

## CHAPTER EIGHT: Industry Awards and Agreements

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Industry research is supported at the University of Louisville by awards to and agreements with the University of Louisville Research Foundation, Inc. (ULRF). While all such agreements and awards must adhere to the policies of the University, there are special considerations inherent in the acceptance of these awards. For example, industry sponsors might not limit spending to particular budget categories as Federal sponsors typically do. Industry sponsors might give the Principal Investigator/Project Director (PI/PD) more latitude in expending funds, provided the final project stays within budget. Additionally, clinical trials typically are budgeted on a per-patient basis rather than a per-category basis common to Federal agencies.

Industry sponsors generally have a less formal proposal review process but the process from research project inception to final contract/agreement may be more iterative than the processes found in research funded by governmental agencies and non-profit foundations. Most industry research begins with a non-disclosure agreement (NDA) that allows the PI/PD to review confidential information (i.e., a clinical protocol) in order to determine if he/she wishes to participate in the study. A draft contract, budget and budget justification/scope of work (if required) are then submitted for review. After negotiation, an acceptable agreement is executed and the research study may begin.

### *8.1 Industry-Sponsored Agreements*

The University of Louisville encourages interaction with the private sector. These interactions are essential to the vitality of the University and the community it serves and are recognized as an integral part of the University's mission and goals.

An agreement outlining the responsibilities of University personnel, ULRF, and the industry sponsor must be in place prior to beginning work on a research project. The agreement must contain basic understandings, including an agreed-upon budget and statement of work, an agreement on the University's ability to publish, and clarification of the ownership of intellectual property.

PIs/PDs should be familiar with the following guidelines and convey them accurately to a potential industry sponsor during preliminary discussions. Additional information can be found on the [Clinical Contracts Division For Sponsors](#) website and on the [Office of Industry Engagement](#) website to assist in this process. Sharing this basic information promotes better

understanding between the parties and allows negotiations to proceed smoothly. The following considerations are important when dealing with industry sponsors:

- 1) The statement of work should be detailed enough to allow a clear understanding of the research project and the expected deliverables (i.e., technical reports or prototypes).
- 2) A fixed time period, with provisions for extension or renewal of the project, should be included. Provisions for mutual termination, such as would occur with the departure of a PI/PD or other unforeseen circumstances, should be stated.
- 3) The full costs of the project, including recovery of associated faculty and staff salaries and of the appropriate University indirect cost rate, must be included in the budget.
- 4) The University may neither warrant nor guarantee research products, but will use reasonable efforts consistent with good scientific practices. Reasonable changes in research direction by the PI/PD should be allowed, and if the change is significant allowances for a cost adjustment included.
- 5) For projects established with expenses invoiced on a milestone basis, some initial payment (typically 20-25% of the project budget) should be made at the time of execution of the agreement. Final payments should not exceed 20-25% of the total project budget.

When the above guidelines are followed, the final agreement should be mutually beneficial to the University and to the Sponsor. A sample [Sponsored Research Agreement](#) is available for review.

Some industry sponsors obtain Funding from federal agencies and will subcontract a portion of the research to the University. This is referred to as “Federal flowthrough.” The F&A rate for research work funded by the Federal government via industry must be the appropriate F&A rate for Federally funded projects. SBIR and STTR proposals fall into this category. Additionally, such projects generally must conform to Federal standards for the proposal, possibly requiring a formal budget justification, line-item budget, or other such standards as outlined in the solicitation from the granting agency.

## ***8.2 Clinical Study/Trial Agreements***

Clinical trial agreements provide for testing of a drug or device on a human subject. In addition to the considerations for industry sponsored agreements, certain considerations apply to clinical trial agreements:

- 1) Clinical trials expose the investigator and the ULRF to potential legal action by third parties claiming to have been harmed as a result of participating in the study. Industry sponsored clinical trial agreements must therefore include an appropriate liability/indemnification clause.

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- 2) Clinical trials carry a risk for unanticipated adverse effects, injuries, illnesses or reactions and Sponsors are expected to pay for any injuries to subjects resulting from the use or application of the Sponsor's investigational drug or device in the study.
- 3) The agreement must contain a statement that indicates that the sponsor supports the principles of the Belmont Report, the Helsinki Report, Good Clinical Practices, or some statement indicating that the Sponsor supports accepted research practices that protect human subjects in research.
- 4) The agreement must allow for the maintenance of the confidentiality of patient records and personal information and be in conformity with applicable Federal and state privacy laws and regulations (e.g. HIPAA and KRS 61.931).
- 5) The Sponsor must use protected health information in accordance with the HIPAA-compliant research authorization and conduct the study in accordance with the provisions outlined in the Informed Consent.
- 6) The agreement should address the ability for the University and/or PI/PD to publish study results.

Some clinical trials are operated or coordinated by a Contract Research Organization (CRO). The CRO may execute the agreement with the University and manage the trial on behalf of the Sponsor. It is important to determine which entity, the CRO or Sponsor, will be making the payments to the University and include this information on the appropriate transmittal form. If a CRO is involved, typically a separate letter of indemnity (LOI) is obtained from the Sponsor.

The University of Louisville has agreed to the use of the Accelerated Confidential Disclosure Agreement (ACDA) and to use the terms of the Accelerated Clinical Trial Agreement (ACTA) for industry-sponsored, multi-center trials. See [Accelerated Research Agreements \(ACDA and ACTA\)](#) for additional information.

### ***8.3 Service Agreements***

Service Agreements enable the conduct of a specific procedure, often on materials supplied by the Sponsor. For example, running a Sponsor-supplied pharmaceutical compound through a published and established animal model, or analyzing a Sponsor-supplied material sample with a scanning electron microscope both constitute service projects. Essentially, Service Agreements are best used when the Sponsor is requesting data from established methodologies or procedures, and not investigation or analyses. The Agreement should reserve the right to use the results for academic and research purposes, including publication of overall results or methods.

Financial considerations include recovery of the full direct costs and the appropriate F&A rate. Rates must be competitive with costs assessed by commercial organizations for comparable work and may be subject to unrelated business income tax.

The University's Service Agreement templates are available on the [CCD website](#) and on the [OIE website](#).

#### ***8.4 Equipment Loan Agreements***

If a University researcher wishes to participate in a research program involving the loan of equipment (i.e., hardware or software) for research use, the agreement should minimize ULRF risk and liability and should define the responsibility for maintenance and the disposition of the loaned equipment. The department should contact the [University's Risk Management](#) office to address risk of loss and insurance.

#### ***8.5 Material Transfer Agreements***

Material Transfer Agreements (MTAs) are necessary when a researcher at UofL either receives or sends materials (often biological, but possibly chemical or other) from or to an outside party without an exchange of funds. MTAs are stand-alone agreements, used when the transfer is not included in an existing agreement (for example, most clinical trial agreements provide for the provision of study drug to UofL). For more information on MTAs, visit the [Office of Technology Transfer](#) website.

#### ***8.6 Special Considerations for Budgeting of Industry Awards***

Industry awards may be budgeted by category like most Federally sponsored awards, or they may provide only an overall budget without categories. If an industry sponsor does not require categorical budgeting, the PI/PD should notate this in the budget section of the appropriate transmittal form (e.g., Proposal Clearance Form (PCF) or Multi Institutional Research Application (MIRA)).

08/11/2015