



Rensselaer

**Sponsored Research Agreement Review
Procedures
Research Administration and Finance**

I. Introduction

All sponsored research agreements are negotiated by Research Administration and Finance (RAF). When negotiations are completed, the agreement may only be signed by the Director, RAF or other Institute officer who has a specific delegation of authority from the Board of Trustees of Rensselaer to sign agreements on the Institute's behalf.

A. Proposal Review and Preparation

A research proposal, following written submission to RAF by a Principal Investigator (PI), is reviewed by a RAF Grant Administrator in collaboration with the PI. All required documentation is prepared by the Grant Administrator with the assistance of the PI, including the budget and scope of work, and is submitted by RAF to the sponsor in a timely fashion.

Should the PI become involved in any preliminary discussions with the sponsor regarding proposed agreement terms, the PI should be aware of the basic elements of the Institute's policies concerning sponsored research agreements, particularly those reflected in the Criteria for Bayh-Dole Review, and the Criteria for IP Review, set forth in Part II below. The PI is also encouraged, at any stage, to contact RAF for assistance or to determine any current relationships or pertinent history with the sponsor that may be of use in the proposal development and agreement finalization. When discussions are held between sponsor representatives and Rensselaer faculty or staff, it should be understood that these are preliminary only and cannot bind Rensselaer.

If the proposal is accepted, the sponsor will submit for Rensselaer's approval and execution a research agreement, which will be managed under the procedure set forth below.

B. Summary of the Agreement Review Process and Expected Timelines

1. The agreement is received by RAF and immediately entered into an Agreement Log upon receipt. The PI is notified of receipt of the agreement by email.
2. Within 1 to 3 business days, the agreement is assigned to a Grant Administrator for initial review.
 - 3a. If the agreement contains Rensselaer-defined standard terms, RAF reviews the agreement with the PI and, if acceptable to the PI, executes the agreement. Standard processing time is approximately 7 business days.
 - 3b. If the award involves non-standard terms, further review and discussion is necessary. This process is coordinated by RAF, in active collaboration with the PI, and as necessary, representatives of the Office of General Counsel, and the Office of Technology Commercialization (OTC). This process involves the following steps:

- Entry of the agreement in a “Negotiation” log;
 - Review of the agreement to determine compliance with Bayh-Dole obligations; (*See* Criteria for Bayh-Dole Review, set forth below)
 - Review of the agreement for IP ownership, licensing and option issues; (*See* Criteria for IP Review, set forth below)
 - Review of the agreement for publication and export control issues, or for other problem contract clauses. (*See* Review of Policy and Compliance Issues and Review of Problem Contract Clauses, set forth below)
4. Weekly meetings occur at RAF with legal counsel and OTC, as needed, to discuss the status of all outstanding agreements. At each meeting, action items are determined for each unresolved agreement and memorialized in the Negotiation log. Email or telephone communication is made to the PI regarding new developments as they occur, and at least weekly.
5. RAF commences communications and negotiations with the agreement sponsor. If the negotiation process does not result in a mutually satisfactory agreement, RAF will confer with the PI, and if necessary, refer the matter to the Appeal Process.

C. Tracking the Process of Research Awards

An essential step in the process is to establish effective communications with members of the Rensselaer faculty and staff who are now, or may in the future become, involved in sponsored research. RAF has a detailed process in place to track research awards from the date that they are received in RAF until they have undergone the complete review process and are either fully executed or declined. The agreements are logged in when received and dates and pertinent information are recorded for each step of the process. RAF also has a detailed process in place to track: (1) which agreements are in the negotiation process; (2) what problems have been identified in the agreement; (3) what has been accomplished regarding each agreement at any given stage of the negotiation process; and (4) exactly when this information has been communicated to the PI. The PI is frequently informed of the status and of new developments as they occur and is copied on all correspondence related to the negotiation process. The PI is also welcome to contact the Director, RAF at any time, by phone or by email, to ascertain the precise status of pending agreements.

II. The Review Process in Detail

A. Initial Review

Agreements are received and logged in at RAF. RAF performs an initial review of agreements with assistance, if needed, from a representative of the Office of General Counsel. If the agreement, either as is or with changes as a result of initial negotiations, meets accepted parameters, RAF will review the agreement with the PI and, if acceptable, execute the award. However, if the agreement does not meet accepted parameters and initial contact with the sponsor reveals that it wishes to negotiate non-standard provisions, RAF commences a process to

negotiate terms in the agreement which will meet acceptable Institute parameters. This process involves the PI and as necessary, designated individuals from the Office of General Counsel and OTC.

B. The Negotiation Process

During the negotiation process the focus is on the mutual purposes of the sponsored arrangement: supporting research, educating students and facilitating technology transfer while keeping in mind the relevant policy considerations and regulatory concerns. Negotiations will consider the various stakeholder groups involved in the process. The interest and needs of the Institute from the perspective of a non-profit, tax-exempt research and educational institution are to be compared to the commercial, for-profit goals of the sponsor. Special needs, goals or requirements of governmental, nonprofit foundation or other institutional sponsors must also be considered, along with the history of the relationship between the parties. The negotiation relies on interpersonal relationships on both sides and frequent contact for status updates is essential to achieve timely results.

No contract can cover every contingency; therefore every agreement involves some level of trust between the parties. Negotiations should be conducted so as to continually build upon the level of trust that has been developed between the PI and the sponsoring agency, company or other party. Among other things, this means unfailing courtesy in dealing with negotiating counterparts, prompt responses to inquiries and counterproposals, the presumption that the counterpart is negotiating in good faith, continual mindfulness of the counterpart's objectives, and having as a goal a long-term relationship with the sponsor.

As stated above, RAF reviews the agreement under the Criteria for Bayh-Dole Review, the Criteria for IP Compliance, and the considerations set forth in the Review of Policy, and Compliance Issues, and the Review of Problem Contract Clauses, set forth below.

Following this review, RAF commences negotiations with representatives of sponsors which involve, as appropriate, the exchange of draft redlined agreements offering alternative contact language, and telephone and/or face-to-face negotiating conferences. RAF actively consults with the PI at all stages of the negotiation process. The negotiation process continues until an agreement which meets accepted parameters is made with sponsor or an impasse has been reached. The PI is advised and in the event of impasse, the PI or any interested stakeholder may request that the agreement be referred to the Appeals Committee.

C. The Appeal Process

If, following negotiations, the agreement still does not meet accepted parameters regarding policies of the Institute, the issue of whether to accept or reject the award is referred to appeal. RAF solicits the opinion of all interested stakeholders and refers these positions to appeal with the pertinent supporting documentation. The appeal will then promptly be heard and determined by an Appeals Committee comprised of the Vice President for Research, the Provost, and the General Counsel of Rensselaer.

D. Criteria for Bayh-Dole Review

1. The Legal Background

The Bayh-Dole Act imposes its requirements on a “*subject invention*” - an invention which is “first conceived or reduced to practice in the performance of work under a funding agreement [any agreement with a federal agency for research work].”

- Under the Act, the Institute must:
 - *report* a subject invention promptly to the federal government;
 - either *retain title* to a subject invention or turn it over to the government (and no one else); and
 - provide a *royalty-free, non-exclusive license* to the subject invention to the U.S. for government use.
- The Institute *cannot* assign title to “subject inventions” developed under federally sponsored projects to a third party such as an *industry sponsor*.
- Use of the broad phrase “conceived or reduced to practice” suggests that a *broad interpretation* of when a “subject invention” has been developed must be assumed, and therefore, any non-federal project that is (a) either *concurrent with* or *before or after* a federal project, and (b) has a Statement of Work which covers the *same or similar invention or technology*, should *also* be considered to be encompassed by the Act.
- If the non-federal project(s), although closely related, falls *outside the planned and committed activities of a government-funded project* and *does not diminish or distract from the performance of such activities*, inventions made in performance of the non-federally sponsored project are *not* subject to the Act.
- An *example* of this type of related projects which do not implicate Bayh-Dole concerns would be a federally sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology.
- The fact that an invention has been developed with the aid of an item of *equipment purchased with federal funds* does *not*, standing alone, implicate the requirements of the Act.

2. The Screening Process

RAF will review the agreement in accordance with the following:

- Gather PI input on *all* sponsored research projects (including consortia), *past or present*, which involve either (1) the *same or similar* Statements of Work or (2) the *same or similar* invention, patentable technology or research result(s).
- Discuss with the PI the relationship among all such projects, and document exactly *how* and *in what manner* the Statements of Work are related.
- Consider whether Bayh-Dole applies to the new award.
- Review *all* involved agreements for rights in intellectual property. If *all* involved agreements include intellectual property rights that follow Bayh-Dole (Institute retains IP ownership and no exclusive license rights are granted to a third party), the new project is compliant with Bayh-Dole obligations.
- If *any* of the clauses in *any one* of the projects do not follow Bayh-Dole, work with the PI to analyze the new project to determine:
 - (a) whether any non-federally sponsored work is *separate and distinct* from the federal work *and* does not *diminish or detract from* the performance of the federal work;
 - (b) whether administrative means are in place to maintain separate and distinct project tracking.
- If the answer to any of these questions is no, the new award may implicate the requirements of the Act and the terms of the agreement must be re-negotiated so as to ensure compliance with the Act.

E. Criteria for IP Review

1. Ownership of IP

The standard IP ownership clause acceptable to the Institute provides that any intellectual property conceived or reduced to practice in the performance of the research project by Rensselaer personnel will be owned by Rensselaer, IP conceived or reduced to practice by sponsor personnel will be owned by sponsor, and jointly invented IP will be jointly owned by Rensselaer and the sponsor in accordance with U.S. patent law.

The Rensselaer Intellectual Property Policy provides that Rensselaer will retain title to all intellectual property that its personnel develops in the course of performing a sponsored research agreement.

2. IP Licensing and Option Rights

A sponsored research agreement, in addition to an IP ownership clause, may give the sponsor a limited right to use technology that has been developed in the performance of the project. All license rights are subject to negotiation after review by RAF, in

consultation with the PI, legal counsel and OTC, of all pertinent factors, as described in more detail below.

Some of the types of license rights that a sponsor may request are set forth below:

- A “time-limited evaluation license” is typically a limited right provided to sponsor to internally use the IP developed in the performance of the research project for evaluation purposes only. The license is usually for a limited period of time (3 to 9 months) and patent costs may or may not be charged.
- An “internal use license” is a limited right provided to sponsor to use the IP developed in the performance of the research project for internal use.
- A “non-exclusive royalty-free license” (“NERF”) is a non-exclusive, non-transferable, royalty-free license to IP developed in the performance of the research project. It may be for internal use or commercial use and it may be limited to a field of use. It may be conditioned upon payment of patent costs and is memorialized by a separate license agreement negotiated after the IP is developed and after the sponsor agrees to pay patent costs in designated countries.
- Alternatively, or in addition to the above, a sponsor may also request an option right. Option clauses can grant the sponsor a time-limited exclusive or non-exclusive option to negotiate with Rensselaer for an exclusive or non-exclusive royalty-bearing license to IP developed in the performance of the research project.
- It is even possible that a sponsor might offer a non-exclusive, “cross-license” right to its own IP in partial or full consideration of the performance of the project and/or for license rights to IP developed by Rensselaer in the performance of the research project.

Rensselaer has developed a set of definitions for commonly used terms relevant to intellectual property matters and that glossary is posted at www.rpotechnology.com

The determination of what would be “reasonable” licensing and option rights for a sponsor is made on a case by case basis. Before such clauses can be negotiated, it is important to discuss with the sponsor their needs, what commercial rights they require, and why. RAF will also discuss these issues with the PI. The terms are tailored to suit the technology, its development status, the marketplace, investment required and other commercialization factors. Once the commercial needs and desires of the sponsor have been considered, as well as the amount of funding, the scope of work, and the collaborative nature of the project, the Institute is in a better position to make a judgment as to the appropriate rights to grant up-front in the research contract. The following issues will be considered:

- The amount of compensation for the sponsored research project (including facilities and administrative costs), the field of research, and the expected outcome of the

research – including an assessment of the value of what will come out of the research and how the granting of the license will affect the entire portfolio of the Institute.

- Whether the contemplated research project offers benefits that are above and beyond the stated compensation. Examples include: furthering research capabilities or institutional knowledge of Rensselaer through the use of sponsored funds; a grouping with sponsor would facilitate Rensselaer’s entry into new technology markets and/or funding opportunities; research funds would support additional graduate students.
- The anticipated effect of providing IP rights to the sponsor on other commercialization efforts by the Institute, i.e. whether giving commercial licensing rights to research results to the sponsor would have an adverse effect on Rensselaer’s ongoing or anticipated commercialization efforts.
- Whether the sponsored project involves confidential or proprietary technology of sponsor that would make the research results not independently capable of commercial development by Rensselaer.
- Whether alternate “no-strings” research support could be obtained from other sources.
- Whether any IP rights provided to sponsor could adversely impact further research or development activities of Rensselaer, the PI, and/or prospective or current licensees.
- Company’s contribution to the IP generation in terms of initial conceptualization of the research, background IP, and the joint development of the IP.
- The relative value of the subject invention, or anticipated invention, to the market value of the product or service that it may enhance.

3. Other Intellectual Property Considerations

- (a) Whether the project will affect background IP issues.

The issue of whether the award under review will ultimately implicate background intellectual property previously developed by the Institute, and if so, whether this request will affect either: (a) third party rights; or (b) ongoing or anticipated commercialization efforts need be reviewed and resolved.

- (b) Whether equipment, material, technology or resources used on the project involves third party rights.

The issue of whether any equipment, material or other resources that is contemplated to be used on the new project may involve intellectual property rights held by a third party should be carefully reviewed. Examples of such interests include:

- rights conferred to a provider of biological or other tangible material or technology under a Material Transfer Agreement (MTA) or an equipment loan agreement which provides to a third party license rights to Institute inventions;
- rights held by another institution or an individual faculty member in pre-existing technology or research tools used in the project that may cloud or impair Institute IP rights in technology and inventions resulting from the project;
- rights to third parties which may result if a researcher working on the project is a visiting scientist, an employee of a private company, or otherwise subject to a separate intellectual property agreement or policy which might provide that the work results of that researcher might be owned by a third party.

In each case, these rights must be identified and pertinent information must be forwarded to RAF for proper management.

(c) Whether third-party royalty obligations are present

Some sponsors (eg, NYSERDA) may impose “reach-though” royalty obligations, where the Institute may be ultimately required to pay that granting authority a back-royalty in the event that a technology developed with that funding is successfully commercialized. Therefore, the proposal announcement or solicitation, if available, should be reviewed to determine whether such an obligation exists, and if so, reported to RAF. In addition, just as with Bayh-Dole screening, the PI should review all contemporaneous or past awards involving the same or similar Statements of Work for such obligations and report them to RAF.

F. Review of Policy and Compliance Issues

Assuming that the Bayh-Dole, IP ownership, licensing and option rights issues are resolved, remaining issues may concern publication rights, export controls, and other regulatory issues that are triggered by the terms of the research agreement. These also must be addressed. The most prominent of them are the following:

1. Publication restrictions

It is the policy of Rensselaer that all of the results of a research project must be publishable and that persons associated with Rensselaer and engaged in research pertaining to the project must be permitted the unfettered right to present the research results at symposia, national, or regional professional meetings and to publish this information in journals, theses, or dissertations. Rensselaer will not accept any clause in a research agreement which imposes a restriction on this right. However, a sponsor may be permitted the opportunity to review a proposed publication in advance of its submission, presentation and/or publication and be allowed to either request removal of their

confidential information or be provided a short delay, generally not to exceed thirty (30) days, to allow for the filing of patent application(s) directed to patentable subject matter contained in the proposed publication or presentation.

2. Export control laws

Export control laws are federal laws which have been implemented by the U.S. Department of Commerce through its Export Administration Regulations (EAR), the U.S. Department of State through its International Traffic in Arms Regulations (ITAR), and the U.S. Department of Treasury through its Office of Foreign Asset Controls (OFAC).

The Department of State regulates export of technologies relating to military applications listed on the Munitions Controls List (MCL) under the International Traffic in Arms Regulations (ITAR).

The Department of Commerce regulates export of technologies relating to civilian applications listed on the Commerce Control List (CCL) under the Export Administration Regulations (EAR). This list is sometimes also called the “Dual-Use” list.

The Department of the Treasury administers the Office of Foreign Asset Control, (OFAC) which prohibits outright any transactions (including exports) to certain designated embargoed foreign countries, such as Afghanistan, Armenia, Azerbaijan, Belarus, Cuba, Iran, Libya, North Korea, Sudan, Syria, Tajikistan, and Vietnam without a (very rarely granted) license.

Significant criminal sanctions (including money and/or prison sentences for individuals) can apply in the case of violations. It is therefore essential that faculty and other researchers in departments, laboratories and centers understand their obligations under these regulations and adhere to them.

The term “export” in the regulation refers not only to technology leaving the shores of the United States (including transfer to a U.S. citizen abroad whether or not it is pursuant to a research agreement with the U.S. government), but also encompasses transmitting the technology to an individual other than a U.S. citizen or permanent resident *within* the United States. A disclosure to a foreign researcher or student in a laboratory *on campus here at the Institute* is therefore considered a “deemed export.” If research involves protected technologies, the ITAR and/or EAR may therefore require universities to obtain a license from the responsible federal agency before allowing foreign nationals to participate in the research or to receive any research related information – orally or in writing.

However, in the case of academic or research institutions, there is a very important exclusion from the requirements of export controls under ITAR and EAR – the exclusion for materials or information that is created as a result of fundamental research, the results of which are or are about to be in the public domain.

Fundamental research is generally defined under export control laws as basic or applied research in science and/or engineering taking place at an accredited institution of higher education within the United States when the resulting information is expected to become part of the public domain, i.e. when there are *no restrictions on publication* beyond those intended to protect pre-existing proprietary information or intellectual property rights.

It is *critically important* to recognize that research projects are *not eligible* for the fundamental research exemption if the federal government designates the research results as classified, administratively controlled, or otherwise restricted or sensitive.

Therefore, it is essential to seek the removal of clauses in sponsored research agreements which either: (1) seek to limit the performance of the work to US citizens only; or (2) seek to impose any restriction on publications other than a short delay to allow for the redaction of sponsor confidential information or an opportunity to secure appropriate intellectual property protection on the developed technology.

It is the policy of Rensselaer to uniformly remove all publication and access restrictions from sponsored research agreements so as to permit the Institute to claim that the resulting research results are excluded from export control requirements by asserting the fundamental research exclusion.

G. Indemnification, Warranties and Penalties

Sponsors may include certain provisions in agreements which need to be negotiated. Examples of these include the following;

- Indemnification clauses. These clauses purport to require the Institute to defend, at Institute expense, and hold sponsor harmless from and against any loss or damage which may arise out of the project or the use of any project deliverable. It may or may not be conditioned upon a finding that the Institute is negligent. It may strictly confine itself to personal injury or property damage liability or may encompass other kinds of damage, like lost profits, contract breach damages or other kinds of compensatory or incidental damages. It may include an obligation to defend and indemnify sponsor against resulting damages and liability if the research deliverables infringes third party patent or copyright rights. The Institute generally does not accept indemnification clauses.
- Warranty clauses. These types of clauses have the effect of representing and promising to a sponsor that certain work or products meet certain special characteristics: that they are of merchantable quality; fit for the use or purpose intended by the sponsor; free of defects; or meet certain technical standards or professional standards. These clauses may or may not promise to redo work that is found to be insufficient. These clauses sometimes also provide that the Institute is liable for damages for the cost of remedial work if the warranty is breached. The Institute generally does not accept these clauses and will, as necessary, insert language that the research work will be performed on a “best-efforts” basis and that any research results are provided “as-is” without representation or warranty.

- **Penalty Clauses.** These clauses provide that if the Institute does not finish the requested work, or finishes it in a manner that is unsatisfactory to the sponsor, that the Institute may be liable to the sponsor for costs and damages, which may include a set amount of damages (“liquidated damages”), or the amounts incurred by the sponsor to remedy allegedly inferior work or to have it re-performed. The Institute generally does not accept these clauses

- **Accounting/Financial Clauses.** RAF also reviews agreements to determine whether they meet accepted Institute parameters regarding financial effort and other reporting requirements, invoicing and payment terms and other financial issues. These financial issues include the following:
 - a) US Dollars as currency of payment;
 - b) Acceptable frequency of interim invoices and reports;
 - c) Acceptable frequency of payments;
 - d) Acceptable terms for final invoicing and reports, and due date;
 - e) Standard level of detail required for invoicing;
 - f) Acceptable terms for effort reporting;
 - g) Acceptable terms for re-budgeting authority;
 - h) Acceptable termination provisions; and
 - i) Detailed contact information for financial reporting requirements.