

Office of Research Services  
University of Pennsylvania

Handbook for Negotiation of Sponsored Research Agreements

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## A. OVERVIEW

### 1. Introduction:

The purpose of this handbook is to serve as a resource and guide for negotiation of sponsored research agreements (SRAs) at the University of Pennsylvania.

Sponsored research agreements are a significant source of funding for investigators at the University as well as a valuable opportunity for research collaborations with industry. At the University of Pennsylvania, about 100 SRAs are negotiated each year and a total of about 250 SRAs are active during any one year, yielding an aggregate direct cost income of ~ \$10,000,000 per year. SRAs are contracts that establish the terms and conditions under which corporate research funding is accepted and conducted by the University.

Individuals negotiating SRAs will find this Handbook helpful in identifying and explaining the University's governing policies and procedures for the negotiation of SRAs. In addition, alternate contract clauses are included to cover certain specific situations, which may arise in negotiations.

Negotiations of SRAs should consider the various stakeholder groups involved in the process. The interests and needs of the University from the perspective of a non-profit, tax-exempt research and educational institution, with a mission of public service are to be contrasted with the commercial, for-profit goals of the corporate Sponsors. Yet, the SRA is beneficial to both in the resulting research collaboration: Faculty learn about industrial technologies, their research receives substantial support, and they contribute to the development and transfer of technologies that benefit the public. In addition, Sponsors gain access to the expertise of the faculty and facilities of the University.

Where positions outlined here differ from standard University policy, they are presented with the explicit approval of the Vice Provost for Research.

### 2. Authority and Review

The Vice-Provost for Research is the University official responsible for the development and implementation of policies and procedures relating to extramurally sponsored projects. (See [Research Investigators Handbook, Section IV.B.](#) See also [Handbook for Faculty and Academic Administrators, Section III.A.5.](#), and [Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 2.b.](#))

The Trustees have given different offices specific authority to approve and execute specific agreements. The Office of Research Services (ORS) has authority for approving and executing SRAs. ([Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 2.b.](#)) Resolutions on the Authority to Execute and Perform Research Grants and Contracts provide that the Vice Provost for Research and the Executive Director, Associate and Assistant Director(s) of Research Services are authorized to sign, perform and

execute on behalf of the University all research and training contracts, grants or other agreements which have been reviewed and approved pursuant to University policies and procedures. This authority includes the signing of any and all documents required in connection with the initiation, operation and termination of such grants, contracts or agreements.

Individual faculty members do not have authority to bind the University to research arrangements. Informal agreements and those that have not been approved by the appropriate officials are the personal responsibility of the individual faculty member making such arrangements. ([Handbook for Faculty and Academic Administrators, Section III.A.4.](#))

In general, SRAs should not be coupled with license agreements because this tends to confound and delay their negotiation. Where SRAs are coupled with license agreements, they will be negotiated by the Center for Technology Transfer (CTT). This will likely delay completion of negotiations of the SRA. The Faculty should be apprised of this and advised to decouple the negotiations unless a license by the Sponsor is critical to some aspect of the SRA.

All matters requiring legal advice or legal action should be referred to the Office of the General Counsel (OGC) ([Handbook for Faculty and Academic Administrators I.C.7.](#)) It is the responsibility of ORS, in consultation with the VPR, to determine whether an SRA deviates sufficiently from the standard agreements to require OGC review and approval.

### 3. Administration and Processing of Sponsored Research Agreements

University policy stipulates that every SRA be evidenced by a formal document that outlines the research objectives and administrative requirements of the project. All proposals seeking external support for research and other sponsored projects must be submitted to ORS with a completed Proposal Transmittal and Approval Form.

All funds provided from external sources to support research and other projects at Penn are administered in accordance with University policies and contractually agreed Sponsor requirements. All research and teaching activities which involve human subject, laboratory animals, use of radioactive materials, or biohazard activities must be reviewed for compliance with University policies and government regulations.

ORS has been charged with the review, negotiation and execution of SRAs. However, before the SRA is negotiated, a research proposal must be reviewed and approved through use of the research Proposal Transmittal and Penn internal review procedures.

The standard University SRA was revised in November 2001, after an extensive review process. The standard SRA should be used whenever possible since it contains provisions that are mandatory (e.g., publication, disclaimer of warranties, indemnification), as well as additional provisions that reflect the University's preferred position on other matters. The agreement should be provided to potential Sponsors as part of the research proposal. Doing so can speed the process of negotiation because the Sponsor is made aware at the outset of University contract requirements.

Any correspondence proposing modification of the terms or conditions of a SRA, including changes in the research proposal, or an increase or decrease in the total estimated budget should be submitted to ORS. Renewals or extensions involving additional costs must also be reviewed through normal procedures in the same way as new proposals. Similarly, copies of any correspondence with Sponsors concerning problems, which may affect the agreement, such as delays, financial problems, unavailability of personnel and other matters should be forwarded to ORS.

#### 4. Conflicts of Interest

Possible conflict-of-interest situations include arrangements under which investigators have consulting arrangements with the Sponsor, a management position with the Sponsor, a substantial equity interest in the Sponsor, or any other financial interest in the outcome of the research. The University's Policies on [Conflict of Interest](#) and the [Financial Disclosure Policy for Research and Sponsored Projects](#) provide further information on these concerns.

While not directly related to the negotiation of SRAs, ORS needs to be aware of and report research programs with potential Investigator conflicts to the Conflict of Interest Standing Committee (CISC). The primary responsibility for disclosing significant financial interests lies with the faculty investigators. However, individuals negotiating SRAs should be cognizant of possible conflicts and should alert the investigator(s) and the CISC when appropriate.

#### 5. Fee-for-Service (Contract Research) and "Private Business Use of Facilities"

There are some limitations on the type of "research" that can be conducted under the SRA and they deserve detailed consideration.

Some research programs will entail fee-for-service or "contract research". This sort of work often involves analysis, evaluation, or diagnostics assessment that does not represent original research. The concern is that "contract research" is inappropriate as a sponsored research activity at the University. Generally speaking, the type of research conducted at Penn should be, given Penn's status as a non-profit institution, beneficial to the general public and not solely for the commercial benefit of a Sponsor. Contract research subverts a non-profit research institution's obligation to do research for the benefit of the public in general.

The inappropriateness of "contract research" is based on two considerations, which can be generalized as "academic" and "economic".

Academic considerations. In the typical "contract research" agreement, the Sponsor controls the scope of the research project, has complete ownership of results and any Intellectual Property (IP), and imposes confidentiality on the University. In addition, publication may be forbidden. Such provisions are unacceptable at Penn for several reasons. Penn must control the research (conduct of the research rests with the investigator) and the results of such research should be made available to the public through publication and presentation.

Economic considerations. One economic concern is that it is inappropriate for a non-profit institution such as Penn to compete with for-profit organizations; such competition violates Federal (NSF and NIH) policies. Unless Penn owns any IP that is generated, the work could be considered to be contract research. If research is determined to be primarily for the benefit of the Sponsor and not the public, it may be considered “private business use” under IRS Revenue Procedure 97-14, and the research funds received may be subject to the Unrelated Business Income Tax. The restrictions on “private business use” of facilities financed with tax-exempt bonds are part of a larger legal framework that ensures that non-profit institutions perform research for the benefit of the general public and do not unjustly benefit for-profit entities. Too much contract research could jeopardize an institution’s non-profit status. As contract research puts non-profits in direct competition with for-profit research organizations, it can lead to legal disputes with these entities.

Sponsored Research Agreements should avoid features that could lead to characterization of the arrangement as “contract research.” If a Sponsor defines the nature and scope of a given research project, or if an SRA grants the Sponsor the right to restrict publication of the research, or assigns to the Sponsor intellectual property created in the research, or requires deliverables that will be owned by the Sponsor, such research could be considered “contract research”. In order for research that is funded by for-profit entities to be considered part of Penn’s non-profit activities, Penn must control the research and the results of such research must be freely available to the public. Sponsors may receive certain limited rights, such as an option to negotiate to obtain a license to inventions created in sponsored research.

## 6. Collaborative Research Agreements (CRAs)

Collaborative research activities with commercial entities, those in which the commercial entity plays an active role in the conduct of one or more of the scientific aspects of the research program, are a category of sponsored research. This type of research is handled through a Collaborative Research Agreement (CRA). As such, CRAs are subject to all University policies governing SRAs. Care should be taken in such arrangements to ensure that the University’s publication rights are protected, and that the Sponsor does not obtain automatic rights to intellectual property created in the research. Approximately a dozen CRAs are negotiated each year at the University.

## 7. Facilities and Administrative Costs

Facilities and Administrative (F&A) costs are true costs of research that must be fully reimbursed by the Sponsor. F&A costs pay the University for the cost of operations and maintenance of its research facilities and for the general administrative costs associated with monitoring and accounting of sponsored projects. F&A costs are not “profit” nor are they “fabricated”. Commercial sponsors are well aware of these costs of the University, which are typically lower than the analogous costs of the Sponsor. This differential in costs is another factor in Sponsors wishing to conduct basic research at universities.

Acceptance of an SRA without full compensation of F&A costs places the University at risk from two perspectives. First, by providing research for amounts lower than its costs, the University is subsidizing a for-profit commercial organization, a violation of IRS regulations governing 501.c.3 entities. Second and more importantly, use of F&A rates lower than that charged to the federal government jeopardizes the federal F&A rate.

## B. CONTRACT TERMS

This section of the Handbook reviews the terms and conditions in the revised SRA, and its organization follows that of the revised SRA. The item-by-item commentary is meant to assist in understanding the rationale of the provisions of the SRA, and provide guidance on negotiations. In some cases, alternate language is provided to cover different situations, which may arise in the course of a negotiation.

### RECITALS

The Whereas clause asserts the non-profit status of Penn and emphasizes that the University enters into the SRAs to generate new knowledge and in furtherance of its public service and educational missions. Although the recital does not have the contractual force of a legal term it reinforces the intent of the parties.

### ARTICLE 1. DEFINITIONS

Intellectual Property is distinguished from Research Results. Research Results are data, materials, and information that are not protectable by one of the well-defined categories of intellectual property.

Intellectual property is defined as those elements of the research that can be protected as patents, copyrightable software, and trademarks. These various types of intellectual property are defined by law and are fairly easy to define, protect and license. The policies of the University state that patentable inventions and tangible research materials developed at the University in the course of sponsored research projects is the property of the University. Sponsors may have access to Intellectual Property (IP) through licensing agreements.

Patentable inventions are inventions that are tangible, useful, novel, and non-obvious. Patenting is the most valuable form of IP protection in scientific areas and is the most important for technologies developed in the University. In the definition of patentable inventions, the terms “conceived” and “reduced to practice” are utilized. Conception is the point at which the perception of an invention in the mind of the inventor occurs (Conception is the mental “idea” of an invention that occurs to the Inventor). Reduction to practice is the physical manifestation of the idea, which demonstrates that the conception will work in the real world. For example, a process is reduced to practice when it is successfully performed in the laboratory, such as a machine that can be assembled and shown to function. For an invention to be patentable, both conception and reduction to practice criteria must be met.

Some Sponsors will seek to have “conceived and reduced to practice” changed to “conceived or reduced to practice”. This change would broaden the range of possible inventions covered by the SRA and could overlap with inventions which are partially developed from other projects, including federally sponsored projects, creating competing contractual obligations. Accordingly, the “or” provisions are not to be accepted.

Copyright protection is provided by Title 17 of the United States Code for original works of authorship fixed in any tangible medium of expression that can be perceived, reproduced or otherwise communicated either directly or with the aid of a machine or device. Works of authorship include literary works, musical works, dramatic works, pantomimes and choreographic works pictorial or graphic works, audiovisual works, sound records, architectural works, and computer software.

Under the statute, copyright protection does not exist for any idea, procedure, process, system, method of operation, concept, principle or discovery, regardless of form in which it is described, explained, illustrated or embodied in such work. Copyright protection exists as soon as the work has been created. No copyright notice or registration is needed to obtain copyright protection. Copyright provides the owner of the copyright with the exclusive right to reproduce, prepare new versions (derivative works), to publicly display and distribute and perform the derivative.

Tangible Research Materials were not included in the standard template, as most SRAs do not involve Tangible Research Materials. Tangible Research Materials are covered by the University's Intellectual Property policy and are the actual biological and chemical materials created in the course of research. Unlike the other types of IP discussed, these represent a form of tangible intellectual property. Such materials may be owned by the University as described in the IP policy and made available to Sponsors under the option/license sections of the SRA. If necessary, it is possible to include in the SRA, language dealing with tangible research materials.

Trade secrets are another type of intellectual property. A trade secret is commercially valuable information kept confidential to maintain a competitive advantage. However, trade secrets are not included in SRAs, because the University cannot maintain trade secrets that result from sponsored research activities. Maintenance of a trade secret would require maintaining information in confidence for an unspecified period of time, which is contrary to University policy on the dissemination of knowledge. In addition, know-how is not included in the definition of IP as it is essentially the skill and knowledge of the Faculty and employees. It cannot be clearly defined or licensed or transferred for commercial development. If a Sponsor has interest in working with a Principal Investigator (PI) to obtain "know-how", that might be handled via a consulting agreement between the PI and the Sponsor. Even so, if a PI believes that a "trade secret" or "know-how" exists s/he should disclose this information to the University to allow evaluation as a possible patent.

## ARTICLE 2. SPONSORED RESEARCH

The research program is the scientific or scholarly activity planned by the Faculty investigator, the "roadmap" for the actual research conducted under the SRA.

Control of the research program. Section 2.1 indicates that the PI has the freedom to conduct and supervise the research. The concepts of academic freedom and faculty control over their scientific inquiry are fundamental to Penn's mission. It is important to steer clear of language that would suggest that a Sponsor has control of the research program. Under no circumstances

should language be accepted which casts the PI in the role of Consultant. Neither should language be accepted which imposes on the University obligations to “ensure” or guarantee control of PI activities. Corporate Sponsor should have the ability to review and approve the research program prior to initiation and require adequate reporting of results. While control of the research program must remain with the PI, language may be added which indicates that the Sponsor will be “consulted” on the research program.

Overlapping research projects. Some Sponsors will seek to include language that precludes other sponsors from supporting similar research in the lab of the PI. This is to be avoided. The research program and budget should be sufficiently well defined to avoid confusion over which Sponsor supported the research and any results and data resulting therefrom. It is acceptable to state that confidential information or materials provided by a Sponsor should not be used in other research endeavors.

The University does not knowingly enter into research agreements that involve commitments and obligations that are in conflict with those accepted under other agreements. Special procedures for dealing with actual or potential conflicts may, in appropriate cases, be included in research agreements.

Changes in the research program. If at any time the PI determines that the Research Results, comments from Sponsor or other information dictate a substantial change in the direction of the Research Program, he or she will notify the Sponsor of such determination. Accordingly, the Sponsor and PI will review and agree upon any necessary changes in the scope of the Research Program.

### ARTICLE 3. TERM OF AGREEMENT

Contracts should be for a definite and stated term. If the agreement is to be renewable, an affirmative act on the part of the University should be required to renew. Contracts that automatically renew without mutual agreement should be avoided.

Sponsors should understand that the duration of the research program is at best an estimate and that the stated goals may or may not be completed during the term of the SRA. Scientific research is by its nature unpredictable; in addition, faculty, students and staff may not always be available. In such cases the SRA may need to be extended by mutual agreement.

PI unavailable. Section 2.2 indicates that the SRA may be terminated if the PI is unavailable to continue the study. This is an important provision to retain in contracts, as it is a situation that occurs from time to time. It also underscores the notion that the work being performed is not “contract work” or routine and is dependent on the knowledge and skill of the particular investigator.

### ARTICLE 4. REIMBURSEMENT OF COSTS, PAYMENT

Time of payment. Some research funds must be provided by Sponsor in advance of the conduct of the research. The exact amounts and frequency of payment will depend on a number of factors, including the risk that the Sponsor may not be able to meet its financial obligations. Typically, however, advance payments would consist of 25% of the total costs of the project. Advanced payments should be requested and be in amounts that assure uninterrupted work on the research projects. Advance funding provides security for salaries and benefits for staff and students working on such research projects. Research at Penn is entirely dependent on external sources of funding and there are no reserves to draw upon if costs are not covered. Furthermore, the University's payment of costs in support of any industrial research agreement for which it is not subsequently reimbursed could be viewed as use of non-profit funds to support a commercial entity.

The Sponsor is required to pay in advance for each phase of the research, not after expenses are incurred. Efforts by a Sponsor to have the University invoice for expenses after they have been incurred should be resisted. In many cases, Sponsors may be late or unable to make payment, requiring the impacted Department to pay for the costs. Unusual payment terms should be reviewed with ORS.

#### ARTICLE 5. RECORDS AND REPORTS

Under the terms of the SRA, Sponsors receive research reports from the faculty investigator. Satisfactory research reports are essential for Sponsors to monitor the progress of the research and identify inventions resulting from the research program.

Reporting requirements should keep in mind the impact on faculty. Some Sponsors have suggested weekly or even monthly reporting requirements. Most faculty would object to this, at least for written reports to the Sponsor. In addition, requirements for long technical reports that would unduly burden the PI should be avoided. A good compromise is a brief report every six months and one final report. Any reporting requirements and the schedule should be reviewed and approved by the PI.

Care should be taken to ensure that any financial reporting requirements are reasonable in the context of University fiscal capabilities. In Section 9.2, the SRA provides for a final report of financial costs 90 days after termination.

#### ARTICLE 6. SPONSOR'S RIGHTS IN RESEARCH RESULTS AND REPORTS

##### Research Results

Research Results are results, materials, information which are not protectable by one of the well defined categories of intellectual property and which arise from the conduct of the research program sponsored under the SRA.

The University is committed to making the results of research available to the public. Investigators do this through publications and presentations. The standard SRA makes clear in Section 6.1 that Sponsors may utilize results and data (but not intellectual property) for any reasonable purpose. This is based on the notion that such results and data will be available to the public in any case. Sponsors may have an advantage in that they will have access to research results prior to others. Once the research results are placed in the public domain, they are freely available for the use of anyone.

Ownership of results: Some Sponsors will request exclusive ownership of research results resulting from the SRA. Exclusive ownership of research results by Sponsor is both unnecessary and inconsistent with the policies of the University since Research Results need to be available to the PI for their own research use and development, such as with other research proposals and further work in the lab. In addition, the University must have the right to publish and present the results and data resulting from the sponsored research. This is an especially important principle in order for students to publish dissertations. Both the internal use of research results and the right to publish and present them are inconsistent with exclusive Sponsor ownership.

In certain cases, Penn may agree that research results are the joint property of the Sponsor and Penn. This would allow both parties to freely utilize them. Joint ownership makes particular sense in cases involving research results that are based on research involving a Sponsor's proprietary materials and data. The rationale for this would be that such results, while created by the PI at Penn, would not have been possible but for the materials or data supplied by a Sponsor.

Alternate language:

*Data and results emanating from the Research Program shall be the joint property of Penn and Sponsor, provided, however, Penn will be free to use the data and results emanating from the Study for internal, non-commercial research and educational purposes and patient care purposes and will be free to publish and present the data and results. Sponsor may use the data and results for any reasonable purpose.*

Copyright

Copyrightable works from a SRA would generally include interim and final technical reports, software, and other works first created in the performance of a sponsored agreement. Copyrightable works would not include journal articles, lectures, books or other copyrighted works created through independent academic effort and based on the findings of the sponsored project, unless the sponsored agreement states otherwise.

***Excerpt from the University's Copyright Policy***

***"V.E.1. Policy Statement on Copyrights.*** *The Trustees of the University of Pennsylvania, subject to the exceptions declared in Sections V.E.1.a., V.E.1.b., and V.E.1.c. affirm the academic custom that creators of intellectual property own the copyright to works resulting from their research, teaching and writing and have the individual right to apply for, own all right, title*

*and interest to, enforce, profit by and transfer to other parties, such as publishers, copyrights in their works under the laws of the United States and other jurisdictions. Computer software and courseware (the tools and technologies used to present courses), to the extent not protected by patent law, are governed by this policy. With respect to works such as journal articles and other similar publications, when an author transfers an interest in these copyrightable works, the author should use reasonable efforts to secure for the University the right to reproduce such works, royalty free, for all traditional, customary or reasonable academic uses. With respect to computer software and courseware, the University shall enjoy a permanent, non-exclusive, royalty free license to make all traditional, customary or reasonable academic uses of these works.*

***V.E.1.a. Sponsored Research.*** *Exceptions to this custom may arise when works are made under government sponsored research, industry sponsored research, and certain grants in which the University assumes specific obligations with respect to a copyrightable work resulting from a given sponsored program. To the extent necessary, where the sponsored program agreement provides that the sponsor will acquire rights to copyrightable works produced under the program, the University will own all right, title and interest to the copyrightable works created under such sponsored programs.”*

Contract terms and conditions relating to copyrights must take into account the University’s Copyright policy. The Copyright policy indicates that, when copyrightable materials are generated during the course of the research, then ownership of such copyrightable works lies with the University to the extent necessary to comply with Sponsor rights, rather than the faculty. However, the Sponsor may be provided with certain rights to such copyrightable materials. Alternatively if the SRA does not give the University ownership, than it should provide the University with a free-of-cost, nonexclusive, worldwide license to use and reproduce the copyrighted work for education and research purposes.

Section 6.2 provides for a limited non-exclusive copyright license for the Sponsor to use research reports created in the course of the SRA: a non exclusive license to copy, reproduce and distribute research reports generated under the SRA. This is a relatively benign clause that does not impair some of the more important rights in copyright, such as derivative works.

Sponsors may request additional copyright language in the SRA during negotiations that are not found in the template. Such additional language probably should be located in Article 7 and the PI should be consulted on any additional language.

#### Alternate Copyright Clauses Applicable in Unusual Situations.

Alternate 1.

*Penn grants Sponsor an irrevocable royalty free license to make and distribute copies of any publication under any copyright privileges that Institution or PI may have.*

Alternate 2.

*Penn grants Sponsor a nonexclusive license in any right title or interest that Penn has in all information and data developed pursuant to the research including source codes, object codes or other software.*

Alternate 3.

*Penn grants to Sponsor a non-exclusive, royalty-free license to use copyrightable material for its own internal research purposes with no right to sublicense or commercialize for any purpose. If Sponsor desires to sublicense or to use, sell, distribute said copyrightable materials in whole or in part in any form Sponsor shall notify Penn of such. Penn as its own discretion, may grant Sponsor such requested license on reasonable business terms.*

Alternate 4. (Alternates 4 and 5 allow Sponsor to recast presentation of data and so should be used cautiously and with the agreement of the PI)

*Penn acknowledges that Sponsor shall have the right to develop or otherwise create any derivative works of the Final report. Sponsor shall own all right, title and interest thereto.*

Alternate 5.

*Penn hereby grants to Sponsor an irrevocable, royalty-free non-exclusive nontransferable right and license:*

- 1. to prepare derivative works based on the works of authorship and derivative works*
- 2. to use, execute, reproduce, display, and perform and distribute internal and externally copies of works of authorship and derivative works.*

## ARTICLE 7. INTELLECTUAL PROPERTY

### Patents and Licensing

The long-standing practice of the University is to grant commercial sponsors of research an option to negotiate to obtain a license for intellectual property that may be created in the research they sponsor. The University will not agree to assign inventions to commercial sponsors, nor will it agree to specific financial terms for a license before an invention is made. The University, under certain circumstances detailed below, may provide a non-exclusive royalty-free license to PENN INTELLECTUAL PROPERTY.

***The University of Pennsylvania Patent Policy is excerpted below:***

*“2.0 Policy Statement on Inventions and Patents. It is the policy of the University that all inventions, together with associated materials, which are conceived or reduced to practice by inventors in the course of employment at the University, or result from work directly related to professional or employment responsibilities at the University, or from work*

*carried out on University time, or at University expense, or with substantial use of University resources under grants or otherwise, shall be the property of the University as of the time such inventions are conceived or reduced to practice. Inventors shall assign to the University all right, title and interest in and to the inventions, materials and related patents and shall cooperate fully with the University in the preparation and prosecution of patents.*

*“2.2.1 Licensing. The University may convey rights to its inventions through license agreements under the terms of which the University retains all right, title and interest in and to its inventions, while granting to a commercial entity the right to make, use, and/or sell products based on the invention(s).*

*“3.0 Policy Statement on Tangible Research Property. tangible research property made by investigators in the course of employment at the University, or work directly related to professional or employment responsibilities at the University, or work carried out on University time, or at University expense or with substantial use of University resources under grants or otherwise, is the property of the University.*

*“4.0.15 materials means lab notebooks, records, drawings, sketches, photographs, radiographs or other images, models, biological specimens, chemical samples, or other materials needed to support the preparation, submission, prosecution, defense or enforcement of a patent in the United States or other applicable jurisdictions.*

*“4.0.19 tangible research property means unique research products such as biological materials or chemical moieties, whether or not patentable. Categories of biological material include organisms, cells, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information and crystallographic coordinates. Some specific examples of biological materials include specialized and/or genetically defined cells, including normal and diseased human cells; monoclonal cell lines; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; and transgenic mice or other animals. Categories of chemical moieties or engineered products include sample compounds, reagents, intermediates, models, sensors, devices, equipment, computer hardware or firmware, diagrams, or computer media.”*

These policies are grounded in sound principles. Often, inventions made during the course of commercially sponsored research are the result of years of activity using University facilities and resources that have not been supported by the Sponsor. While commercial sponsorship may defray a portion of the actual cost of carrying out a sponsored research program, it does not and is not intended to compensate the University for the commercial use of inventions that may be made during the research.

Applicable laws and regulations provide an additional basis for Penn’s position on Sponsor rights. One such law that bears on Penn’s handling of intellectual property created during commercially sponsored research relates to use of facilities that have been built or enhanced with

tax exempt bonds. The general rule is that the tax-exempt status of bonds issued for the construction of research facilities may be lost if the facilities are used for private, rather than public, purposes. Such a loss of tax-exempt status would have serious consequences for Penn and its bondholders.

### **Licenses.**

By sponsoring research at the University the Sponsor gains an opportunity to work closely with University investigators and early access to the results of the research. These benefits, in themselves, may be of significant value to the commercial sponsor. In addition, the Sponsor receives the first opportunity to negotiate with the University for a license (which may be exclusive) to inventions made during the research, but is not guaranteed a license on any particular terms until an invention or discovery exists. As is the case with inventions arising from research that has not been commercially sponsored, the University is entitled to market value for the license of technologies that arise from sponsored research activities.

In order to ensure that useful technologies are developed quickly and to avoid administrative burden, the option contained in SRAs should set reasonable time periods both for exercise of the option and for the negotiation of a license. The period in 7.4 is six (6) months which is the norm in SRAs. The option must provide that if an agreement is not reached during the negotiation period, the Sponsor's option shall expire and the University shall be free to license the technology to another entity. An option is preferable to a right of first refusal. In an option, failure to conclude a license agreement means that the option holder has no further rights, allowing the University to freely pursue other prospective licensees. Under a right of first refusal, if an initial negotiation with a Sponsor fails to produce an agreement, the University may pursue other licensees, but may not enter into an agreement with a third party without first offering the same deal to the original Sponsor. Such an obligation severely limits the University's licensing efforts and may effectively stall development of the technology. In cases where a right of refusal is crucial to closure of the SRA, it may be possible to consider, but generally should be avoided.

### **Research in Facilities Financed with Tax-Exempt Bonds.**

Because much research at Penn takes place at facilities financed with tax-exempt bonds, SRAs utilizing such facilities must be careful to avoid designation as "private business use" under IRS Revenue Procedure 97-14. IRS Revenue Procedure 97-14 stipulates that intellectual property created under an SRA cannot be licensed to the Sponsor on terms more favorable than would be offered to a non-sponsor without risking being categorized as "private business use". Under IRS guidelines only a nominal amount of "private business use" can be situated in such facilities without jeopardizing the tax-exempt status of the bonds.

The standard of "more favorable terms" would be met if the intellectual property being created, or licensed was valued prior to its creation, and if it were built into the SRA. Thus, the SRA cannot license intellectual property that has not yet been created at a set royalty rate or other set consideration, including a royalty-free license.

## Research in Facilities Not Financed with Tax-Exempt Bonds.

A primary objective of Penn is to promote the progress of science and technology and to assure that discoveries and inventions are utilized in ways most likely to benefit the public. In certain circumstances, this goal may be served by granting to Sponsors the right to request a nonexclusive license for internal research purposes. This would be granted to the sponsor of the research from which the invention resulted upon request after the relevant IP is developed. This avoids the problem of granting licenses to IP prior to valuation. The internal research use license could not be used for any commercial activities (sale or distribution of materials and products). Accordingly, the Sponsor would retain the options of royalty-bearing, non-exclusive or exclusive licenses for commercial purposes. The term of the right to request an internal research use license is limited to the term of the Agreement plus one year. This will ensure that the need to negotiate a commercial license continues and that the Sponsor exercises due diligence in evaluating the IP for commercial use.

The internal research use license may be included in the SRA when necessary to complete the agreement. Care should be taken to ensure that tax free exempt issues are not implicated and that the internal use license is acceptable to the PI. In general, the preferred position is still to limit the Sponsor to the normal 6-month option for any license.

Alternate License Language (to be used in Facilities not financed with Tax-Free Bonds):

Alternate 1

*In consideration of SPONSOR's funding of the SPONSORED RESEARCH, PENN grants SPONSOR a right to request a non-exclusive royalty-free license for internal research purposes only to PENN INTELLECTUAL PROPERTY disclosed to SPONSOR under the terms of the AGREEMENT. The term of the internal research purposes license shall be for the term of the AGREEMENT plus one year, any extensions to the original term notwithstanding.*

Alternate 2

*Upon written request, PENN will grant SPONSOR a non-exclusive royalty-free license for internal research purposes only to PENN INTELLECTUAL PROPERTY disclosed to SPONSOR under the terms of the AGREEMENT. The term of the license shall be for the term of this AGREEMENT plus one year thereafter, any extensions to the original term notwithstanding.*

Federal rights. It is important for Article 7.6 to make clear the rights that may be reserved to the Federal Government in University inventions.

Certain Bayh-Dole Requirements to keep in mind in negotiating SRAs:

- The Bayh Dole provisions apply to all inventions conceived or first actually reduced to practice in the performance of a federal grant, contract, or cooperative agreement. This is

true even if the federal government is not the sole source of funding for either the conception or the reduction to practice. The provisions do not, however, apply to federal grants that are primarily for the training of students and postdoctoral scientists.

- Upon election of title, the university must file a patent application within one year, or prior to the end of any statutory period in which valid patent protection can be obtained in the United States. The university must, within ten months of the U.S. filing, notify the agency whether it will file foreign patent applications. If the university does not intend to file foreign applications, the agency may then file on its own behalf in the name of the United States.
- If the university elects to retain title, the university must provide the government, through a confirmatory license, a non-exclusive, non-transferable, irrevocable, paid-up right to practice or have practiced the invention on behalf of the U.S. throughout the world.
- The university must submit periodic reports regarding the utilization of the invention as requested by the funding agency, but no more often than annually.
- **Universities may not assign their ownership of inventions to third parties, except to patent management organizations.** (Emphasis added.)
- Agencies may decide, for compelling reasons, that title should be vested in the federal government. Such decisions must be consistent with provisions within the Bayh-Dole Act and made in writing before entering into a funding agreement with a university.
- Under certain circumstances, the government can require the university to grant a license to a third party, or the government may take title and grant licenses itself (these are called “march-in rights”). This might occur if the invention was not brought to practical use within a reasonable time, if health or safety issues arise, if public use of the invention was in jeopardy, or if other legal requirements were not satisfied.

Alternate Language:

*Nothing in this Agreement shall be construed to restrict the right of Penn to transfer to the U.S. Government such rights as the Government may be entitled to under any agreement Penn has or will have with the U.S. Government, whether or not consistent with the terms of this Agreement.*

### Background Technology

Often in sponsored research proposals, Sponsors may need or want to utilize existing technology owned or controlled by the University. This is common in engineering research programs that develop improvements or enhancements to existing technologies and software. This scenario creates significant problems. For example, how can a Sponsor be given rights in technology that

it did not fund and/or was funded by other industrial sponsors or government? How is such technology to be identified?

Giving Sponsors rights in Background Technology should only be done for the most compelling of reasons: essentially, to allow for the sponsored research project to proceed. For ease of administration, Penn, when considering possible terms regarding a Sponsor's use of Background Technology, should limit use of such technology to applications that are necessary to conduct the sponsored research. Background Technology should not be permitted for commercial use. Background Technology should be limited to patents, copyrightable works, and trademarks owned and controlled exclusively by the University, and in existence prior to the initiation of a research project.

Possible clause:

*Penn grants to Sponsor a nonexclusive internal use license to Background Technology identified at the start of the Research Program which Penn is legally able to license to Sponsor. Background Technology means patent applications and patents of Penn outside the scope of the research proposal. It also includes computer software, including source code, application and object code, whether machine executable or not, or derivative works, thereof, outside the scope of the research proposal performed under this Agreement which Penn has the right to disclose, license or sublicense and is necessary to perform the research under this Agreement. Penn will use reasonable efforts to identify significant Background IP, including patents and pending patent applications, in conjunction with Sponsor and PI, that are necessary to conduct the research program. Penn will be held to a reasonable efforts standard, and nothing herein will require Penn to conduct a thorough search of its existing IP.*

## ARTICLE 8. CONFIDENTIALITY, PUBLICATION, USE OF NAME

### Publication.

First and foremost in importance among the policies that apply to SRAs are those dealing with confidentiality and publication rights. Other than a minimal period of delaying publication (customarily up to 2 or 3 months) for purposes of determining patentability, there can be no restrictions on the dissemination of any and all data, information, findings and conclusions generated in research at Penn. (Handbook for Faculty and Academic Administrators, Section III.A.4; Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 3.) Furthermore, the preferred position is that there be no restriction on any information received from the Sponsor that is necessary for the scientifically sound publication of the research or to allow the research to be produced by others. (Handbook for Faculty and Academic Administrators, Section III.A.4.) A faculty member or other investigator cannot waive these policies, even if they do not intend to publish.

Alternate publication clauses:

Alternate 1

*PENN shall have the right to publish the research results of the research program, but shall provide to Sponsor a copy of any proposed publication or presentation before submittal. PENN agrees to give good faith consideration to any comments or suggestions offered by Sponsor. In order that publication or presentation of research results not adversely affect Sponsor's patent interests, PENN shall delay submitting said paper for publication for a period of sixty (60) days from the time the proposed paper is submitted to Sponsor for review. In such event, Sponsor will notify PENN of its desire to delay submission, within thirty (30) days of receipt of the proposed publication or presentation.*

#### Alternate 2

*Penn and/or Investigator will be free to publish and present the results of the Study subject to the following conditions: Sponsor will be furnished with a copy of any proposed publication or presentation for review and comment forty-five (45) days prior to such presentation or submission for publication. At the expiration of such forty-five (45) day period, Penn or Investigator may proceed with the presentation or submission for publication; provided, however, that in the event Sponsor has notified Penn and/or Investigator in writing that Sponsor reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration applications, Penn and/or Investigator shall delay such publication or presentation for an additional forty-five (45) days or until the foregoing action(s) have been taken, whichever shall first occur, or (2) if Penn and/or Investigator are unwilling to delay the publication, Penn and/or Investigator will remove from the publication or presentation the information which Sponsor has specified it reasonably believes would jeopardize its intellectual property interests, provided this is done entirely at the discretion of the Investigator and does not involve information necessary for the scholarly integrity of the publication or presentation. Under certain circumstances, Sponsor may grant a shorter review period in writing. Penn and/or Investigator will assist Sponsor in obtaining reprints of Penn or Investigator's publication(s) resulting from the Study.*

#### Confidentiality.

Because of the negative impact confidentiality obligations have on the free communication of research results, the University's preferred position is to not undertake to keep proprietary information provided by the Sponsor confidential. (Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 2.e.).

In case a Sponsor wants to provide to the PI confidential information, the normal policy of the University is to allow the Faculty researcher the option of signing a confidentiality agreement under which a Sponsor may provide to the Researcher confidential information (Attachment B). Typically, the University will not agree to assume any institutional responsibility for maintaining the confidentiality obligations.

Under certain terms and conditions, Penn will accept Sponsor owned proprietary information where access will provide important background information for a research project. Like other

agreements, non-disclosure and confidentiality agreements do not bind the University unless an authorized official signs them.

Along with the free disclosure of scientific information, open identification of sponsors and actual sources of funding must be permitted in any Sponsored Research Agreement. (Handbook for Faculty and Academic Administrators, Section III.A.4.)

*Alternate Confidentiality Language:* (Use when Sponsor requires Penn to maintain confidential information. Under no circumstances should this be expanded to include oral disclosures unless reduced to writing within ten (10) days.)

*Institution will accept only information required for conduct and review of the Research study and which must be retained for Institution's records. All such information must be in writing and marked confidential. The obligations of confidentiality shall be in place for three (3) years following termination of this Agreement. Notwithstanding anything to the contrary contained in this Agreement, Sponsor Confidential Information does not include*

- (i) the study results and information regarding the study that are reasonably required by Scientific standards for publication of the study results, or any information that is necessary for other scholars to verify those results;*
- (ii) information that is the public domain at the time Sponsor discloses it to Institution or that thereafter enters the public domain through no fault of Institution;*
- (iii) information that was know to Institution before the date Sponsors discloses it to Institution or that becomes know to Institution through a third party having any apparent bona fide right to disclose information;*
- (iv) information that is independently developed by Institution personnel;*
- (v) information that is disclosed by Institution or its personnel in accordance with the terms of Sponsor's written approval;*
- (vi) Information that is required to be disclosed for compliance with any Federal, state or local law or regulation or required to be disclosed by a court of law or governmental authority.*

*If Sponsor desires to furnish any confidential information to Institution personnel, Sponsor may request such individual to sign a Confidentiality Agreement with Sponsor in an approved form such as the attached "Agreement between Sponsor and Principal Investigator concerning Sponsor Confidential Information". Institution bears no institutional responsibility for maintaining the confidentiality of any confidential information of Sponsor provided under such an individual agreement.*

### Secret Research.

One question that sometimes arises in SRAs with companies doing business with the Department of Defense, or other mission-oriented agencies is secret research. The University does not possess a government security clearance and can not as a corporate entity possess classified material. It is the policy of the University not to accept agreements that require access to classified data, require University employees to obtain security clearances, or restrict the

dissemination of the results. (Handbook for Faculty and Academic Administrators, Section III.A.4.)

### Use of Name

Sponsorship of research at the University does not entitle the Sponsor to use the University's name for promotional purposes. (Handbook for Faculty and Academic Administrators, Section VI.A.) It is essential that the standard provision 8.4 governing the sponsor's use of the University's name be included in every sponsored research agreement. The University of Pennsylvania as a nonprofit entity is generally required to place limitations on the use of its name by external organizations. Only with the explicit consent of the University may there be an endorsement or support for a commercial organization.

### ARTICLE 9. TERMINATION

Termination provisions are important as contracts often end prior to the planned date. The termination clause in this section allows for termination upon breach of the contract. A breach may occur when one party of a contract fails to carry out or perform its obligations, promise or a condition of an agreement or contract. If requested, it is certainly possible to agree that the Sponsor may terminate the contract with 30 days prior notice. However, this should be made mutual.

Provision 9.2 is important in maintaining Penn's rights to recover expenses incurred even though the contract may be terminated. Sponsors may argue that a terminated research program is of no value and they should not have to pay. However, Penn cannot be left "holding the bag" on expenses. Research programs are conducted on a best efforts level and there are no guarantees, including completion of a research project with useful results for the Sponsor. Efforts to make payments contingent on reports or results should be resisted. Since some outlays cannot be stopped once activated, it is important to retain the language indicating the non-cancelable obligations (such as salaries of students, Postdocs or technicians) will be charged against the Sponsor, in case of termination.

Under no circumstances should a contract contain a penalty for default, such as returning funds expended or covering Sponsor costs by the University. The University can not agree to any penalties for failure to make progress or to provide results which depend on the satisfaction of the Sponsor. Sometimes corporate sponsors will seek this type of language because such firm commitments on performance and guarantees are common in industry

Alternate language:

*This Agreement may be terminated by either party hereto by giving written notice to the other party ninety (90) days in advance of the specified date of termination. In the case of such termination, the University shall be reimbursed for all commitments made under the terms of this Agreement prior to such termination. In the event of termination of this Agreement before*

*expiration of its specified term, the Sponsor will also pay University costs associated with the orderly termination of the research program and any final reporting by University.*

## ARTICLE 10. DISCLAIMER OF WARRANTIES, INDEMNIFICATION

### Warranty Disclaimer.

All SRAs should include a disclaimer of warranties with respect to the research and any results (Section 10.1). The University undertakes research only on a best efforts basis and will not guarantee a successful outcome or any particular results. (Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 2.c.). Generally speaking, “best efforts” is the standard since state-of-the-art research is by nature unpredictable and without guarantee of success. Penn receives no fee or profit on its research with which to cover business risk. For this reason, and because it is inconsistent with the best efforts principle, Penn cannot accept contract provisions which establish firm performance deadlines, impose penalties for failure to complete the statement of work within the estimated cost, or provide for withholding of payment if the Sponsor is not satisfied with the results.

### Indemnification.

The University will not undertake to indemnify the Sponsor for any loss or damage suffered by the Sponsor in connection with the research, or incurred as a result of the Sponsor's use of the Research Results. Furthermore, the Sponsor should agree to defend and indemnify the University from claims or liabilities arising from the research, except those arising from the University's negligence or willful misconduct. (Policy Information for Potential Commercial Sponsors of Research at the University of Pennsylvania, Section 6). Care should be taken that the Indemnification from the Sponsor is as broad as the standard language and covers Sponsor's use of all IP, Research Results, or commercial development.

Language that limits the indemnification recovery of the University in terms of special, consequential, incidental or special damages should be carefully examined and generally rejected. If accepted, this should only apply to claims as between the Sponsor and Penn.

## ARTICLE 11. ADDITIONAL PROVISIONS

Article 11.1 is the non-assignment clause. This provision essentially precludes a Sponsor from assigning the agreement to another party (transferring the rights and obligations of Sponsor to another Company, for example). The prohibition is important to the University as it precludes transactions with Companies that are not known to Penn, may not be financially sound, or otherwise not convenient to conduct business with under an SRA (i.e. Company located in another country). Penn may agree that an assignment is possible to a third party which has purchased substantially all of the original Sponsor's assets without prior written permission.

## EXHIBITS

All of the exhibits or attachments referenced in the contract should be complete and attached to the agreement at the time it is submitted for approval. Exhibits often contain important and necessary information that assist in defining the obligations of the parties under the contract, the amount to be paid, or other important issues relating to interpretation of the contract.