare and file a patent application. Thus the period allowed for review and patent application filing is generally less than 120 days.¹² Periods of time are negotiable, however, and in certain rapidly moving fields shorter periods may be appropriate.

B. Procedures for patents

1) The university owns the invention

It is customary for the university to file the patent application, and most companies are willing to reimburse the university for reasonable patenting costs if they wish to obtain a license to the patent.¹³ The sponsor usually has the right to review and comment on the application and subsequent prosecution of the case including patent expenses. When a sponsor pays for filing a patent

¹²There are two possible ways for giving the sponsor time to review research findings to be reported in the publication or presentation of dissertations, theses, and their oral defense without interfering with the student's matriculation:

- (1) Dissertations, theses, and their defense may be considered separate from other publications and presentations. The presumption would be that the university and the sponsor are working together to assure an adequate dialogue—particularly when a graduate student is participating in the research—so that, at the time of defense and publication, the sponsor has already had adequate consultation on the material. This is especially true if the student has been giving public seminars on the material as part of a job-hunting process.
- (2) The research agreement may spell out that, at the completion of the thesis, the major professor will request that the thesis be sequestered at the library until the sponsor has completed its review. This approach allows time for sponsor to review the thesis, but it does not take into account the fact that the thesis defense often is considered a public presentation, and therefore, it too would be subject to review.

¹³In many instances, the sponsor and the university may want to establish a procedure for reimbursement costs. Some procedures include: consultation and review of costs; sponsor monitoring of the preparation, filing, and prosecution of the patent application; sponsor pre-approval of outside patent counsel or of all costs; or sponsor carrying out the patent application filing and prosecution task in the university's best interest.

Usually, sponsors are closely involved in the process so that consultation and review or monitoring are typically acceptable to both parties. Some companies, however, as a matter of policy, require pre-approval of costs to be reimbursed. In the absence of such a policy, the paperwork and time associated with pre-approval can require more effort than either the university or the sponsor may want to undertake. Lastly, on occasion, the sponsor is better able to prepare and file a patent application, and it will take the lead for the university. This procedure can create difficulties, however, because of the potential for liabilities and conflict of interest.

¹⁴Once a patent application has been filed in the United States, the patent applicant has 12 months in which to file corresponding foreign Convention patents, if the U.S. filing predates any public disclosure. (Some countries, Taiwan, for example, do not allow Convention filing).

Contract language for "Patent procedures when the university owns the invention"—University shall promptly notify Sponsor of any University Intellectual Property disclosed to it by the researcher(s). Such disclosure shall be provided and maintained in confidence. Sponsor shall have up to forty-five (45) days from the receipt of the disclosure by Sponsor in which to request the filing of patent application(s).

University shall promptly file and prosecute patent applications, using counsel of University's choice after due consultation with Sponsor. University shall keep Sponsor advised as to developments with respect to application(s) and shall promptly supply copies of all papers received and filed in connection with the prosecution in sufficient time for Sponsor to comment. Sponsor's comments shall be taken into consideration.

Sponsor shall reimburse all reasonable out-of-pocket costs incurred in connection with such preparation, filing, and prosecution of patent applications. Such applications shall include all items considered by Sponsor to be of commercial interest and importance.

Within nine (9) months of the filing date of a U.S. patent application, the Sponsor shall provide to the University a written list of foreign countries in which applications should be filed.¹⁴

[Contract language continued on next page.]

application, such costs may be considered a credit toward future royalty payments. Absent an agreement by the sponsor to pay patent costs, the university should be under no obligation to file a patent application or to continue prosecution.

The research agreement may include language to allow the sponsor to discontinue paying patent costs. The consequences of such action should be addressed in negotiations.

In the case of a non-exclusive, royalty-bearing license, the patent costs may be paid by the initial licensee, who may be reimbursed on a *pro rata* basis from revenues obtained from other licensees. In the case of a non-exclusive license when the sponsor does not reimburse patent costs, the university retains the right to decide whether to apply for or maintain patents without further obligation to the sponsor.

2) The university and sponsor jointly own the invention

In the case of joint ownership of an invention, the university and the sponsor together should decide which party is responsible for filing and prosecuting the patent application. The other party retains the right to review the patent prosecution documents, and patent costs are usually shared. When the sponsor has an option to obtain an exclusive right to commercialize the joint invention, the sponsor generally pays all patent costs, with what would have been the university's share of such costs being deducted from royalties.

Contract language for "Patent procedures when the university owns the invention," continued—
If Sponsor elects to discontinue the financial support of any patent prosecution, in any country, University shall be free to continue prosecution at University's expense.

In such event, University shall have no further obligation to Sponsor in regard to such patent applications or patents in such country. In the event University does not file in a reasonable time an application on the invention, as directed and paid by Sponsor, or intends to discontinue prosecution of any patent application or maintenance of any patent, University shall so notify Sponsor and Sponsor may elect to continue prosecution and maintenance at Sponsor's sole expense.

Contract language for "Patent procedures when the university and the sponsor jointly own the invention"—*The University and Sponsor shall decide which party shall be responsible for the prosecution of patent applications on joint inventions. If Sponsor has an option to obtain an exclusive license to the joint invention, Sponsor shall be responsible for all patent costs; otherwise patent costs shall be shared. Whichever party is responsible for patent filing and prosecution will provide the other party with an opportunity to comment on papers filed in connection with the patent application. Such comments shall be taken into consideration.*

C. Confidential information

Most universities will agree not to disclose to third parties confidential information that is provided by the sponsor for use in the sponsored research. Similarly, most companies will agree to protect university confidential information. Some universities require that the university investigator(s) personally sign a confidentiality agreement to safeguard confidential information received from the sponsor, rather than the university signing. Other universities will assume this liability for persons acting within the scope of their employment.

The sponsor and the university may further agree that only confidential information directly relevant to the research project will be exchanged, unless the receiving party agrees in writing to accept additional confidential information. In practice, this concern is generally more important to the sponsor, who wants to confine disclosure to information relating to the research project to avoid potential conflicts over ownership of inventions that arise from the sponsor's own research.

Sometimes, confidential information will be disclosed by both parties during the course of the research. Rather than deal with this issue in the research agreement, the parties may enter into a separate confidentiality agreement at the time confidential information is disclosed. Otherwise, disclosures not covered by a confidentiality agreement may be considered public disclosure.

The parties should be aware of the terms of their state's Freedom of Information Act, which may limit the conditions under which confidentiality can be maintained.

Contract language for "Confidential information"—
During the term and any subsequent extension of this Agreement, and for a period of ____ years thereafter, the parties shall not use or disclose to any third party without prior written consent of the other party, any Confidential Information of the other party. For the purposes of this Agreement, "Confidential Information" means all information which is disclosed or provided to one party to this agreement (Receiving Party) by the other party (Disclosing Party), whether in written form, or in oral or electronic form which is reduced to written form, and is designated in writing as confidential. The Receiving Party shall have no obligations with respect to any portion of such Confidential Information which:

- (a) is or later becomes generally available to the public by use, publication, or the like, through no fault of the Receiving Party; or*
- (b) is obtained without an obligation of confidentiality from a third party who had the legal right to disclose the same to the Receiving Party; or*
- (c) the Receiving Party already possesses, as evidenced by its written records, pre-dating receipt thereof from the Disclosing Party; or*
- (d) the Receiving Party independently develops without reference to Confidential Information of the Disclosing Party; or*
- (e) is required to be disclosed by law.*

[Contract language continued on next page.]

Contract language for "Confidential information," continued—During the term of the Agreement, the parties will not disclose to each other any information which is confidential or proprietary to the Disclosing Party or any third party, (1) except as is necessary for the Disclosing Party to fulfill its obligations under this Agreement, or (2) unless the Receiving Party has agreed in writing to accept such disclosure. All other communications between the parties shall be on a non-confidential basis.

VI. Special Considerations Involving Copyright

In some research agreements, copyrightable intellectual property, which may take various forms, is treated differently than patentable intellectual property.¹⁵

¹⁵Definitions relevant to issues of copyright in research agreements:

"Author" means the person, using his or her own independent efforts, who creates an original work by translating an idea into a fixed, tangible expression that is entitled to copyright protection.

"Derivative Work" means any work substantially based on one or more preexisting works, such as revisions, annotations, elaborations, translations, or modifications, which as a whole represent an original work of authorship. A work is derivative if it would be considered infringing on the original copyright if the material or pre-existing work from which it was derived has been taken without the consent of the original copyright holder.

"Employer" means the hiring party who had the right to control the manner and means of the author/employee's work. Copyright protection will be afforded the employer by statute for works made by its author/employee in the regular course of business.

"Fair Use" means the use of a copyrighted work for purposes such as criticism, comment, news reporting, teaching, scholarship or research that do not infringe the copyright after consideration of the following factors: (1) the purpose and character of the use, including whether the use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the relative amount and substantiality of the use compared to the whole copyrighted work; and (4) the effect of the use on the marketability or value of the copyrighted work.

"Improvements" on a preexisting work, by their very nature, tend to be derivative works. If the work is a software program, improvements may take the following general forms: (1) error corrections—such as "maintenance" or "bug" corrections; (2) additional features—"enhancements;" or (3) a substantial rewrite of the program having new features, yet retaining "portability" from the original program.

"Originality" means that the work is independently created and not copied from other works. Originality of a derivative work means any variation of an original work which is sufficient to render the derivative work distinguishable from its prior work in any meaningful manner.

"Owner" means the person entitled to a claim of copyright. This person must be either the author or have succeeded to the right of the author (e.g., employer).

"Work Made for Hire" means a work prepared by an employee within the scope of his or her employment or a certain work specially ordered or commissioned, and so designated in writing.

In general, copyrights protect the original expression of ideas in a tangible form, while patents protect original ideas (inventions) that are reduced to practice. Hence, the expression of an original idea may be protected by a copyright, while an invention arising from the idea may also be protected by a patent. For example, consider a new drug XYZ that is a patentable invention. Disclosing the composition of drug XYZ in a patent protects the drug composition. One can write an article or book about the drug, its composition, its uses, or its efficacy without infringing the patent. The author would own a copyright to his or her "literary work" on drug XYZ, and others would be prohibited from copying this article or book. However, one author's ownership of a copyright does not mean that another author cannot write a different article or book on the same subject.

A. Forms of copyright

In industry-sponsored university research, copyright issues arise over information and data; articles, dissertations, theses, and books; research reports; software; and other copyrightable works generated during the sponsored project. Each of these categories of material may require special contract language in the research agreement.

1) Information and data

Original expression of information and data developed in the performance of sponsored research, such as a report or manuscript, may be copyrightable, but alternative forms of expression or use of the information and data by other parties may not be protected by the copyright. Sponsors and universities both may have concerns about how information and data are used and how to protect potentially commercially valuable ideas they contain. In some universities, determining who owns the copyright will depend on whether the information and data are "deliverables" of the sponsored project. Many universities and sponsors have found that it is easier to deal with rights to information and data if the discussion centers on use rather than ownership.

Contract language for "Information and data"—*The Sponsor may use all information and data developed by the University under the research agreement, except as otherwise specified, that is obtained by Sponsor, in any manner without further license from or payment to the University.*

2) Articles, dissertations, theses, and books

In general, copyrights to articles, dissertations, theses, and books are not intellectual property to which the sponsor has rights under the research agreement. Many university intellectual property policies do not claim these "scholarly

works" as works for hire, nor do they require employees or students to assign these works to the university. However, these materials may be subject to review by the sponsor under the publication clause of the agreement, and the sponsor may use any information and data described in the materials.

3) Research reports

Research reports are usually required under the research agreement. Universities, on behalf of the authors of the reports, may assign copyright to the report delivered to the sponsor. The university, however, will explicitly reserve the right to continue to use data and information contained in the report. If the report is published by the sponsor, the university may require acknowledgment of the university's contribution.

Contract language for "Research reports"—University hereby assigns its copyright to the Research Report to Sponsor. Notwithstanding the foregoing, University reserves the right to reproduce and use any portion of the Report for non-commercial purposes.

Pharmaceutical companies that rely on clinical trials carried out by universities customarily claim ownership of the case-report forms. This claim is made in an effort to ease compliance with requirements of the Food and Drug Administration. However, the university may retain ownership of the copyright to the final report provided to the sponsor, and grant to the sponsor the right to use the data and information contained in the report. Clinical trials represent a special case for copyrights in research agreements, but this point is also relevant to other situations.

4) Software

Distinctions may be made between object code and source code, although both forms are copyrightable. While universities prefer to retain ownership of both types of code, some institutions may be willing to assign to the sponsor the object code specifically developed for the sponsor. It is generally assumed that the sponsor's application of the object code is not readily useful to other potential licensees. Universities, however, will generally not assign title or give an exclusive license to the source code, if this would impede their ability to use such code for other research or to make derivative works, or to use it to create and license out object code for applications other than the sponsor's.

5) Other copyrightable works

Materials that fall into this category include films, videotapes, music compositions, posters, and artwork. Such works generally are owned by the author, with the rights and acknowledgments negotiated in the research agreement.

Such works may sometimes be assigned to the sponsor, if they are considered deliverables under the research agreement. Deliverables can be treated as research reports or as intellectual property.

B. Software issues

Two issues that are of special consideration for software are derivative works and improvements.

1) Derivative works

The right to make derivative works resides solely with the copyright owner. However, the copyright owner may authorize others to make derivative works. In the case of licenses to copyrightable material, therefore, a licensee would need specific authorization from the copyright owner to develop derivative works. Generally, the university will retain the non-exclusive right to make derivative works for its own purposes, even if it grants the sponsor an exclusive license to the software and to derivative works.

If the sponsor has a license to make commercially available derivative works, it may expect to pay a royalty based on those works. In order to fairly assign royalties, it may be necessary to distinguish among enhancements, improvements, modifications, and derivative works, although these terms are not mutually exclusive.

Both parties should determine whether software used in the research incorporates software owned by others, because this software owned by others may become incorporated into new software arising from the research.

2) Improvements

Rights to improvements in software made by the university may be included in the rights granted under a

Contract language for "Derivative works"—*In the event that Sponsor acquires a license to copyrightable University Intellectual Property, such license specifically includes the right of the Sponsor to make Derivative Works, subject to the definition of University Intellectual Property agreed to by the parties.*

research agreement, when the improvements are made within a defined period after the research agreement ends. In such cases, the university and sponsor should discuss the possibility of options and licenses to improvements. Generally, if the improvement by the university is small, a royalty-free license to the improvement is granted. If it is a substantial enhancement, such as a new algorithm for software in a major piece of equipment, a separate license may be required.

There are several different types of improvements possible.¹⁶ The university and the sponsor need to agree on the definition of "improvements" for the purposes of the research agreement.

**Contract language for
"Improvements"—Improvements¹⁶
to copyrightable University
Intellectual Property made by
University within ____ months
following termination of this
Agreement shall be provided to
Sponsor on a non-exclusive,
royalty-free basis, subject to the
definition of University Intellectual
Property agreed to by the parties.
(For the purposes of this
Agreement, "Improvements" means
_____.)**

VII. Conclusion/Summary

Four major intellectual property rights issues have been addressed in this document: (1) ownership of intellectual property; (2) rights to use intellectual property; (3) procedural issues; and (4) special considerations involving copyright. Given the different nature and culture of universities and industry, the scenarios and corresponding contract language represent compromises that university and industry representatives on the Task Force believe will provide negotiators with reasonable options for dealing with these issues and with a framework for the general consideration of intellectual property rights within research agreements.

The objective of the Task Force was to facilitate the negotiation of intellectual property rights in research agreements between universities and industry. To the extent this document is helpful in those endeavors, the Task Force will have accomplished its main objective.

¹⁶See footnote 15 on page 17.

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