

STATEMENT OF PRINCIPLES AND GUIDELINES GOVERNING SPONSORED RESEARCH AND SCHOLARLY ACTIVITIES AT IOWA STATE UNIVERSITY

INTRODUCTION

In pursuit of excellence in the areas of learning, discovery, and engagement, Iowa State is committed to establishing effective partnerships with external sponsors who support research and scholarly activities. In managing these relationships, the university must abide by certain regulations to preserve the integrity of the educational, research and scholarly activities of the university and its employees and students while also ensuring that the objectives of sponsored activities are met. Iowa State seeks collaboration with a broad range of sponsors to bring synergistic and diverse opportunities to the University. Stated below are the guiding principles used by Iowa State University when establishing sponsored research and scholarly activities.

Contact the Ames Laboratory's Office of Industrial Outreach and Technology Administration for procedures and guidelines for initiating third party sponsored research agreements independent of ISU (www.external.ameslab.gov/oipp).

1) PUBLIC DISCLOSURE.

Principle. Iowa State University is committed to the appropriate disclosure of the results of its sponsored activities. In collaborative efforts, the review and input of all collaborators is desired and welcome to ensure that the proposed disclosure does not reveal sponsor confidential information or negatively impact patent filing.

Guidelines. ISU is obligated to publicly disclose the results of its sponsored activities. The review and input of all collaborators and sponsors is encouraged and may be contractually required. Review is necessary to ensure that public disclosure does not reveal sponsor confidential information or negatively impact patent filing. However, ISU faculty/staff members are responsible for the final decision on what is publicly disclosed. It is important to remember that public disclosure includes posters, abstracts, verbal presentations, published articles, and web sites and may include funded grant applications and email messages.

2) CONFIDENTIALITY

Principle. Iowa State University encourages open discussion and exchange of ideas. At times, however, it may be necessary to provide an umbrella of protection to preserve or maintain the confidentiality of disclosed information. Exchange of information under confidentiality must respect the confidentiality of information disclosed to or by ISU and preserve the ability to publish results without undue restrictions or delays.

Guidelines. Confidentiality language is necessary to protect intellectual property and/or trade secrets and prevent the early release or misappropriation of ideas and data. The presence of confidentiality language facilitates professional discussion and collaboration and assists in commercialization efforts. Confidentiality can be a *one-way* transfer of information from Sponsor to ISU, from ISU to Sponsor, or a *mutual* exchange of information between the parties. Mutual language is preferred because it permits the free exchange of information between parties and all parties' interests are protected.

ISU considers research results confidential *only* on a temporary basis in order to seek intellectual property protection. ISU recognizes the confidential information provided by businesses under sponsored agreements and agrees not to make this information public.

3) INTELLECTUAL PROPERTY

Principle. The Iowa State University Research Foundation, Inc. (ISURF), on behalf of Iowa State University (ISU), retains ownership of intellectual property invented or created by ISU employees. As a public institution, ISU is committed to the transfer of innovations from the university to the public to be used for the benefit of society.

ISU is guided by the Internal Revenue Code for all sponsored activities and the principles of the Bayh-Dole Act for projects supported in whole or in part by agencies of the Federal government. For projects supported by non-Federal sources, ISU is mandated by the Iowa Board of Regents, under the patent policy, to manage intellectual property in a manner consistent with the Bayh-Dole Act.

Guidelines. The objectives of ISU's intellectual property policies are to manage inventions and other innovations in the best interests of the university, the public, the inventor/creator, and the sponsor. Intellectual property includes any invention, discovery, technology, scientific or technological development, computer code, copyrightable work, integrated circuit mask work, trademarks, service marks, trade secrets, and tangible research property (e.g. germplasm, vectors, software, and new material samples).

Appropriate intellectual property language in sponsored agreements is necessary to allow the timely review and protection of any intellectual property and permit public disclosure of results without undue delay. The Office of Sponsored Programs Administration (OSPA) consults with the Office of Intellectual Property and Technology Transfer (OIPTT) in developing and negotiating intellectual property language within sponsored agreements. The interests of the sponsor in intellectual property may be met by providing an option to negotiate a license to the resulting intellectual property. The option language provides a specified time period for the sponsor to review the intellectual property and make a determination as to their interest in negotiating a license.

ISU does not claim any rights to Sponsor's proprietary information or materials and works with each Sponsor to ensure specific needs are met. Please refer to the Confidentiality and Material Transfer sections for additional information.

ISURF, on behalf of ISU, retains ownership of intellectual property invented or created solely by legal inventors and authors who are employed by ISU or, as a result of collaborative efforts, jointly with other legal inventors and authors not employed by ISU. OIPTT in collaboration with ISURF, is the ISU office responsible for marketing and licensing intellectual property and for reviewing intellectual property language within sponsored agreements. Neither ISU nor ISURF claims copyright rights to traditional scholarship produced without significant university support.

The employee's obligation to assign intellectual property to ISURF, for the benefit of ISU, can be found in the Faculty Handbook, the Office Procedure Guide, and the "GoldSheet" signed by faculty in acceptance of sponsored funding.

Please refer to the intellectual property handbook for additional information (www.iastate.edu/~isurf). Additional information regarding the legal basis for ISU's intellectual property position may be found at www.iastate.edu/~isurf.

4) MATERIAL TRANSFER

Principle. Iowa State University is committed to the appropriate receipt and transfer of biological and non-biological materials to facilitate collaborative efforts. Material transfer language is necessary to document provider's ownership in the materials, recipient's rights to possession, and related obligations associated with use of the materials, and to ensure that materials remain available for other purposes.

Guidelines: For the protection of proprietary property, material transfer language is strongly recommended by ISU for biological and non-biological materials sent to or received from external collaborators, including, but not limited to, other universities, research foundations, industries, and special interest groups. Language addressing the transfer of materials applies to all materials, independent of the existence of intellectual property.

USDA and CDC have issued rules regarding transfer of potentially hazardous biological materials (see Compliance section) and enforcement of export controls and traffic in arms regulations. For materials that fall under these rules, an MTA is required.

The Office of Sponsored Programs Administration (OSPA) reviews and negotiates material transfer language for the receipt and transfer of materials that are *not* related to ISU intellectual property disclosures. Iowa State

University Research Foundation (ISURF) reviews and negotiates material transfer language for the transfer of materials related to ISU intellectual property disclosures.

ISU and ISURF are both signatories to the Uniform Biological Material Transfer Agreement (UBMTA) published in the Federal Register on March 8, 1995. Use of this agreement is only appropriate with those organizations listed as signatories. Please refer to http://www.autm.net/index_ie.html and click on the "Agreements" link for a listing of all signatories and the document.

5) RESEARCH COMPLIANCE

Principle. Iowa State University is committed to ensuring that research conducted on or off campus, including collaborative research with third parties, is in compliance with University, local, state, federal and sponsor regulations. All research protocols involving biohazards, animals or human subjects conducted at ISU and ISU laboratories utilizing radioactive devices and/or materials require institutional review and approval.

Guidelines. ISU's Research Compliance Officer oversees campus-wide research compliance including four committees responsible for reviewing compliance. Additional information can be found at http://grants-svr.admin.iastate.edu/vpr/research_compliance/.

Committee On Animal Care (COAC). All research involving the use of live vertebrate animals must be reviewed and approved by the COAC prior to initiation of research. To receive Public Health Service (PHS) funding and comply with the federal Animal Welfare Act, ISU must have an established animal care and use program. The program must include 1) a properly constituted and functioning Institutional Animal Care and Use Committee; 2) self monitoring procedures; 3) a veterinary care program; 4) a program for personnel training; 5) a program for management, environment and housing for animals; and 6) appropriately maintained housing and support facilities. Please see www.iacuc.iastate.edu for additional information.

Institutional Review Board (IRB). All research involving the use of human subjects must be reviewed and approved by the IRB prior to initiation of research. As part of ISU's federal wide assurance (FWA) with the Office of Human Research Protection, the IRB reviews studies involving human research participants. As agreed in ISU's FWA, all projects must be reviewed regardless of funding source. Research involving human subjects encompasses biomedical and clinical studies; social and behavioral research, such as surveys; exercise and nutrition studies; learning experiments; etc. Please see <http://grants-svr.admin.iastate.edu/vpr/humansubjects> for additional information

Biohazards and Public Health Committee (BPHC). All research protocols involving biohazards must be reviewed and approved by the BPHC prior to initiation of research. As required by the May 7, 1986, Federal Register and amendments, the BPHC serves as the institutional biosafety committee in all matters involving recombinant DNA, human or animal pathogens, or biological toxins. The BPHC also reviews the biological and public health and safety programs at ISU and for assisting in the development of policies that comply with federal, state, and local regulations and recommendations. Please see www.ehs.iastate.edu/bs/bphc.htm for additional information.

Radiation Safety. All laboratories using radioactive materials or radiation-producing devices must be reviewed and approved by the Radiation Safety Committee (RSC) prior to initiation of research. The principal function of the RSC is to assist in establishing ISU policy for the safe use of radioactive materials and radiation-producing devices that comply with federal, state, and local regulations. Please see www.ehs.iastate.edu/rs/rsc.htm for additional information.

Compliance HelpLine. For questions or concerns about research compliance, the Office of Research Compliance has a confidential help line (515-294-9264), which is answered only by the Research Compliance Officer.

6) TERMINATION

Principle. Iowa State University is committed to the successful completion of all collaborative agreements. Upon termination, issues to be addressed may include resolution of financial considerations, transfer of deliverables,

submission of appropriate reports, property/equipment disposition, and management of any material or confidential information that has been exchanged.

Guidelines. Upon termination of any agreement, coordination with the appropriate ISU administrative office is needed for the resolution of financial considerations, transfer of deliverables, submission of financial, technical, and other reports requested by the sponsor, property/equipment management, and appropriate management of any material or confidential information that has been exchanged. These conditions apply in the case of early termination for cause, early termination for convenience, or expiration of the natural term of the agreement. Termination for cause occurs most often when either Party has breached a term of the agreement. Early termination for convenience may occur when the project is not progressing as expected, through no fault of either Party.

Written notification of termination is required from Sponsor.

Natural Termination. The date of natural termination should be specified in the agreement and will dictate the financial parameters under which project closeout takes place. Confidential Information and Materials should be returned or destroyed, except for the retention of one copy of Confidential Information (and occasionally, a sample of the Material) for archival purposes to show compliance with the agreement. Equipment purchased may need to be returned depending on the terms of the agreement.

Early Termination. In the event of early termination, notification as required by the agreement is necessary. Written notification sent certified or registered is preferable. The termination date dictates the financial parameters under which project closeout takes place. Outstanding obligations such as personnel appointments and equipment purchases need to be addressed, as well as submission of reports and deliverables. Every effort should be made to cancel ongoing obligations. Confidential Information and Materials should be returned or destroyed, except for the retention of one copy of Confidential Information (and occasionally, a sample of the Material) for archival purposes to show compliance with the agreement. Equipment purchased may need to be returned depending on the terms of the agreement.

7) AUTHORIZED SIGNATURES

Principle: All documents that obligate Iowa State University personnel, facilities, intellectual property, or other resources in any way require an authorized ISU signature to ensure that appropriate policies, procedures and legal requirements have been addressed and a signature from the principal investigator indicating he/she understands and agrees with the terms and conditions.

Guidelines: With regard to sponsored agreements, intellectual property management, and other collaborative agreements, the responsibility for compliance resides with designated ISU signatories. The Office of Sponsored Programs Administration (OSPA) is the designated signatory for documents related to externally funded projects and other collaborative agreements, such as confidentiality, material transfer, and professional services agreements. The ISU Research Foundation (ISURF) is the designated signatory for documents such as confidentiality, material transfer, research, and license agreements related to intellectual property disclosed to that office. When applicable, signatures from both OSPA and ISURF are required. These offices coordinate this activity.

In addition to the required, authorized ISU signature, the Principal Investigators (PIs) sign agreements. This signature provides acknowledgement that the PI has accepted the terms and conditions of the agreement and approves the scope of work. Department and College procedures govern whether the Deans, Directors, and/or Department Chairs should also sign the agreements. The PI is responsible for informing all persons working on the project of the terms and conditions of the agreement and their obligation to comply.

The Sponsor will also have an authorized signatory to the agreement. Very often, the sponsor's authorized signatory is *not* the technical contact for the agreement.

8) CONFLICT OF INTEREST

Principle. As a land-grant institution with a strategic plan focused on learning, discovery, and engagement, Iowa State University employees traditionally interact with individuals outside the university. ISU is committed to ensuring all appropriate parties are fully aware of any personal, professional, contractual, or purchasing conflicts that may influence collaborative efforts. Internal procedures exist to manage and resolve potential conflicts of interest and commitment.

Guidelines. For the ISU policy on Conflict of Interest, please see sections 3 and 10 of the Office Procedure Guide (www.adp.iastate.edu/vpbf/prod/docs/opg/opg.htm) and/or section 8.2.3 of the Faculty Handbook (www.provost.iastate.edu/handbook/2002/fh-8.pdf).

A potential conflict of interest occurs when a faculty or staff member is or may be in a position to influence the university's business, research, or other decisions in ways that could lead to personal gain. This potentially occurs when a faculty member contracts research to his/her university lab from his company, when faculty consult with a company on research they are also conducting in their lab, or employ graduate students to work for the company (see below).

ISU employees must take appropriate measures to document potential conflicts of interest. Annually or when a potential conflict arises ISU employees must fill out a form notifying the university. Examples of potential conflicts include, having an equity interest (ownership) by the ISU employee or the employee's immediate family in a company that does business with ISU, or a research involvement with a company that sponsors ISU research in the ISU employee's lab and pays the ISU employee personally to be on a scientific advisory board.

For example, very early in the process of a faculty/staff member or a member of his/her immediate family starting a new company that may do business with ISU, the department head(s), the associate dean(s) of the appropriate college(s) and the Office of the Vice Provost for Research and Advanced Studies, should be notified. A conflict-of-interest form must be filled out and filed with the Office of the Vice Provost for Research and Advanced Studies, identifying the nature of the conflict. A disclosure meeting will be held to determine proper operating procedures. The initial meeting will discuss the nature of the conflict and will determine if an oversight committee is necessary. The three most common types of conflict of interest are:

Contracting Research Back To Your Own Lab. The most common type of conflict is the situation where a faculty or staff member starts a company based on a technology he/she developed and then wants to form a collaborative research agreement between the company and his/her lab at ISU. A faculty or staff member cannot act as both the company representative and the ISU principal investigator on collaborative research agreements – this is a conflict of interest! Instead, a different grant administrator is chosen as the principle investigator for the research. In many cases, the department head acts as the grant administrator.

Employing Graduate Students in Your Company. Graduate students can be employed in the ISU employee's company; however, a faculty member cannot serve as both the major professor and the supervisor of the student in the company's organization.

Sales To ISU. Another situation that causes a potential conflict occurs when a faculty or staff member is involved with a company that wants to sell a product or service to ISU. Board of Regents' approval is required in those cases and is coordinated through Purchasing.

Another type of Conflict of Interest can occur if you begin discussing similar sponsored projects, including confidential information, with two or more companies about similar efforts. In this situation, it is likely that something will be learned from one company or project that would be of benefit to the other company. Because the companies are likely in competition with each other, this will most likely result in negative consequences for both the university and the companies.

9) BUDGETS & AWARDS.

Principle. Iowa State University conducts sponsored research and sponsored scholarly activities on a cost-recovery basis. The Office of Sponsored Programs Administration (OSPA) administers gifts, grants and contracts in order to

comply with the terms and conditions specified by the sponsor; meet state and federal reporting requirements; recover all project costs, both direct and indirect; and provide accountability for these funds.

Guidelines. ISU must accurately identify and classify all costs associated with sponsored research and sponsored scholarly activities. OSPA is the unit responsible for providing institutional approval of proposals, which include budgets, submitted to external sponsors in addition to the management and administration of grants and contracts awarded to ISU. External sponsors include organizations such as local, state, or federal government agencies, private foundations, associations, and corporations.

When external sponsors wish to fund a project for an amount different than originally proposed, it may require a revised budget and scope of work to be reviewed and approved by OSPA.

The acceptance and processing of awards may require additional information from the sponsor or investigator to determine the nature and intent of the award.

10) OVERHEAD

Principle. Iowa State University is committed to the full recovery of all project costs, including overhead, for all externally funded projects. The basis for ISU's overhead rate is in accordance with OMB Circular A-21 "Cost Principles for Institutions of Higher Education" and negotiated with the Department of Health and Human Services.

Guidelines. Please refer to ISU's Indirect Cost Policy, <http://grants-svr.admin.iastate.edu/vpr/indirectcost.html> and Indirect Cost (overhead) rate information, <http://grants-svr.admin.iastate.edu/vpr/indirectcostrate.pdf>

Definition of Overhead

Overhead costs are broad categories of costs narrowed down into two categories, facilities and administration. "Facilities" is defined as depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements, operation and maintenance expenses, and library expenses. "Administration" is defined as general administration and general expenses, departmental administration, sponsored projects administration, accounting, purchasing, and all other types of general administrative expenditures not listed specifically under one of the subcategories of Facilities.

Background

Overhead costs represent the expense of doing business that are not readily identified with a particular grant, contract, project function or activity, but are necessary for the general operation of the sponsored project at ISU. Overhead costs are actual costs such as heat, light, accounting, purchasing, phones, clerical support, and maintenance that cannot be easily identified as direct costs in a project budget. Therefore, overhead rates are used to distribute those costs to internal units that support sponsored projects.

Federally funded research is a prominent feature at all major American research universities today. The negotiation of overhead costs is based on the principles outlined in the Office of Management and Budget Circular A-21 and negotiated with the Department of Health and Human Services. Universities across the country apply their federally negotiated rates to all sponsored activities.

11) GOVERNING LAWS AND REGULATIONS

Principle. Sponsored projects at Iowa State University are governed by University policy and any combination of the following: the laws of the State of Iowa, which include the Code of Iowa and the Iowa Administrative Code, the Federal Government, and/or agreements and guidelines of the sponsor.

Guidelines. Please refer to the university web site, www.iastate.edu; OSPA, www.ospa.iastate.edu, (515) 294-5225; and/or OIPTT, www.public.iastate.edu/~isurf, (515) 294-4740 for issues related to governing laws and regulations.

12) CONTACT INFORMATION

Questions or comments regarding the above information can be addressed to any of the following:

Office of Sponsored Programs Administration

Thane Peterson, Director
2207 Pearson, Rm. 15
Ames, IA 50011
Ph: 515-294-5225
grants@iastate.edu
www.ospa.iastate.edu

Office of Intellectual Property and Technology Transfer & ISU Research Foundation, Inc.

Kenneth Kirkland, Executive Director
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310 Lab of Mechanics
Ames, IA 50011
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Office of the Vice Provost for Research and Advanced Studies

Lisa Lorenzen, Director of Industry Relations
2810 Beardshear
Ames, IA 50011
Ph: 515-294-0926
llorenze@iastate.edu
www.biotech.iastate.edu/Industry_resources.html

For matters involving research compliance (Section 5): Office of the Vice Provost for Research and Advanced Studies Research Compliance Office

Diane Ament, Research Compliance Officer
2810 Beardshear
Ames, IA 50011-2810
Ph: 515-294-3115
Fax: 515-294-7288
HotLine: 515-294-9264
dament@iastate.edu

For non-ISU research matters involving the U.S. Department of Energy's Ames Laboratory: Ames Laboratory, Office of Industrial Outreach and Technology Administration

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