

CHAPTER ONE: General Information

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Purpose

This handbook provides assistance and guidance to faculty and staff who are involved in the preparation of proposals to and in the administration of awards received from external sponsors. When the University of Louisville Research Foundation, Inc. (ULRF) accepts extramural support as the limited agent for the University of Louisville, the Institution also accepts the responsibility of complying with the sponsor's terms of agreement as well as various regulatory and compliance requirements. The intent of this handbook is to define responsibilities for the preparation, review, management and reporting requirements of sponsored programs that will allow the Institution to comply with these agreement terms and compliance requirements. The responsibilities of principal investigators/project directors (PIs/PDs), chairs, deans, and the Office of the Executive Vice President for Research and Innovation are outlined in the handbook.

The handbook includes links to University policies and procedures, including the Red Book, relevant Board of Trustees policies and other guidelines important to those involved in sponsored programs. Suggestions for revisions or requests for clarification should be submitted to the [EVPRI Service Account](#).

1.1 Definition of Sponsored Activities

Sponsored Activities must be cleared through the appropriate unit within the Office of the Executive Vice President for Research and Innovation to assure appropriate treatment in the

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University financial and administrative systems. This handbook provides guidance to assist in determining which agreements fall into this category.

Sponsored agreements generally include two or more of the following characteristics:

- Investigator-initiated project that specifies proposals for research, training, or service activities to an outside entity;
- The proposed project binds the University to a specific scope of work;
- A formal agreement for a specified term is established, with the agreement between the University of Louisville Research Foundation, Inc. and the sponsor. This agreement is signed by an authorized signatory of ULRF and the sponsoring agency and may be a grant, contract, cooperative agreement, fee-for-service arrangement or other sponsored agreement;
- The project involves disposition of property, whether tangible or intangible, that may result from the project (e.g., equipment, records, inventions, copyrights, or rights in data);
- The sponsor has written policies concerning Facilities & Administrative (F&A, also referred to as indirect or overhead) cost recoveries. Projects normally requiring F&A cost recovery must be established by either the Office of Sponsored Programs Administration, the Office of Industry Engagement or the Clinical Contracts Division. The absence or prohibition of F&A costs does not automatically preclude the award from being considered a sponsored agreement;
- Progress, technical, final reports or other deliverables are required, excluding stewardship reports on gifts;
- Invoices and/or financial reports are required;
- Unexpended funds are returned to the sponsor or a fixed price contract has been negotiated;
- The proposed activity involves human subjects, laboratory animals, radiological hazards, biohazards, or recombinant DNA.

Roles and Responsibilities for Research

Numerous offices and individuals have responsibilities related to both the processing of proposals, and in conducting and reporting sponsored projects once they are funded. The following includes a high-level description of the primary offices and individuals responsible for the administration of sponsored programs. Additional details can be found on the [Office of Sponsored Programs Administration \(SPA\)](#), [the Office of Industry Engagement \(OIE\)](#) or the [Clinical Contracts Division \(CCD\)](#) web sites.

1.2 Offices of the Executive Vice President for Research and Innovation

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[The Mission](#) of the Office of the Executive Vice President for Research and Innovation (EVPRI) is to:

- Promote and support research, scholarship, and creative activities;
- Assist faculty and staff in obtaining intramural and extramural support;
- Serve as an advocate for the value of research in an educational setting;
- Enhance the vitality of campus-based research and to encourage its use to enrich education, enhance technology transfer and serve the community.

The Office of the EVPRI contains the offices of Clinical Contracts Division, Export and Secure Research Compliance, Human Subjects Protection Program, Industry Engagement, Research Integrity Program, Sponsored Programs Administration, and Technology Transfer. A complete listing of the staff is provided on the [EVPRI's staff](#) website. The individual units and their responsibilities are described below.

1.3 Office of Sponsored Programs Administration – Development Division

The [Office of Sponsored Programs Administration - Development Division](#) is responsible for identifying funding opportunities and providing support to faculty and staff during the proposal development process. The staff is trained to assist researchers in identifying potential funding sources, writing competitive proposals and submitting proposals to the sponsoring agency. The following is a list of the services the Development Division provides:

- Train researchers in grant writing;
- Provide updates on legislative policies;
- Assist investigators in seeking funding for research;
- Provide individual seminars for academic departments;
- Assist with proposal editing;
- Coordinate multi-investigator proposals;
- Provide information on current sponsor guidelines and grant application forms;
- Provide contacts with federal funding agencies;
- Assist with cooperative activities with industry, government, and other institutions;

- Provide oversight for limited submission proposals.

1.4 Office of Sponsored Programs Administration – Grants Division

The [Office of Sponsored Programs Administration - Grants Division](#), is the official authorized signature authority for sponsored program agreements from governmental and non-profit sponsors. The office provides guidance and assistance relating to grants management from proposal development through award closeout. Responsibilities of the office include:

- Provide guidance and assistance in completing external applications consistent with the policies and procedures of both the University and sponsors;
- Provide administrative support for budgetary matters related to sponsored programs activities, including the review of budgets and approval of applications for submission to external sponsors;
- Negotiate final terms for government and not-for-profit grants, contracts, subagreements, and other agreements from governmental and non-profit sponsors;
- Administer and monitor the individual and departmental research incentive funds (RIF) as well as the Executive Vice President for Research and Innovation matching research funds;
- Establish chartfields and set up budgets for government and non-profit awarded grants, contracts, subawards, cooperative and other related agreements;
- Process budget revisions and no-cost extension requests;
- Act as a reference for questions regarding cost allowability, cost sharing, indirect costs, and award transfers;
- Issue final patent and invention reports to federal agencies after review and approval from the project director and the Office of Technology Transfer;
- Maintain the official database of all proposals and awards for the University of Louisville and ULRF;
- Assist and consult with other units under the EVPRI, such as the Clinical Contracts Division and the Office of Industry Engagement.

1.5 Office of Sponsored Programs Administration – Financial Division

The [Office of the Sponsored Programs Administration – Financial Division](#), is responsible for the following:

- Financial monitoring of sponsored research accounts. Responsibility for this activity is

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shared with PIs/PDs and Unit Business Managers;

- Preparing periodic billings and reports in compliance with sponsored agreements;
- Assessing cash position on cost reimbursable accounts;
- Drawing federal funds to reimburse research expenditures;
- Preparing periodic and final financial reports. This activity is completed in coordination with PIs/PDs;
- Distributing, collecting, and monitoring effort reports;
- Closing sponsored accounts in the financial system.

[A Guide to Which EVPRI Offices Handle Which Projects](#)

1.6 Clinical Contracts Division

The [Clinical Contracts Division \(CCD\)](#) is the official authorized signature authority for sponsored agreements that are clinical in nature from industry sponsors and research involving human subjects such as clinical trials. In the clinical (human subjects) area, CCD provides guidance and assistance for PIs/PDs obtaining funding from for-profit/industry sponsors and works with faculty and staff in arranging contractual agreements with industry. CCD supports faculty and staff in the negotiation and approval of agreements associated with these sponsored activities. The division is charged with the following responsibilities:

- Review, negotiate and approve industry-sponsored clinical research agreements, clinical service agreements and other clinical agreements, including clinical trial agreements;
- Assist coordinators and faculty investigators with the interpretation of obligations of clinical sponsored agreements and applicable state and federal regulations;
- Establish accounts (chartfields) and set up budgets for industry-sponsored research projects involving human subjects;
- Process budget revisions and no-cost extension requests;
- Review, negotiate and approve confidentiality/non-disclosure agreements for confidential clinical information being disclosed by sponsors to the Institution;
- Assist and consult with other institutional units including the Office of Sponsored Programs Administration and the Office of Industry Engagement.

[A Guide to Which EVPRI Offices Handle Which Projects](#)

1.7 Office of Industry Engagement

The [Office of Industry Engagement](#) promotes the creation and development of relationships with industry, and supports corporate-sponsored partnerships with our faculty, staff, and students. OIE works closely with its sister offices, in particular, the Office of Technology Transfer (OTT). OIE actively approaches companies large and small, both locally and globally, to promote capabilities of our researchers and research centers, and to better understand and address industry needs. OIE staff reviews and negotiates funding proposals and various types of non-clinical agreements with corporate entities. OIE also assists our faculty and staff who partner with small businesses to apply for SBIR/STTR grants - competitive funding programs administered by the federal government for stimulating technological innovation. The office is charged with the following responsibilities:

- Review, negotiate and approve [industry-sponsored research agreements, service agreements and other research agreements](#) for nonclinical projects;
- Review, negotiate, and approve industry-sponsored research agreements, service agreements and other research agreements for nonclinical projects;
- Assist coordinators and faculty investigators with the interpretation of obligations of sponsored agreements and applicable state and federal regulations;
- Establish accounts (chartfields) and set up budgets for industry-sponsored nonclinical research projects, grants, contracts, subawards, cooperative, and other related agreements;
- Process budget revisions and no-cost extension requests;
- Monitor processing of proposals and awards for nonclinical projects sponsored by for-profit industry sponsors;
- Process and approve proposals for investigators submitting proposals to businesses submitting Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) proposals;
- Review, negotiate, and approve confidentiality/non-disclosure agreements for confidential nonclinical information being disclosed by sponsors to the Institution;
- Assist and consult with other institutional units, including under the EVPRI, such as the Office of Sponsored Programs Administration and Clinical Contracts Division.

[A Guide to Which EVPRI Offices Handle Which Projects](#)

1.8 Office of Technology Transfer

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The [Office of Technology Transfer \(OTT\)](#) facilitates the innovation, development, and commercialization of technologies generated at the University of Louisville. OTT also promotes entrepreneurship through the cultivation of a collaborative ecosystem consisting of regional and national partners. OTT's responsibilities include:

- Assessing and protecting Intellectual Property assets (e.g., patents, copyrights, etc.) held by the University;
- Implementing sound commercialization strategies and conducting license negotiations;
- Monitoring and implementing patent and licensing agreements to ensure compliance with financial and administrative requirements;
- Reviewing and negotiating material transfer agreements, data sharing, and nondisclosure agreements on behalf of University researchers;
- Providing information, assistance and guidance to faculty, staff, students and academic units to promote the disclosure and development of intellectual property;
- Functioning as the liaison between the University and its inventors with patent counsel, government officials, companies, other institutions, licensees, etc.

1.9 Research Integrity Program

The [Research Integrity Program](#) is responsible for maintaining broad oversight and knowledge of all integrity and compliance issues relating to the conduct of research at the University. The Research Integrity Program carries out its responsibilities by:

- Monitoring and making recommendations concerning ethical, professional, federal, state and other (e.g. international) policies or requirements related to research, whether proposed or in effect;
- Creating and maintaining the University of Louisville's research integrity and compliance infrastructure;
- Educating and training researchers in the responsible conduct of research and research compliance;
- Implementing policy and procedural requirements relating to research misconduct.

1.10 Human Subjects Protection Program

The [Human Subjects Protection Program](#) (HSPPO) is responsible for protecting the rights, dignity, and welfare of human research subjects by adhering to the principles of the Belmont

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Report and the regulations of the Common Rule (45 CFR 46), the Food and Drug Administration, and any other Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. The Program is committed to advancing responsible conduct in research, promoting ethical treatment of human research subjects, and ensuring that the right of every human being to voluntary, informed consent to research is respected.

The program's responsibilities include the following:

- Reviewing all research involving human research subjects before it is initiated;
- Conducting periodic reviews of research involving human subjects;
- Suspending or terminating research not conducted in accordance with the regulations;
- Working to protect the rights and welfare of human research subjects by fostering and advancing the ethical and professional conduct of persons and organizations that engage in research with human participants;
- Providing education to researchers, research staff and the public; and
- Serving as the Privacy Board for the University of Louisville that approves waivers of authorization in accordance with the HIPAA privacy rule.

The staff of the Human Subjects Protection Program Office (HSPPO) is responsible for providing administrative support for the University Institutional Review Boards (IRBs) and HSPP.

1.11 Principal Investigator/Project Director

The Principal Investigator (PI) or Project Director (PD) is ultimately responsible for the effective and compliant management of all scientific, fiscal and programmatic aspects of a sponsored research project. These responsibilities include, but are not limited to the following:

- Preparing proposals and ensuring that all information provided is accurate and correct;
- Ensuring that reviews by [compliance committees](#) are completed as required;
- [Submitting proposals through an appropriate institutional office](#);
- Ensuring the accuracy of information submitted as a part of the proposal clearance/pre-award process and completing the appropriate transmittal forms (e.g., PCF, MIRA) for processing proposals and other sponsored activities;
- Justifying any special support costs, as well as costs normally charged as F&A but included

as direct costs in a proposal;

- Ensuring that anyone involved in the design, conduct or reporting of the project has complied with the University COI Policy and disclosure requirements prior to incurring costs on an award;
- Making certain that all charges on sponsored projects are reasonable, allocable, allowable and consistent with University cost accounting practices via a monthly reconciliation process;
- Requesting timely approvals for budget changes in compliance with sponsor policies;
- Submitting all sponsor-required project deliverables and reports in a timely manner;
- Monitoring the activities of subrecipients.

1.12 Qualifications for Principal Investigators/Project Directors

The University of Louisville will allow anyone who has a formal relationship with the University to act as a PI/PD on an extramurally funded project. That relationship can be as faculty, staff, postdoctoral fellow or adjunct faculty. The individual must also meet all agency guidelines for eligibility. In addition, the individual must meet all of the University of Louisville eligibility requirements in order to serve on IACUC, IRB, and/or IBC approved protocols. In instances where a conflict of interest in research exists, an individual may be restricted from serving on an approved IRB, IACUC and/or IBC protocol depending upon the nature of the conflict and its required management.

If an individual is not a permanent employee of the University of Louisville, the term of appointment must be sufficient in length to complete the proposed project. Such individuals must obtain formal approval by the appropriate chair and dean to submit the application in the name of the University with assurances that adequate resources and supervision will be available for the project to be successful should it be funded.

1.13 Unit Business Manager (or Designee)

While ultimate responsibility for the financial oversight of any sponsored research agreement remains with the PI/PD, other individuals, such as a unit business manager, typically provide assistance with budgetary and compliance issues. The following list includes responsibilities this individual may have:

- Preparing the proposal budget by providing accurate information about the status of the PI/PD and his/her institutional base salary and related fringe benefits;
- Reviewing proposal documentation to ensure that purchasing regulations are met;

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- Providing budgetary oversight for the project;
- Assisting the PI/PD in managing the financial compliance aspects of the project;
- Ensuring that charging practices are consistent with university and sponsor guidelines;
- Reviewing proposals for appropriate treatment of direct and indirect charges;
- Preparing financial documents such as rebudgeting forms, cost transfers or salary distribution;
- Documenting cost sharing;
- Recording program income;
- Monitoring the effort certification process;
- Assisting the Office of Sponsored Programs Administration – Financial Division with resolving overdrafts;
- Providing information for financial reports;
- Reconciling sponsored accounts to the financial system on a monthly basis per the University’s Account Reconciliation Policy.

1.14 Department Chair/Dean

Department chairs and deans both play a role in the research function of the University. The department chair’s responsibilities include the following:

- Assuring departmental personnel are available to support PIs/PDs;
- Approving proposal components, including the technical aspects and the budget;
- Reviewing all proposals to confirm consistency with the mission of the department and compliance with the policies and procedures of the University and the sponsor;
- Encouraging and supporting appropriate education in responsible conduct of research. The dean’s responsibilities include the following:

- Ensuring proper oversight by the department chair;
- Approving proposals prior to submission to the cognizant office within the Office of

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the Executive Vice President for Research and Innovation.

The following are responsibilities shared by both the department chair and dean:

- Assisting in identifying and developing plans to manage significant conflicts of interest;
- Ensuring that departmental resources necessary to carry out the project have been identified;
- Indicating commitments and approvals on the appropriate transmittal forms (e.g., Proposal Clearance Form [PCF] and Multi-Institutional Research Application [MIRA]);
- Department chairs and deans are responsible for proper conduct and handling of fiscal matters.

1.15 Compliance Committees

Numerous committees and individuals have responsibilities related to research compliance. Research compliance activities are summarized in [Chapter 9](#) of this Research Handbook.

9/11/2015