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## INDUSTRY SPONSORED RESEARCH AT USU

Utah State University (USU) is dedicated to fulfilling its engagement mission by supporting economic development. Consequently, increased focus is being placed on developing partnerships with technology-based companies. Negotiation of industry agreements is becoming more complex, especially as federal regulations increase for both higher education and business.

This document has been prepared to help potential industrial sponsors understand some of the guiding principles the university follows in negotiating contracts and performing research. It provides information that will help collaborators understand university research opportunities, constraints and alternative approaches that have been successfully employed by USU and its peers.

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## Regulatory & Policy Considerations

### a. Research Appropriate to USU's Mission

The quality of USU's educational experience is enhanced by the active participation of faculty and students in research. Sponsored research, whether basic or applied, is encouraged when it is of such a nature and scope as to enhance the learning and engagement programs of USU. It is inappropriate for the university to undertake activities such as product development and routine testing; however, the USU Research Foundation may have the ability to provide development support that would not be deemed "basic" or "fundamental" research under federal guidelines.

### b. Use of Research Facilities

Under federal law, research performed in USU facilities which were built or are operated using tax-exempt bonds must be related to the university's educational mission. There are restrictions against using publicly financed facilities for private business purposes (see IRS Procedure 97-14), or for performing work that would be in competition with for-profit taxable entities. However, under certain circumstances, USU may enter into a Specialized Service Agreement through which a third party could use university equipment and facilities with reimbursement at an established, auditable rate.

### c. Publications

In order to fulfill its learning, discovery and engagement objectives, and to meet statutory requirements related to its tax-exempt status, USU research must be disseminated on a non-discriminatory basis. The university cannot undertake studies in which results cannot be freely published or which require prior approval of the sponsor. USU's policy allows for a brief review period by the sponsor in order to identify and remove any sponsor-proprietary information, or to protect any intellectual property that would be disclosed in the publication.

One of the unique characteristics of the university in comparison to a corporation is that its mission includes the involvement of students in performing and disseminating the results of research. Such dissemination is central to USU's mission, and is necessary for it to maintain important exemptions under federal guidelines including exemption from taxation and from export controls. National Security Decision Directive 189 (NSDD-189) exempts universities from the requirement to seek export licenses when performing "fundamental research," defined as, "Basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community."

When the university is asked to perform research under a subcontract where the prime contract is with a federal agency, NSDD 189 should be taken together with

DoD Instruction 5230.27, which states that "the mechanism for control of information generated by DoD-funded contracted fundamental research...is security classification." It is clear that publication is appropriate. 5230.27 states even more explicitly that "it is a DOD policy to allow the publication and public presentation of unclassified contracted research results."

While USU does not accept classified research and does not accept publication restriction clauses, the USU Research Foundation is equipped to accept classified contract work, and may be able to perform proprietary research under which research results are controlled by the sponsor. The decision guiding placement of a contract in the Foundation is made by the Foundation's Board of Trustees, based on the type and classification of the research to be performed.

d. Involvement of Foreign Nationals

It is the intent of the university to extend to all registered students, faculty and staff the opportunity to participate in every aspect of the university's mission, including the conduct of research. Where the participation of an individual might be deemed an export under U.S. law, the university will seek a license from the Department of Commerce or the Department of State, as required. An individual who is otherwise qualified to participate in a research project will not be excluded from a project based on his/her race, nationality, religion or country of origin.

e. Institutional and Individual Conflicts of Interest

Conflicts of interest arise in any situation where an individual or an entity with a primary interest - such as fulfilling the university's mission - also has a secondary interest which may come into conflict with that primary interest. Under federal guidelines, universities are required to reduce or eliminate such conflicts. A common management strategy used to minimize the potential for bias arising from conflicts of interest is to have the conflicted individual step away from one of the conflicting interests. USU seldom makes such divestiture mandatory, but some arrangements involving outside interests - including some consulting and technology licensing - may require an increased level of oversight of the research project in order to protect the individual, the institution, and the sponsor.

f. Human Participants in Research

Research conducted at USU or by USU investigators that involves the use of human subjects requires review by USU's Institutional Review Board (IRB), or by a review body approved by the IRB. USU maintains a Federal Wide Assurance (FWA) with the Department of Health and Human Services. Under the FWA, USU is committed to conducting human research in accordance with 45 CFR 46 (The "Common Rule") and the ethical principles outlined in the Belmont Report. Any human research contracted to USU, either by a government entity or by a private sponsor, or subcontracted by USU to an industrial sponsor, must adhere to these guidelines. Policy guidance is provided in USU Policy #308, Research with Human Participants. The Human Subjects Research website (<http://irb.usu.edu/>) provides more information on requirements for safeguarding human participants and contact information for

the IRB. These requirements include strict adherence to regulatory guidelines, laws and the policies of USU. All research must be conducted in accordance with the protocol reviewed and approved by the IRB, or by the entity authorized by the IRB.

The Office of Compliance Assistance, which has responsibility for implementing USU's Human Research Protection Plan, may be contacted at (435) 797-8305.

Clauses to be included in industry contracts, when human research is to be conducted:

#### HUMAN RESEARCH PROTECTIONS

All human research work to be conducted by USU under this contract shall be subject to the Federal Wide Assurance held by USU with the Department of Health and Human Services, and shall adhere to federal, state and local regulations and guidance governing those activities, and to university policy. Human research conducted at or by USU is regulated under 45 CFR 46, and is conducted in accordance with USU Policy #308, "Human Participants in Research." No human research may begin under this agreement until approval for the study has been obtained from the USU Institutional Review Board (IRB), or by such other body as the IRB may direct.

All applications submitted to the IRB and all informed consent documents to be used in connection the human research under this contract shall address care for research-related injuries and harms in a manner acceptable to the IRB.

If [SPONSOR] has responsibility for monitoring human research performed under this contract, a plan shall be developed and made a part of this agreement by reference that ensures that [SPONSOR] reports to USU any findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval of the study. Said plan shall include provisions for communication of results to study participants when participant safety or medical care may be affected. Communication with participants shall be aligned with the Standard Operating Procedures of the IRB, Chapter x.x, which are hereby included in this agreement by reference.

The requirements set forth in this section shall flow down to all subcontractors involved in performing work associated with this contract.

#### g. Intellectual Property

The Bayh-Dole Act of 1980 gives universities the opportunity and responsibility to manage inventions made using federal funding. Through the Utah Employee Inventions Act, USU also claims the rights to inventions made by university employees. All intellectual property agreements are therefore negotiated with the Technology Commercialization Office (TCO) which has been given the responsibility for managing USU's technology portfolio. The objective of the TCO, a unit of the USU Research Foundation, is to make USU technologies available for the public good through licensing and equity-based ventures.

## II. Agreements with Industry

### a. Entering into Contractual Relations with Industrial Partners

Faculty members at USU are not authorized to commit the university to contractual relationships. To establish an agreement with an industry sponsor the USU Principal Investigator (PI) must submit a proposal to the Sponsored Programs Office (SPO) for review and approval. Once the proposal has been approved internally, it is sent to the company by the PI, along with a copy of the appropriate USU agreement template. A sponsored programs administrator within SPO will then have lead responsibility for negotiation of the terms and conditions of the agreement. The PI also works with the SPO representative to clarify the scope of work and technical matters.

When negotiations have been completed, the agreement will be signed by the Director of the SPO as signatory for the university. The SPO will notify the PI, the department and university accountants of the new contract, and an account will be set up that is unique to that contract.

Proposed modifications of the terms or conditions of a contract or grant, including changes in the scope of work, a change in the project's total cost, a renewal or an extension must be submitted to the sponsor by the SPO. Similarly, any correspondence from the sponsor that may affect the agreement must be sent to the SPO so that the university can take appropriate and timely action.

### b. Intellectual Property Licensing

Standard terms and conditions of USU research agreements include clauses dealing with the disposition of intellectual property that arises as a result of the research. Whenever a technology is disclosed under these clauses, responsibility for management of the university's technologies rests with the TCO. In some cases conditions will exist that will require the involvement of the TCO during the initial negotiation of the research agreement. This may be the case, for example, where the sponsor or the university has rights to a pre-existing technology that will be used in the execution of the research. Whether triggered by a new discovery or a pre-existing technology, TCO will assign a licensing officer to participate in negotiations involving intellectual property including inventions, copyrightable materials including software, tangible research properties and other technologies. Additional agreements (as discussed in section IV, below) may be required to sufficiently define the relationship between the sponsor and the university with regard to intellectual property.

In cases where a research agreement is being contemplated with a company that is a licensee of USU technology, an additional step is required for the management of the conflict of interest that often arises, based on the university investigator's potential interests in both the company and the university. The Office of Compliance Assistance provides support in these cases to ensure that the interests of the university, the PI and the sponsor are protected.

### III. USU Standard Research Agreements

#### a. Cost Reimbursement Agreement

USU's Cost Reimbursement Agreement is the most frequently used agreement for industry-sponsored research. USU conducts research on a "reasonable efforts" basis. Because leading edge research is unpredictable by nature, and because as a not-for-profit institution USU receives no fee or revenue to cover business risk, the university does not accept contract provisions that would impose penalties for non-delivery or delivery that does not comply with a certain fixed deadline. The USU Research Foundation, however, may accept contracts with fixed deadlines and deliverables. The Cost Reimbursement Agreement allows for the recovery of actual direct and indirect costs experienced by USU in carrying out the research program contemplated in an associated Scope of Work.

#### b. Fixed Price Agreement

The purpose of the fixed price agreement is to provide for a price determined by the PI that will cover all costs for performing the research proposed by the PI and approved by the sponsor. This contract type places upon USU maximum risk and full responsibility for all costs and resulting profit or loss. If the cost of the research goes above the stated price given to the sponsor, USU will assume all additional costs. If the cost of the research is less than the stated price, the PI may keep a portion of such residual in an account for future research endeavors. This type of agreement provides maximum incentive for USU to control costs and perform efficiently and imposes a minimum administrative burden upon the parties involved in this type of agreement.

#### c. Teaming Agreement

The purpose of the teaming agreement is to provide means for USU to work in collaboration with an industrial sponsor during the preparation, submittal and evaluation of a proposal. The outcome of the teaming arrangement would potentially be a subcontract between the sponsor and the university under a prime contract to be held by the sponsor. Under normal circumstances, each of the parties to the agreement would bear their own costs associated with development of the proposal materials. Unless specifically disallowed by the awarding agency, if the proposal were accepted USU would expect to enter into an agreement with the sponsor to carry out the work it proposed.

#### d. Master Agreement (with associated Task Agreements)

In situations where collaboration with a sponsor is expected to be ongoing, and where the development of the research plan is fluid, a Master Agreement is established with a sponsor so that as new tasks are identified they can be performed under the terms and conditions established under the Master Agreement. Generally, the sponsor will be charged for the actual direct and indirect costs experienced by USU in performance of each task.

#### e. Specialized Services Agreement

The University may provide services to sponsors that are not generally available in the private sector. In such cases, set fees shall be pre-determined for the use of facilities and equipment that may be available for such services. Companies should be aware that USU's tax-exempt status is dependent on it focusing its resources on scientific research, which by definition does not include "activities of a type ordinarily carried on as an incident to commercial or industrial operations." In general, USU does not accept this type of project.

### IV. Other Agreements Related to Research

#### a. Confidential Disclosure Agreements

In certain situations, sponsors and/or the university may have proprietary information which, in order to effectively complete the research, must be shared with the other party. Confidential disclosure of such information may be accomplished when the conditions and term of the disclosure are carefully defined in the Confidential Disclosure Agreement (CDA). The TCO has responsibility for negotiation of outgoing CDAs that disclose USU confidential information. A sponsored program administrator in SPO will be able to direct the sponsor to the appropriate TCO representative. Incoming CDAs that anticipate disclosure of sponsor proprietary information are negotiated and approved by SPO.

#### b. Material Transfer Agreements

When tissue cultures, cell lines, or other biological materials are required for sponsored research to be conducted, the exchange of the materials, whether into or out of the university, will be governed by a Material Transfer Agreement (MTA). All outgoing MTAs must be approved by the TCO, and the sponsored programs administrator will be able to direct the sponsor to the appropriate representative from that office to facilitate the negotiation of the MTA terms and conditions. Any incoming MTAs containing only sponsor materials must be negotiated and approved by SPO.

#### c. Intellectual Property Agreements

##### i. General Technology License and other agreements

The TCO has been assigned the responsibility for licensing of all USU technologies to third parties. A variety of agreement types have been designed that allow licensing rights to USU technologies to interested companies, and a TCO representative will be familiar with each technology available for license.

ii. Development Option

In some cases, a technology which is still under development will be of interest to a research sponsor. In these cases, an option to license future rights in a technology under development is also available from USU.

iii. Inventor Release

All employees of USU are required to assign rights to inventions made at the university, or using university resources, to USU. This ensures that sponsors can confidently work with the TCO to acquire rights to technologies developed under sponsored programs. However, work performed by faculty members through independent consulting may result in the intellectual property associated with the work being assigned to the company. For more information concerning technology licensing, contact the TCO at the USU Research Foundation (435-797-9607).