University of Louisville

Research Handbook

Table of Contents

Chapter 1: General Information

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 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 the Office of Sponsored Programs Administration. 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.

1.2 Offices of the Executive Vice President for Research and Innovation

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 Commercialization EPI-Center, Export and Secure Research Compliance, Human Subjects Protection Program, Research Development & Strategic Initiatives, Research Integrity Program, and Office of Sponsored Programs Administration. A complete listing of the staff is provided on the EVPRI's office/staff website. The individual units and their responsibilities are described below.

1.3 Research Development & Strategic Initiatives

The Research Development & Strategic Initiatives Office (RDSI) 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 RDSI 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

The Office of Sponsored Programs Administration, is the official authorized signature authority for sponsored program agreements from governmental, non-profit and industry sponsors. The office provides guidance and assistance relating to grants management from proposal development through award closeout. In the clinical (human subjects) area, OSPA provides guidance and assistance for PIs/PDs seeking funding from sponsors and supports faculty and staff in the negotiation and approval of agreements associated with these sponsored activities. OSPA promotes the creation and development of relationships with industry, and supports corporate-sponsored partnerships with our faculty, staff, and students. Working closely with the Office of Commercialization EPI-Center, OSPA 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. OSPA staff reviews and negotiates funding proposals and various types of agreements with corporate entities. OSPA 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.

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; including proposals to

government, nonprofit sponsors, industry, and businesses submitting to Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs;

- 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;
- Review, negotiate and approve industry-sponsored research agreements, service agreements and other agreements, including clinical trial agreements and agreements for nonclinical projects;
- 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 accounts (chartfields) and set up budgets for all grants, contracts, subawards, cooperative and other related agreements;
- Process budget revisions and no-cost extension requests;
- Review and approve compliance with federal regulations concerning agreements and the issuance and monitoring of subrecipient agreements;
- Assist coordinators and faculty investigators with the interpretation of obligations of sponsored agreements and applicable state and federal regulations;
- Act as a reference for questions regarding cost allowability, cost sharing, indirect costs, and award transfers;
- Review, negotiate, and approve confidentiality/nondisclosure agreements for confidential information being disclosed by sponsors to the Institution;
- Issue final patent and invention reports to federal agencies after review and approval from the project director and the Commercialization EPI-Center;
- 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.

1.5 Office of Sponsored Programs Administration – Financial Administration Core

The Office of Sponsored Programs Administration – Financial Administration Core, is responsible for the following:

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

1.6 Commercialization EPI-Center

The Commercialization EPI-Center facilitates the innovation, development, and commercialization of technologies generated at the University of Louisville. The EPI-Center also promotes entrepreneurship through the cultivation of a collaborative ecosystem consisting of regional and national partners. The EPI-Center'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.

1.7 Research Integrity

The Office of Research Integrity is responsible for maintaining broad oversight and knowledge of all integrity and compliance issues relating to the conduct of research at the University. The Office of Research Integrity 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; Creating and maintaining the University of Louisville's export control program;
- Monitoring and making recommendations concerning international research engagements and disclosure of such activities
- to funding agencies;
- Maintaining the University of Louisville Conflict of Interest in Research program; and
- Implementing policy and procedural requirements relating to research misconduct and non-compliance.

1.8 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 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.

1.9 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 the Office of Sponsored Programs Administration;
- 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 named in the project documentation is compliant with the University COI Policy and disclosure requirements prior to proposal submission and throughout the life cycle of the project;
- 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.

1.10 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's UofL research activities may be modified depending upon the nature of the conflict and 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.

1.11 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;
- 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 Administration Core 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.

1.12 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 Office of Sponsored Programs Administration.

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

- Assisting in implementing and monitoring plans to manage identified 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.

1.13 Compliance Committees

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

Chapter 2: Pre-Proposal Activities

Finding Funding Opportunities

The Office of the Executive Vice President for Research and Innovation maintains a comprehensive website with links to an array of information designed to support all of the research and creative activities within the University community. This includes service units under the EVPRI, links useful in locating funding opportunities, electronic forms, workshop schedules, research-related policies, and compliance support. The site also includes links to shared scientific resources and research centers and institutes at the university.

2.1 Search Process & Resources

Sponsor agency grant programs and program priorities change from year to year; therefore, the Office of Sponsored Programs Administration (OSPA) has the responsibility to remain current in its knowledge about possible funding sources. Links to several searchable databases are listed on the Funding Sources and Notification Services site. This contains a variety of information concerning public and private funding agencies, agency application forms, proposal writing information, and grant deadlines.

The most comprehensive of these databases is the Sponsored Programs Information Network (SPIN). SPIN is a grant program database of over 6000 programs covering all disciplines that makes searching for funding sources convenient. Searches for information can be performed using keyword, program type, sponsor, and deadlines as search drivers. The search results consist of pertinent information necessary in approaching a funding agency with a request for financial support. SPIN also allows researchers to save specific search criteria and have these searches automatically run at specified time intervals; e.g., every two weeks. The results of these automatic searches are then emailed directly to the investigator. This is a subscription service that is domain protected; therefore, access is limited to computer accounts registered within the University.

2.2 Research Databases

The Office of Sponsored Programs Administration matches faculty with funding opportunities as they become available. It also assists the staff with identifying possible collaborators, consultants and mentors for developing more comprehensive programs.

University faculty have access to a number of these databases where they have the ability to profile their research expertise in order to receive automatic updates when grant programs become available that match their identified areas of interest. The Research Development & Strategic Initiative Office can answer questions concerning these databases.

2.3 Potential Funding Sources

The compatibility of proposed research and agency interests should be considered in reviewing possible funding sources. These interests are usually described in detail in the guidelines of the

program. Potential applicants should call the program manager and discuss ideas prior to submission of a proposal. Subtleties that are not apparent in the guidelines and a slight adaptation in the method in which the project is presented can greatly increase the chance of it being received favorably. However, keep in mind that some private foundations have strict policies on contacting the foundation. Be sure to read the guidelines carefully.

The following is a checklist of questions to consider while researching a funding agency:

- How competitive is this program? What is the typical number of proposals received for a particular program or solicitation, and what is the number of grants awarded annually by the agency?

- What are the agency's eligibility requirements? What types of institutions and investigators does this agency fund? Are there geographical restrictions connected with its program? Are there citizenship requirements?

- What is the maximum and average award amount? How much total funding will be distributed through the granting process?

- What is the agency willing to support with funding? Will the agency allow researchers to offset salary for the time dedicated to the project? Will they allow equipment purchases? What activities, such as research, training and community service, do they specifically fund?

- Will cost sharing be required if an award is granted?

- What is the duration of the grants it supports? Are those grants renewable?

- Are there formal guidelines and application procedures? Is a preliminary proposal necessary or required? Are there application deadlines for grant programs or can proposals be submitted at any time?

- What does the agency expect in return for its funding? Are periodic updates required in addition to a final report? Are there terms the University cannot accept, such as restrictions on publications or intellectual property rights?

- Will the proposal be reviewed by an individual who is proficient in the subject of the research (peer reviewed) or by others with a principal role in the foundation/agency?

2.4 Types of Funding Sources

Government Agencies

Federal, state, and local government agencies constitute the primary source of external funding for grants and contracts at the University of Louisville. Major sources of federal funding at the University have included the U.S. Departments of Health and Human Services, Education,

Defense, and Justice and the National Science Foundation (NSF). Links to these agencies can be found on the Funding Sources and Notification Services page.

Most government agencies have a legislated mandate that restricts the types of programs they can fund and the rules are usually detailed in their guidelines. Most will use a peer review system to make funding decisions.

While individual federal agencies may inform their constituents via newsletter, website or other means of communication, the federal government in general uses two primary publications for advertising financial assistance programs. The Federal Register is a daily newsletter outlining the business that is being conducted by the federal government. It includes new policies and regulations pertaining to government grants, as well as requests for applications. Contract Opportunities, (formerly FedBizOpps), is a listing of contract solicitations published to seek bids on activities that the federal government wants to
complete or products that it wants to purchase. In addition, the federal government now operates a clearing house web site for all federal grants (Grants.Gov). This site offers search capabilities based on keyword and agency. Researchers also have the option to sign up for email notification of funding opportunities based on keyword or agency criteria.

Foundations and Other Nonprofit Organizations

There are over 37,500 foundations in the United States that give grants. It is important, however, to carefully target those foundations most likely to be interested in the project topic.

As many as 80 percent of all applications to private foundations are inappropriate or misdirected, largely as a result of the presumption that all private foundations share a common purpose. Approaching a funding source is a highly individualized process and what may be appropriate to one sponsor may not be suitable to another.

When targeting a private foundation, be aware that these nonprofit organizations fall into several categories. National foundations, such as the Ford Foundation and Rockefeller Foundation, have highly competitive, nationwide grants programs. Special-interest foundations restrict their grants to programs within a single field. For example, the Robert Wood Johnson Foundation funds only health projects. Corporate foundations prefer grants that benefit company employees or the corporation's interest and often are restricted to locales where they have a corporate presence. Family foundations often are restricted in geographical area and usually make small grants for projects in areas of family interest. Community foundations are public organizations that serve a specific geographical area, such as the Community Foundation of Louisville. For local foundations, be aware that the Development Office would like for PIs to contact them before making any contact. Other nonprofit organizations that award grants include associations for industrial or other special groups, fundraising organizations, and professional societies. Some of these organizations run formal grant programs and issue Requests for Proposals while others operate informally.
Information on some of the organizations described can be found through the Council On Foundations or the Foundation Center.

Business and Industry

Corporations may give by means of a company-sponsored foundation or by means of a separate corporate giving program. In either case, corporate giving is almost always limited to programs of benefit to the shareholders, the employees, their families, or residents of specific locations where the company conducts business.

Since most industry sponsors do not run formal grant programs or issue Requests for Proposals, collaborative projects tend to originate through informal networking or prior contacts such as consulting relationships. Some nonprofit industry associations, such as the Electrical Power Research Institute, do make grants through organized research programs.

When approaching corporate grant makers, always consider the self-interest of the potential sponsor. A proposal to a corporation should emphasize how its support of the project will benefit the corporate goals.

2.5 Limited Submissions

Frequently, funding opportunities are designated as “limited submission programs”, meaning that due to restrictions placed by the sponsor the university can only submit a specified number of proposals for consideration for an award. The Executive Vice President for Research and Innovation coordinates the internal screening and review process to determine which proposals can go forward on behalf of the University of Louisville. Before you begin to develop a proposal, please notify the EVPRI's Research Development & Strategic Initiatives office via email if the sponsor's program guidelines place any limits on the number of proposals that can be submitted by the university.

2.6 Executive Vice President for Research and Innovation Internal Grants Programs

EVPRI Internal Grants Programs web site

2.7 Information for Student Researchers

The University of Louisville recognizes the value of creative research and scholarship to the educational process. The following includes a high-level description of the primary programs aimed at promoting both Graduate and Undergraduate participation in these activities. Additional details can be found on the EVPRI web site.

Vice President for Research Undergraduate Research Scholar Grant (URS)

The primary purpose of a URS grant is to enrich the research, scholarship or creative arts experience of the undergraduate student by involving the student in research collaboration with a faculty mentor. The student is expected to become intellectually involved in the design and execution of the research project. The undergraduate student prepares the URS proposal after he or she has identified a faculty mentor with interest in the student’s endeavors. The faculty mentor is expected to make arrangements for the student to receive up to three (3) credit hours for the

research or creative activity and provide a grade for the work completed by the student. Students are encouraged to present a poster at the Undergraduate Research Day. The student may request up to $300 for supplies and expenses required for conducting the research or creative activity.

Graduate Assistantships

The Graduate School awards assistantships on a competitive basis, both for research and teaching. These assistantships provide a stipend and full tuition in exchange for 20 hours of University service. Information about deadlines and qualifications can be obtained in the graduate department of the school or program to which the student is applying for admission.

Student Support and Fellowships

Students seeking support for University research projects have access to the resources in the Research Development & Strategic Initiatives Office. Students with a valid University e-mail account will have access to the on-line databases in order to conduct their own searches. The Student Financial Aid Office provides information and counseling on a variety of loan, grant, and scholarship programs for students seeking direct financial assistance for educational purposes.

Chapter 3: Development, Budgeting

The Office of Sponsored Programs Administration website provides a comprehensive overview of the Proposal Preparation and Submission process. Most often a proposal involves a request for financial support to cover the cost of the project, the purchase of equipment or the payment for services rendered to an outside agency. For the definition of sponsored activities, see Chapter 1, Section 1.

3.1 Preliminary Proposals

Preliminary proposals, also known as pre-proposals, white papers, or letters of intent, may be requested by a sponsor to ascertain interest in a project. Preliminary proposals are abbreviated proposals used by an agency to prescreen applications. These proposals, usually 3-5 pages in length, highlight ideas rather than procedures and may provide for projected composite budgets. The results of prescreening may be binding, where the agency will only review formal proposals that have been invited back; or advisory, where the agency may suggest revisions or discourage resubmission of a formal proposal but not reject it outright. If the preliminary proposal or white paper makes a financial, space, matching, or cost-sharing commitment, the proposal must typically be submitted through the Office of Sponsored Programs Administration prior to submission.

A Letter of Intent is a specific type of preliminary proposal. These are frequently requested by agencies prior to submission of a formal proposal. The Letter of Intent allows the agency to get an idea of what is likely to be submitted and plan ahead to secure the resources needed to conduct the review process. This Letter of Intent can be optional or mandatory and usually will not generate any feedback from the agency. For LOIs the documents should be submitted to the Office Office of Sponsored Programs Administration.

3.2 Formal Proposals

Formal applications or proposals are documents that are submitted to an external sponsor that outline the components of an investigator-designed work plan. Proposals generally include a request for financial assistance to support the proposed work.

The funding agency may provide financial assistance through several different mechanisms:

- A grant is an award given by a funding agency for a particular purpose without an expectation of repayment. A grant allows a fair amount of creative or intellectual input in the design of a project, but still requires the PI/PD to adhere to a pre-approved budget and project outline.

- A cooperative agreement is a funding mechanism that includes an active role for the funding agency and for which there is greater oversight by the sponsor than there would be for a grant.

- A contract is the most restrictive of the funding mechanisms that a PI/PD will encounter. In a contract, the PI/PD is undertaking a project for the sponsor under program parameters designed by the sponsor. A contract generally has negotiated terms in the award agreement that allow less flexibility on the part of the PI/PD.

- A donation/gift is funding provided by a private party, such as a foundation or corporation, for which there are minimal restrictions placed on use of the funds. PIs/PDs should review the Guidelines for Designating Funding as a Gift or a Sponsored Program. Gifts must be processed through the Office of Advancement.

The format of the proposal is likely to be dictated by guidelines of the sponsor and it is the responsibility of the PI/PD submitting the application to read these guidelines and design the program as required by the sponsor. For institutional requirements related to proposal submission please refer to Chapter 4 of the Research Handbook.

3.3 Administrative Information

Most proposal applications submitted for extramural funding will request certain administrative information about the University. Tables containing the most commonly requested information (general information, and fringe benefits) can be found on the Office of Sponsored Programs Administration

Most sponsors provide guidelines for proposal preparation and it is recommended that PIs/PDs use any sponsor-provided proposal outlines. Individuals reviewing submissions expect adherence to sponsor guidelines and non-compliance may cause the proposal to be disqualified. The following items are typical components of a standard proposal but requirements vary by sponsor.

3.4 Proposal Cover Page

Most sponsors will provide a form or a format to use as a cover page. If a standard format is not provided, the coversheet should contain at a minimum:

1. Proposal title
2. Sponsoring agency and/or Program receiving the grant proposal
3. Applicant legal name, typically University of Louisville Research Foundation, Inc.
4. PI/PD’s name and his/her contact information
5. Date submitted
6. Authorizing Official and a line for signature
7. Contact information for the Authorizing Official

3.5 Abstract or Project Summary

Most sponsors require a summary of approximately 250 to 500 words outlining the proposed scope of work and significance of the project. The abstract should be a good marketing piece for the application, summarizing what need(s) the project meets, its objectives, why the researcher and institution are best suited to achieve the objectives, and why it is critical for the funding to be

granted. This section should focus more on the objectives and anticipated outcomes of the project than the methodology. Each specific aim should be briefly addressed to demonstrate its value in the project. While this is usually the first section read, it should be the last section written in order to provide an accurate, thorough and complete overview.

3.6 Project Description or Proposal Narrative

The project description is the detailed narrative outlining the project rationale, the goals and objectives, the methodology, the work plan, and the evaluation criteria. This is likely to be divided into one or more of the sections outlined below.

Introduction

The introduction should effectively market a proposal. It should be written in a way that entices the reviewer to want to read the rest of the proposal. The introduction should be used to set up the argument for funding this project. It should describe the researcher(s), how this proposed program complements the sponsor's strategy and resources, the accomplishments the PI/PD has in this area, and why he/she is best positioned to address the problem at hand.

Demographic information about the University can be found in Just the Facts published by the Office of Academic Planning and Accountability. Data about resources at the University that pertain to the specific program are generally helpful; however, much

too often proposal writers are tempted to simply insert a piece of boilerplate text into the introduction. This does little to gain the interest of the reader and unless it directly pertains to the problem at hand, it takes up valuable space in the narrative.

Example for a K-12 Education Program:

Weak: The University of Louisville recently celebrated its 200th birthday. Located in Kentucky's largest metropolitan area, the U of L was designated as the state's urban university when it joined the system in 1970 after many years as a municipally supported institution.

Better: The University of Louisville is a public institution located in Kentucky's largest metropolitan area where more than 92,000 K-12 students are enrolled in the Jefferson County Public School System. The close partnership between these two entities provides an exceptional educational opportunity for the 2000 students currently enrolled in the U of L School of Education.

Problem or Needs Statement

While the introduction lends credibility to the PI/PD's ability to address this issue, the needs statement focuses on the problem itself. The idea is to show that the researcher can bridge the gap from the current state to a more desirable outcome. The logical order of this section will move the reader from what the problem is and how it is currently being addressed to how the proposed solution is a better option.

Example:

1. X number of people died from {disease} according to 2014 statistics.
2. Traditional treatments require hospitalization due to extreme side effects.
3. Our new treatment program shows promising results with few side effects and no hospitalization, meaning a higher rate of compliance at a lower cost.

This section should be well referenced and arguments should be based on documented facts, not opinions. Pilot studies supporting your hypothesis should be referred to, but explained in detail in the Methodology section. This needs assessment should set up the basis for the specific aims statement, therefore an effective transition into the next section is necessary.

Specific Aims: Goals and Objectives

The specific aims of a proposed project will describe the successes or outcomes that can be anticipated if the project is funded. The aims must grow out of the needs statement and relate to the method that will be employed to close the gap between the current and ideal state. Goals and objectives should be addressed in this section and an explanation of how the project will contribute to these goals and objectives should be provided.

A goal is normally understood to be a more global target to which the proposed program will contribute, such as curing cancer or achieving world peace. An objective is a more intermediate accomplishment that will contribute to the overall goal. An objective can and should be accomplished during the tenure of a grant while it is unlikely that a goal will be. The objectives should be specific, well defined, measurable and timely. They must clearly explain how they contribute to the overall goals.

Objectives can be either outcome-based or process-based, but care should be used when writing process-based objectives so process and methodology do not become confused.

Example:

Goal: To solve the problems of Public Housing.

Outcome Objective: To create 30 new first time homeowners from public housing residents by the summer of 2024.

Process Objective: To create a training program in home ownership for low income public housing residents.

Methodology

This section will describe how the objectives will be accomplished. It should include what will be done, what resources are necessary, the roles of each individual contributing to the project, and why certain approaches are taken to solving the problem at hand. This section should be

structured to show the logical flow of the work, the sequence of activities, and the interrelationship of each of the particular tasks. Milestones and decision points that are planned to show the progress of the project should be included.

A description of the decision to utilize one methodology over another is very effective, especially if using a unique approach. It is also useful to discuss the obstacles that may be encountered as the project proceeds and what alternatives might be necessary to ensure successful completion.

Evaluation

This section should set up the criteria by which the researcher and the funding agency will determine the success of the project. The evaluation should flow out of the criteria described in the objectives section with regard to time, cost, and other measurement indicators. It is sometimes useful to include funding requests for a third party to evaluate the work that will have been accomplished, especially if the outcomes are fairly subjective and hard to measure. If working with a large data set, a statistician should be included on the project team to provide analysis of the success of the project.

Personnel

The responsibilities of all personnel must be delineated clearly in the narrative. If students or postdoctoral fellows are included in the work plan, there must be a clear discussion of their involvement in the research, the training benefits to be derived, if any, and how they will be supervised.

Biographical Sketches

Biographical sketches should be provided for all key personnel and consultants whose role will contribute significantly to the project. Full curriculum vitae are seldom appropriate for this purpose. Sketches should highlight the contributor's current title, educational background and relevant professional experience. Read the guidelines carefully because the format for biographical sketches varies from sponsor to sponsor and can be revised by a sponsor such as NIH. Most federal and private foundation guidelines will stipulate the format to be used for the biosketches. Biosketches must include international appointments.
Additional guidance can be found at:
https://ori.ops.louisville.edu/confluence/display/2IAR/Disclosing+to+Sponsors

Current and Pending Support

Key personnel may be required to list any active grants or proposals pending at other agencies. Any relative scientific or budgetary overlap between a funded project and the proposed effort should be explained.

This section should also outline the percent of effort committed to each project along with a timeline for each project. Each investigator should be careful to manage his/her time so that

he/she is not committing more than 100 percent effort to all job- related activities, including funded research. If the success of the submitted proposal means that the total percentage of effort becomes too high, a statement must be included to describe how the individual will reallocate time and effort to meet all of his/her commitments.

Disclosure of all current and pending resources that support the research endeavors must be disclosed, foreign and domestic. Additional guidance can be found at: https://ori.ops.louisville.edu/confluence/display/2IAR/Disclosing+to+Sponsors

Note: Research proposals to the Biological Sciences Directorate at the National Science Foundation will not be reviewed simultaneously with a proposal pending at any other federal agency. Junior faculty members applying for their first federal grant are exempt from this rule.

Facilities and Equipment

This section will be used to describe any specialized equipment, services or resources available to the PI/PD that are beneficial or necessary to the success of the proposed work. More information on shared scientific resources can be found at the research cores website. If the facility is not part of the University of Louisville property, a letter should be obtained from an administrative authority at that facility that clearly commits the facility to the project. Likewise if the equipment described is not under the direct control of the research team, a letter from the individual responsible for that equipment must be included outlining an agreement and terms for use of the equipment for this project.

Proposal Appendices

If the sponsor permits appendices, this section may include letters of commitment or partnership, relevant publications, or other materials that enhance the proposal. Tables, figures or graphs that are referenced in the narrative should be incorporated into the body of the narrative rather than appended to it. Appendices may not be used to circumvent the stated page limit for the body of the proposal.

3.7 Proposal Budgeting

Budgeting is dictated by sponsor guidelines but broadly there are two types of budgeting: (1) Modular and (2) Detailed.

Modular

More information on modular budgeting can be found at the NIH website for Modular Grants. Although the NIH does not require detail, the Office of Sponsored Programs Administration will require enough detail to assure accuracy of the budget and unit commitments to appropriately budget by cost pool categories in the PeopleSoft Financial System.

Detailed

The PI/PD should show all necessary costs and resources of the project in the budget, even those covered as cost sharing, so that there is an accurate accounting of the actual total cost of the project. When requesting funding for any line item in the project budget, it is imperative that the PI/PD show how the cost of that item is necessary to complete the proposed project. Each item in the budget should tie back to the project to substantiate the request for funding.

Allowable Costs

Any requests for support from a federal agency must be in compliance with requirements outlined by 2 CFR 200. Sponsor guidelines published for a specific program announcement may be more restrictive than the 2 CFR 200 guidelines and will take precedence.Costs reimbursed under the Facilities and Administrative costs (indirect costs) agreement will not normally be allowable as direct costs on a proposal budget to a federal agency.

Example: Postage is not normally an allowable cost on a sponsored project. A project requires a 5-page survey to be mailed to a targeted audience of 1000 people; estimated cost to mail each survey is 50 cents. The PI/PD can request $0.50 x 1000 = $500 in postage specifically for the survey. Additional funding cannot be requested to cover routine office mailings.

Requests for support from non-federal sponsors must be consistent with the sponsor's guidelines on allowable and reasonable costs, as well as any University policies that may apply to that circumstance.

For more information on cost allowability, please refer to Chapter 6, Section 1 of the Research Handbook or 2 CFR 200.

Budget Categories

This section will examine the various categories of funding which a proposal is likely to request and will provide details on the calculations and restrictions in each category.

Salaries

The Salary and Wage section of most proposals will request a listing of the persons working on the project, their roles, the estimated time committed to the project, and the amount of salary to be charged to the project. Salary calculations should reflect the total percentage effort of each member of the project team, whether or not the money is being recovered from the funding agency, with the balance being shown as University cost share. University voluntary cost sharing is discouraged.

Factors that should be considered in salary and wage calculations include:

- If the award is expected to be made in a budget year different from the application year, salary requests should be adjusted to show the anticipated increase in institutional base salaries. Keep in mind the amount of time needed for proposal review;

- Salary escalation factors for subsequent funding years should be calculated using a 2-5 percent escalation factor;

- If a promotion is expected to occur during the project period, the anticipated salary adjustment should be reflected in the proposal budget and an explanation should be provided in the budget justification;

- 10 percent effort is roughly equivalent to one half day per week;

- Salaries for unfilled classified or Professional and Administrative (P&A) positions may be estimated at midpoint of the salary range for that pay grade;

- If time commitments on the grant require a member of the research team to be released from other responsibilities, the immediate supervisor should approve the change of assignment.

- The salary amount that is used for budgeting purposes in the proposal is the total university compensation as defined by the Institutional Base Salary Policy.

Example A:

A faculty member with a twelve-month appointment earns $65,000/year plus a salary supplement of $6,500 associated with being appointed a University Scholar. He/She anticipates spending 30% of his/her time on this project, which is scheduled to begin in the next fiscal year from now.

1. Institutional Base Salary at the time of the award will be $71,500 + a 3 percent raise or $73,645: $71,500 x 1.03 = $73,645 (Salary increases should be calculated for each new fiscal year throughout the project period. Fiscal year begins in July.)
2. Multiply the estimated Institutional Base Salary by the percentage effort: $74,360 x 0.30 = $22,308

Example B:

A faculty member on a B-9 appointment will be earning $45,000/year at the time of the award. He/She anticipates spending two months of the summer plus 20 percent of his/her time during the academic year on this project. (Sponsors generally expect that some time will be taken for vacation during the summer.)

1. Summer salary can be calculated as ($45,000/9) x 2 = $10,000

2. Academic year salary would still be ($45,000 x 0.2) = $9,000
3. Salary request = $10,000 + $9,000 = $19,000

Note: *The National Science Foundation calculates summer salary based on 2/9 of the academic year base.*

Note: *The National Institutes of Health issues a salary cap. Remember this when applying the effort percentage to the base salary for inclusion in the grant budget.*

Example: Professor A earns $250,000 salary, including a Distinguished University Supplement, and the percent effort on the grant totals 25 percent. The grant budget amount should include 25 percent of the NIH salary cap ***NOT $250,000****. The $250,000 salary is still indicated in the budget as the total institutional salary.*

Professor B is earning $90,000 salary and the percent effort is 25 percent. The grant budget amount should include 25 percent of
$90,000.

Student Salaries

A **salary** is paid to students for work or service conducted for the University outside of any educational responsibilities. If a Graduate Assistant is included on a grant the salary must be in alignment with committed effort.

Minimum salary/stipend levels for graduate assistantships are established by the Graduate School Dean's Office. Faculty adding graduate or undergraduate students to their research programs should contact the unit business manager or designee in their home department to determine the correct rate of pay.

NOTE: Graduate students funded under a grant or contract must be provided student health insurance and tuition. Please refer to the Office of Planning and Budget's Policy on Tuition Remission for Graduate Research Assistants Funded from Grants and Contracts for more information.

Administrative and Clerical Salaries

Please see Chapter 6, Section 6.1 of the Research Handbook for guidance on the inclusion of Administrative and Clerical Salaries in proposal budgets.

Fringe Benefits

Fringe benefits are those items that an employee of the University receives over and above salary. This category includes costs such as the University's contribution to Social Security, to retirement funds, to health insurance, long-term disability and life insurance and the Medicare tax. For the purpose of the proposal, fringe benefits may be calculated on a weighted average as a percentage of salary (see Recommended Fringe Benefit Rates). However, using the actual fringe

benefit rate is strongly recommended and will be charged to the project. The actual rates may vary from the average rate depending on a person's salary and benefits package.

Equipment

Equipment, as defined in 2 CFR 200, refers to any single tangible item costing $5,000 or greater with a useful life of greater than one year. Costs necessary for delivery and installation may be included to reach the $5,000 threshold only if they are part of the terms and conditions of purchase. If an item fails to meet either of these standards, it should be listed under the budget category for "materials and supplies."

Note: Applications to sponsors outside the federal government may have lower thresholds for equipment classifications. The following are some other important items pertaining to equipment:

- Software is only classified as equipment when it is operating software necessary for the performance of the equipment in question. Application software is never classified as equipment.

- Equipment is rarely included in the Modified Total Direct Cost base for the purpose of F&A calculation.

Equipment requests should document the necessity of the equipment to the successful completion of the project. Where possible, manufacturer's price quotes should be used to document the cost basis for the particular piece of equipment; however the PI/PD should be aware of the bidding requirement for actual purchase of larger equipment items.

Expendable Materials and Supplies

Items included in this budget category generally refer to consumables and small equipment with a value of less than $5,000. In most circumstances, federal regulations prohibit inclusion of general office supplies in a grant or contract budget. It is important to note that a sponsor's approval of a proposal does not guarantee allowability of the proposed costs.

Tuition

Tuition is an allowable direct charge for students involved on sponsored projects and should be budgeted based upon committed effort. Tuition is never included in the Modified Direct Total Cost base for F&A calculations.

Consultants

Typically consultants are personnel from outside the University whose expertise is needed on a project for a fixed period or for a specific activity. Hiring a consultant usually entails a personal

services contract . The department is expected to follow University policies and procedures for processing personal services contracts. Personal Services Contracts must comply with KRS

164.821(7) which prohibits a member of the administrative or teaching staff to hold an interest in a contract with UofL beyond compensation.

Consultants should be identified by name in the proposal. The budget justification should discuss his/her area of expertise and the necessity of including him/her on the project. The fee basis should be detailed and any reimbursable expenses including travel should be outlined separately.

Additional information on the allowability of consultant or professional service costs is available in 2 CFR 200.459. See Chapter 7, Section 2 of the Research Handbook for additional information on consultants.

Subawards

The need for a sub-recipient should be identified at time of proposal. Subawards are appropriate when:

1) A third party is identified in the original proposal to conduct a significant portion of the scope of work; and

2) The work of the Subrecipient is substantive and independent; the Subrecipient makes programmatic decisions and its performance is tied to the objectives of the project.

The sub-recipient must provide a complete budget including their F&A costs. Total costs for the sub-recipient will be entered into the proposal budget as direct costs to which UofL's negotiated F&A rate will be applied as appropriate. The sub-recipient on PHS awards must maintain a COI policy at least as strict as 42 CFR Part 50 or they must agree to comply with UofL COI Policy. Subawards must comply with KRS 164.821(7) which prohibits a member of the administrative or teaching staff to hold an interest in a contract with UofL beyond compensation.

Travel

Travel can be requested within a proposal budget when the travel provides direct benefit to the project. For example, participation in a meeting or conference must be necessary to accomplish proposal objectives or disseminate results. Additional information can be found in 2 CFR 200.474. All travel is subject to University Travel Policies.

Other Direct Costs

Other costs may include but are not limited to service charges for patient care, statistical evaluation, survey research, repair or maintenance of equipment, rental or adaptation of space, or publication costs. If the request involves renovation of existing space, approval by the appropriate University officials is required prior to proposal submission.

Facilities and Administrative Costs (F&A)

Facilities and Administrative costs are often referred to as indirect or overhead costs and are defined in 2 CFR 200.56. F&A costs are real costs that the University incurs in supporting sponsored research. F&A should be applied according to the University's federally negotiated rate agreement. Detailed information can be found on the Research and Innovation F&A webpage and in the F&A rate agreement.

Cost Sharing and Matching Costs

Cost sharing or matching means the portion of project costs not paid by sponsor funds. In such instances additional funding must be obtained from University funds or from a party external to the University (third-party). **Under federal research proposals voluntary committed cost sharing is not expected.** It cannot be used as a factor during the merit review of proposals but may be considered if it is both in accordance with federal awarding agency regulations and specified in notice of funding opportunity. It is generally not appropriate to cost share on industry sponsored projects.

The following describes the different classifications of cost sharing:

1. **Mandatory Committed Cost Sharing**: The portion of project costs that the sponsor requires the Institution to provide in support of the project.

2. **Voluntary Committed Cost Sharing**: The portion of project costs that are committed and budgeted in excess of mandatory sponsor requirements. Voluntary committed cost sharing is strongly discouraged.

3. **Voluntary Uncommitted Cost Sharing**: The portion of total project costs in excess of sponsor funding that is incurred by the institution but not required by the sponsor nor specifically committed in the proposal budget or budget justification. Voluntary uncommitted cost sharing is not budgeted or tracked and should not be considered as a component of organized research. **Voluntary uncommitted cost sharing is strongly discouraged.**

Cost sharing expenses must be allowable, allocable, reasonable and necessary as described in 2 CFR 200. These expenditures must be treated consistently and must be verifiable through documentation.

Cost sharing or matching costs can be met by grants or commitments from outside the University, such as those from industry partners. However, funds originating from federal sources cannot be used to cover cost share requirements.

Budget Justification

The budget justification is an additional narrative section of a proposal that may be required. It is a breakdown of your proposed budget in a narrative format, and is used to "justify" the expenses identified as being necessary for the project.

Please see Chapter 6, Section 6.1 of the Research Handbook for guidance on the inclusion of Administrative and Clerical Salaries in proposal budget justifications.

3.8 Other Proposal Considerations Material Transfer Agreements

A Material Transfer Agreement (MTA) is required when the University accepts a proprietary substance or product from an outside agency for use or testing. If the outside entity is a signatory of the Uniform Biological Materials Transfer Agreement (UBMTA) or can accept the terms of the UBMTA, this will speed the process. When submitting an MTA for processing, include the name, address, and contact information (e-mail address, phone number, fax number) of the appropriate person at the outside entity should any issues requiring negotiation be present in the agreement. Please refer to the Commercialization EPI-Center for assistance with MTAs. Transfer of materials governed by Export Control regulations must be reviewed and approved by the Export Control Office.

Non-Disclosure Agreement

Nondisclosure Agreements (NDAs) document the transfer or exchange of confidential or proprietary information. An NDA's terms protect the scope of the disclosure and how the information may be used, cover how and to whom information may be disclosed, and establish the time periods during which disclosure may occur and disclosures continue to be protected. As with Material Transfer Agreements (MTAs), some terms may require negotiation in order to be acceptable to the university. It may be

in your interest to put an NDA in place when licensing, commercialization, or sponsored research opportunities arise. Please refer to the Office of Sponsored Programs Administration for NDAs related to sponsored projects, or to the Commercialization EPI-Center for assistance with standalone NDAs.

Data Sharing Agreements

A data-sharing agreement is a formal contract that clearly documents what data are being shared and how the data can be used. Such an agreement serves two purposes. First, it protects the entity providing the data, ensuring that the data will not be misused. Second, it prevents miscommunication on the part of the provider of the data and the party receiving the data by making certain that any questions about data use are discussed. Before any data are shared, both the provider and receiver should talk in person or on the phone to discuss data-sharing and data-use issues and come to a collaborative understanding that will then be documented in a data-sharing agreement. For more information, please contact the Office of Sponsored Programs Administration.

Memo of Understanding

A Memorandum of Understanding (MOU) is a non-binding document that acts as a public declaration of partnership, and is often useful in support of joint grant applications to external funding agencies, facilitating visa and travel document processing, and collaborative activities that involve an institutional presence of some kind. For more information, please contact the Office of Sponsored Programs Administration.

Letters of Support

Support letters within the context of a grant application can be used to convey more than just an endorsement of the proposal. In general, these are portions of the proposal that often have no page restrictions and can actually reinforce attributes of the proposed work, team of investigators, mentorship and institutional resources/leadership. If you plan to include multiple letters of support with your proposal, it is recommended that you consider a different strong point to highlight for each letter. Very often, particularly for large proposals, a template can serve as a useful guide for letter writing. However, it is strongly recommended that each letter be customized to the specific proposal and letter signatory or it will defeat the purpose of providing such letters in the first place. For assistance please contact the Office of Sponsored Programs Administration.

11/24/2020

Chapter 4: Proposal Review, Approval, and Submission

4.1 Review and Approval Responsibilities

Proposals must be reviewed and have the appropriate approvals prior to submission to an external funding agency. The review process includes review by the department chair/unit head, the respective dean or designee and potential review and approval by University compliance offices/committees such as the Human Subjects Protection Program/Institutional Review Board (IRB) and Animal Use/Institutional Animal Care and Use Committee (IACUC). Review and approval by the Office of Sponsored Programs Administration is the final step in the process prior to proposal submission.

4.2 Institutional Cover Sheet iRIS eProposal / Proposal Clearance Form (PCF) / Transmit for Review and Initial Assessment (TRIA)-Multi-Institutional Research Application (MIRA)

All proposals submitted to external funding agencies must list the "University of Louisville Research Foundation, Inc." as the award recipient unless the submission is required to be from the University. At least five (5) business days prior to submission to the Sponsor, the proposal must be submitted to OSPA for final review and approval.

Submission to OSPA is via the Integrated Research Information System (iRIS), by either the eProposal or the Proposal Short Form. The system's eProposal is a comprehensive electronic packet which incorporates information required on the institutional cover sheet, proposal documents and sponsor forms. Alternately, the iRIS system offers a Proposal Short Form to which a conventional cover sheet and proposal documents can be uploaded. In this case, a completed and signed Proposal Clearance Form (PCF) or Transmit for Review and Initial Assessment (TRIA) – Multi-Institutional Research Application (MIRA) must accompany proposal submission to OSPA.

The institutional cover sheet - whether in the form of eProposal, Proposal Clearance Form (PCF) or Multi-Institutional Research Application TRIA-MIRA enables review of administrative, policy, and fiscal issues related to the proposal. The eProposal/PCF/TRIA-MIRA consists of a series of informational items and questions to assist the Principal Investigator/Project Director (PI/PD) and University reviewers in assessing potential risks and obligations should the proposal be funded. In addition to the signatures of the PI/PD and co-Investigators, signatures of the department chair/unit head and respective dean or designee are typically required.

The TRIA-MIRA or PCF Clinical Attachment is utilized for all clinical trials and sponsored research requiring approval of the Biomedical IRB and any other project/study that uses hospital facilities (for example, Jewish Hospital & St. Mary's Healthcare Services, Norton Healthcare, or University of Louisville Hospital) or resources to conduct the research. The information on the PCF/TRIA-MIRA is shared with the respective hospital/study site and is used by the respective hospital/study site to grant approval for the research study to be conducted at their facility.

When University personnel from more than one academic department are participating in a proposed project, all appropriate department chairs/unit heads and deans must provide approval (by signing the PCF/MIRA) prior to submission of the proposal to OSPA for institutional approval.

If an award is received for which no proposal was submitted, an eProposal/PCF/TRIA-MIRA must be completed, signed, and submitted to OSPA prior to award establishment in PeopleSoft.

4.3 Other Pre-Submission Approvals and Requirements

PIs/PDs are required to conduct research and manage the financial and regulatory aspects of sponsored projects in compliance with University policy, Federal and state law and Sponsor requirements. PIs/PDs must ensure that they and members of their research team(s) meet all compliance requirements, including any necessary disclosure(s) and training requirements.

Several areas of regulatory compliance may need to be considered when submitting proposals to an external funding agency. Examples include:

1. Conflict of Interest (COI);
2. Human Subjects Protection;
3. Animal Subjects Protection;
4. Biosafety and Radiation Safety;
5. Export and Secure Research Control.

See Chapter Nine of the Research Handbook for additional information on these and other research regulations.

If a proposed project requires UofL participants to interact with or handle human subjects, animals, or agents impacting environmental health and safety (e.g., recombinant DNA; pathogenic organisms; human blood, tissues, cell lines, or other potentially infectious materials [OPIM]), a proposal must be submitted to the appropriate committee(s) for internal review and approval prior to activation of an award. External Sponsors have different policies regarding the status of regulatory approvals at the time of proposal submission; while most will accept "pending review" or "pending approval," some require full regulatory approval prior to submission. PIs/PDs should review the regulatory requirements of Sponsors when developing proposals for external funding.

Documentation of institutional approval (e.g., an approval letter) for actions "pending" at the time of proposal must be provided to OSPA prior to activation of an award (chartfield establishment). In limited situations OSPA may establish a chartfield prior to regulatory approval. As an example, for clinical trials, a chartfield may be established for site initiation visits and other limited startup activities prior to receiving final Institutional Review Board (IRB)

approval [NOTE: no human subjects may be consented/enrolled into the trial until the IRB has granted formal approval].

4.4 Proposal Review

All applications and proposals for external funding must be reviewed and approved by OSPA for consistency with Sponsor and Federal guidelines and University policies prior to submission. OSPA also reviews the budget for accuracy and proper format, ensure the correct application of fringe benefit and Facilities and Administrative Cost (aka F&A or indirect cost) rates, and verify University cost-sharing commitments.

Draft copies of all documents, including the draft budget may be submitted to OSPA for preliminary review and comment. This is particularly helpful for complex proposals, such as those with multi-year budgets, subagreements, and/or cost sharing commitments. It should be noted that preliminary review and comment does not constitute official approval for submission.

OSPA must receive the following items for review prior to granting approval for proposal submission:

1. eProposal, or completed and signed PCF and PCF Clinical Attachment (if applicable). Completed and signed TRIA-MIRA may be used for non-federal clinical proposals;

2. Proposal, including abstract, budget, budget justification, and Sponsor forms. A final copy of the proposal for OSPA files should be submitted at the time of proposal review (if electronic) or within two weeks following submission;

3. For proposals involving subrecipients, completed Subrecipient Commitment Form, budget, budget justification, and scope of work;

4. Indication of regulatory approval status (e.g., IRB, IACUC, DEHS);

5. Confirmation that all participants on the project, regardless of role, have completed the Attestation and Disclosure Form; and

6. Approval in writing of all committed University cost sharing or matching obligations.

4.5 Signature Authority

Only specific designees within OSPA have been granted signature authority by the President of the University. Under no circumstance is a PI/PD to sign a proposal to an external funding agency on behalf of the University and/or University of Louisville Research Foundation, Inc. without the prior approval of an Authorized Institutional Official.

4.6 Unfunded Proposals

Upon receipt of notification that a proposal will not be funded, the PI/PD should inform OSPA. OSPA retains copies of unfunded proposals for one year following notification that the proposal will not be funded.

Chapter 5: Award Acceptance and Account Establishment

5.1 Types of Awards/Funding Mechanisms

Grants

Grants typically provide financial assistance for basic research, training, or community service projects and are usually Principal Investigator/Project Director (PI/PD) initiated. Funding agencies typically provide standard terms and conditions; therefore, negotiation by the Office of the Executive Vice President for Research and Innovation is often not necessary.

Contracts

Contracts detail the terms and conditions by which a Sponsor will provide financial support for a specific purpose or scope of work. These terms and conditions generally must be negotiated to ensure compliance with University policy. Negotiations are conducted by the Office of Sponsored Programs Administration (OSPA) with assistance from the PI/PD, the Commercialization EPI-Center, University Research Counsel and other Institutional offices as needed.

Subawards

A Subaward is an award provided by a pass-through entity to a subrecipient in order for the subrecipient to complete a specific component of the award received by the pass-through entity. UofL may act as either a subrecipient (incoming subawards) or as a pass-through entity (outgoing subawards). An incoming subaward is handled by OSPA, typically in the same manner as a standard award that is received by the University. Outgoing subawards are also managed by OSPA. Subawards on Federal projects are subject to the Subrecipient Management and Monitoring regulations outlined in 2 CFR 200.

Other Award Types

Cooperative Agreements, state purchase orders, etc., that meet the definition of a Sponsored Activity are reviewed/executed and have accounts established through OSPA.

5.2 Signature Authority

Only specific designees within OSPA have been delegated signature authority by the President of the University. Under no circumstance is a PI/PD or non-designated University employee to sign/execute a sponsored agreement on behalf of the University.

5.3 Establishment of Award Accounts (aka Chartfield/Speedtype)

Upon receipt of official notification of an award, such as a Notice of Grant Award or fully executed contract from the Sponsor, OSPA will establish a chartfield/speedtype for the project.

Awards will not be established in the PeopleSoft financial system until OSPA has received a completed Award Checklist Form (ACF)/Multi-Institutional Research Application (MIRA), current Conflict of Interest requirements (as applicable/required), Cost Accounting Standards (CAS) form (if federal), a copy of the final proposal or scope of work (if applicable), a current project budget, a fully executed award/agreement document and required compliance documents (IRB, IACUC, etc.). NOTE: If a subrecipient is involved in the project all subrecipient documentation must be completed prior to execution of the subaward.

Once OSPA has established the chartfield/speedtype, an email will be generated and routed to the PI/PD and the unit business manager or other designated individual. This correspondence will outline the PI/PD's responsibility in complying with University and Sponsor guidelines and regulations. Additional correspondence will include a copy of the finalized award

documentation and instructions for reviewing and approving the award details (i.e., budget, budget period, cost share, etc.) as outlined in the Award Summary Report (University Report UBM-13A). Once the award details are confirmed/approved by the PI/PD or designee, the chartfield/speedtype is activated and spending may begin on the project.

5.4 Period of Performance

The Period of Performance is the time during which the University may incur obligations and expenditures to carry out the work authorized under an award. The Period of Performance will be defined in the award agreement (i.e., the Notice of Award) and will be entered into the PeopleSoft financial system when the chartfield/speedtype is established. Expenditures or charges to an award may occur only during the Period of Performance unless pre-award costs are allowed as detailed in Section 5.5 Pre-Award Costs. All expenses for an award should be incurred prior to the end date of the award or the expenses may be unallowable as a direct charge to the project. Extensions to the Period of Performance must be approved by OSPA as dictated by the Sponsor.

5.5 Pre-Award Costs

Pre-award costs are those costs incurred prior to the effective date of an award directly pursuant to the negotiation and in anticipation of the award where such costs are necessary for the efficient and timely performance of the scope of work. Some Federal Sponsors allow an institution to incur charges on sponsored agreements up to 90 days prior to the actual start date of the award. Such costs are allowable (per 2 CFR 200, Section 200.458) only with the written approval of the Federal awarding agency; however, some Federal Sponsors (e.g., NIH) have waived the prior approval requirement in certain circumstances.
PIs/PDs should review the specific Sponsor guidelines and terms and conditions prior to requesting pre-award spending privileges. Pre-award costs are always incurred at the risk of the University and these expenditures must meet the same guidelines of allowability, allocability, and reasonableness as described in Section 6.1 of the Research Handbook and in 2 CFR 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

5.6 Establishment of a Chartfield/Speedtype Based Upon the Guarantee of Funds

When a PI/PD is anticipating an award to be issued, he/she may request that a chartfield/speedtype be established ahead of receipt of the official award documentation based upon a guarantee of funding. A guarantee request may be issued to either 1) allow for pre-award spending in advance of the project's start date, if authorized by the sponsoring agency, or 2) allow for the chartfield/speedtype to be established based upon the actual anticipated start date should delays in receipt of the notice of award occur or be anticipated.

The request can guarantee funding in three ways:

1. A guarantee for a certain type of expenditure(s), for instance salary and fringe benefits only;

2. A guarantee for a specified dollar amount in any category of the proposed expenditures;

3. A guarantee for the entire proposed project budget.

In those instances in which a project will continue into another fiscal year (such as an annually renewed state project), OSPA can establish a chartfield/speedtype for the next year during the annual "Planning and Budget preparation" period. This allows payroll appointments to continue in the new fiscal year. The PI/PD must make a request through his/her department chair for a guarantee of funding directly to OSPA.

Chapter 6: Financial Management of Awards

6.1 Criteria for Charging Costs to Sponsored Programs

When charging expenses to sponsored agreements, University faculty and staff must be cognizant of the allowability of the charges. 2 CFR 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," provides the criteria for charging costs to federally sponsored programs. The basic principle is that costs charged to a sponsored project must be allocable, reasonable and necessary, treated consistently and adequately documented in order to be allowable on Federal awards.

1. ***Allocable***: A cost is allocable to a particular Federal award if the goods or services involved are assignable to that Federal award in accordance with the relative benefit received. For example, an investigator purchases a piece of equipment solely for use on a specific sponsored project. The entire cost of the equipment is *allocable* to that project and can be charged as a direct cost. The investigator also purchases office supplies for the entire research group with funds from a sponsored project. These supplies are not directly attributable to the project, are therefore not *allocable*, and cannot be charged as a direct cost. For more information on allocable costs see Section 200.405 of 2 CFR 200.

2. ***Reasonable and Necessary***: The cost must be *reasonable and necessary* for the performance of the project. A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. For example, an investigator purchases lab supplies to complete work on his project. An assessment of cost and quantity was performed on the lab supplies; therefore the purchase of the supplies is considered reasonable. The lab supplies are required to complete the project; therefore the lab supplies are considered necessary. The lab supplies can be charged as a direct cost to the project.

   As a comparative example, the investigator also purchases a new microscope that was on sale through the supplier from which he purchased the lab supplies. The microscope is not needed for his current project but may be needed for an upcoming project. This expense is not necessary for the performance of the current project and cannot be charged as a direct cost. For more information on reasonable costs see Section 200.404 of 2 CFR 200.

3. ***Consistently Treated***: All costs must be consistent with policies and procedures that apply uniformly to both federally funded activities and the other activities of the University. Additionally, a cost may not be assigned to a Federal award as a direct cost if any other cost incurred for the same purpose in like circumstances has been allocated as an indirect cost. For example, a unit business manager purchases stamps for the general use of the department using departmental funds (an indirect cost). An Investigator purchases stamps for various general mailings and charges them as a direct cost to his

award. If the cost of the stamps is included as a direct cost to the Investigator's sponsored project and similar costs incurred in like circumstances (stamps for general purpose departmental mailings) are included in the calculation of the University's F&A rate, then the costs are not being treated consistently. The investigator thereby cannot charge the stamps to the sponsored project.

Any expense that does not meet all of these criteria should not be directly charged to a federally sponsored project. Note that approval of a particular expense as a direct cost by a sponsoring agency does not guarantee that the expense is an allowable cost. The expenditure must also meet the requirements as described above.

Administrative & General Purpose Costs

Administrative costs such as the salaries of clerical personnel or general purpose items such as office supplies and postage should normally be treated as indirect (F&A) costs.

Administrative and Clerical Salaries

Direct charging of the salaries of administrative and clerical staff may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;

2. Individuals involved can be specifically identified with the project or activity;

3. Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; AND

4. The costs are not also recovered as indirect costs.

If it is determined that administrative and clerical services are essential, vital, or fundamental to the project or activity, the salaries section of the proposal budget justification must (1) explicitly indicate how any administrative and clerical services are integral to the project with the proposed percentage of effort and (2) include the following statement in the personnel role description: **Based upon this justification, the University of Louisville is requesting agency approval for support of this position as an administrative cost allowed under 2 CFR 200.413.**

If a proposal is submitted with the required statement/justification outlined above, and the subsequent Notice of Grant Award issued by the Federal agency does not explicitly disallow the administrative cost, the administrative and clerical costs will be considered approved.

General Purpose Costs, Including Computing Devices

If a Principal Investigator wishes to charge general purpose costs directly to a federally sponsored program, the following criteria must be satisfied:

1. The charges must be clearly spelled out in the initial budget submitted to OSPA;

2. An explanation of why these expenses should be charged directly to the project must be provided and the relationship of the charges to the scope of work clearly defined.

Computing devices under $5,000/unit may be directly charged to a project or activity under the following circumstances:

1. The devices are essential* and allocable to the project in that they are necessary to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or "peripherals") for printing, transmitting and receiving, or storing electronic information; AND

2. The PI/PD does not have access to other devices or equipment that can achieve the same purpose; devices may not be purchased for reasons of convenience or preference.

* PIs/PDs are responsible for documenting how the device is "essential" and to what extent the cost of the device is reasonable and allocable to the sponsored project. PIs/PDs and departments must maintain documentation that describes how the computing device meets the above requirements.

Unallowable Costs

Unallowable costs are those costs that cannot be charged directly to a sponsored award due to Sponsor and/or University policy and regulation. Different Sponsors have different policies, regulations, and restrictions, therefore, whether a cost is considered

allowable or unallowable on a sponsored award can only be determined through a close review of the award documentation, Sponsor regulations and guidelines, and University policy. Certain items of cost cannot be charged (directly or indirectly) to federally funded sponsored agreements. The federal government provides guidance as to the type of costs allowed and/or not allowed on federal or federal pass through awards in 2 CFR 200, Subpart E – Cost Principles.

6.2 Cost Transfers

Federal regulations regarding cost transfers can be found in 2 CFR 200, Section 200.405. Cost transfers should be kept to a minimum by initially charging expenses to the appropriate sponsored account(s) in a timely and accurate manner. However, in those instances in which a cost transfer is required, the proposed cost transfer should comply with the following guidelines:

1. Documentation of the original charge must be included with the appropriate cost transfer form. Documentation must include a copy of the monthly ledger sheet reflecting the transaction and other identifying documentation such as an original receipt. This information is necessary to maintain an audit trail;

2. An explanation of the reason for the cost transfer is required on the appropriate cost transfer form. The explanation must address why the expense is being transferred and must provide more explanation than "boilerplate language" such as "to correct an error" or "to transfer a cost." Funding issues are not sufficient justification for moving an expense to a sponsored project.

For an expense to be transferred to a sponsored account, it must meet the following criteria:

1. The expense must have posted to the General Ledger;

2. The expense must be allowable, allocable, reasonable and necessary, and treated consistently;

3. The expense transfer should be posted within 90 days of the initial charge. The reason for this is two-fold; financial reports must be filed within 90 days of the completion of the project; and accounts should be reviewed for proper charges in a timely fashion. If the expense transfer is outside the 90-day window, the requesting department must provide a written explanation as to why. The explanation must be reviewed and approved by the Office of Sponsored Programs Administration Financial Administration Core.

In the event that an expense is determined to be unallowable on a sponsored project, the expense must be transferred to an unrestricted account. Cost transfers of salaries, wages and associated fringe benefits should be processed prior to effort certification.

Department administrators should use the Intra-University Transfer (IUT) form to initiate a cost transfer. All supporting documentation must be included. Contact the Office of Sponsored Programs Administration, Financial Administration for additional information related to cost transfers.

6.3 Rebudgeting

Rebudgeting policies vary among sponsors and are typically addressed in the terms and conditions of the award document. Many sponsors allow flexibility in revising budgets and most budget revisions may be handled directly by the Office of Sponsored Programs Administration (OSPA); however, some Sponsors require prior approval. The departmental administrator or central research administrator can assist the PI/PD in determining whether a budget reallocation requires Sponsor approval. If Sponsor approval is required, a rebudgeting request accompanied by justification should be submitted by the PI/PD to OSPA for review and submission to the Sponsor.

6.4 Deficits on Sponsored Programs

During the lifetime of a sponsored award, primary responsibility for ensuring that expenditures are in accordance with Federal, sponsoring agency, and institutional guidelines resides with the PI/PD. The University’s financial system-of-record, PeopleSoft, is to be utilized by the PI/PD and their designee to monitor the expenditures placed on each sponsored project. Accordingly,

the sponsored account should be reconciled to the PeopleSoft system on a monthly basis per the University's Account Reconciliation Policy.

In the event a cost overrun occurs on a sponsored award, the PI/PD and/or designee should contact OSPA to review and assist in resolving. Resolution may include the transfer of expenditures to a cost-share account or to an unrestricted source/speedtype.

6.5 Effort and Salary Allocation on Sponsored Projects

A University employee may have a portion (and in rare instances, all) of his/her salary charged to sponsored projects as outlined in 2 CFR 200.430. The basic tenets are that costs must be allowable, reasonable and necessary, allocable to the sponsored project, and treated consistently by the University as either direct costs or Facilities and Administrative (F&A) costs.

When salaries are charged to sponsored projects, the charges must be in direct proportion to the effort committed on the project. Available funding is not appropriate justification for charging salaries to sponsored projects. If an employee has committed more effort to a sponsored project than is being charged, a cost share account should be established to cover the additional costs. The department should review the allocation of salary on a monthly basis for all employees working on sponsored projects and make any necessary adjustments.

6.6 Effort Certification

Per Section 200.430 of 2 CFR Part 200, charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed. Accordingly, the University must be able to certify that salary charged to a sponsored project is reasonable in relation to the effort committed on the sponsored project. The mechanism currently used to document that pay charged to a Federally sponsored project is reasonable relative to actual effort is the Effort Certification Report. The University has chosen to certify effort on a semi-annual basis. The first certification period covers July 1 through December 31; the second certification period, which is the official institutional record, covers the entire fiscal year July 1 through June 30.

When Effort Reports are reviewed at the department level it is recommended that the person who is most knowledgeable of the individual's effort certify that effort. In most cases, faculty should certify for themselves and direct supervisors may certify on behalf of their employee(s). It is unallowable for UBMs to certify effort for faculty and staff. An Effort Report must be submitted for all individuals who are paid on Federally sponsored projects.

6.7 Program Income

Program income is defined by the Federal government as "gross income earned by the grantee or subgrantee, which is directly generated by a grant-supported activity or earned as a result of an award." Program income includes, but is not limited to, income from fees for services performed (i.e., fees collected for conferences or training classes incidental to the accomplishment of approved grant purposes), the use or rental of real or personal property acquired under Federally funded projects, and the sale of commodities or items fabricated under an award. In accordance

with Federal awarding agency regulations or the specific terms and conditions of the award, program income may be applied in one or more of the following ways:

1. Added to funds committed to the project by the Federal awarding agency and used to further eligible project or program objectives;

2. Used to finance the non-federal portion (cost share) of the project or program;

3. Deducted from the total project or program cost.

It is the responsibility of the PI/PD to track, document, and report program income. In most cases, this reporting is done at the time of a continuation or renewal of an existing project. The Office of Sponsored Programs Administration-Financial Administration Core can assist the PI/PD in making a determination as to whether income meets the definition of program income as well as provide guidance on the administration of program income.

Additional information on Program Income can be found in Section 200.307 of 2 CFR 200.

6.8 Cost Sharing on Sponsored Projects

Cost sharing or matching funds are the portion of project costs not paid for by the Sponsor. Per 2 CFR 200, voluntary cost sharing is not expected and cannot be used as a factor during merit review of proposals unless it is required by the notice of funding opportunity. PIs/PDs are discouraged from including voluntary cost sharing on sponsored projects.

When cost sharing is committed on a sponsored project it must be budgeted and tracked as part of the project. Mandatory and committed cost share require the transfer of funds from an unrestricted source to a cost share speedtype that corresponds to the related sponsored project.

6.9 Uncollectible Costs

When the University enters into a sponsored agreement there is the expectation that the Sponsor, the PI/PD, and the University will abide by the agreed-upon terms and conditions, including payment terms. In the event that issues with payment arise, action must be taken to address and resolve the issue. The Office of Sponsored Programs Administration will work with the PI/PD and/or designee to develop an action plan for resolution.

There may be instances in which the Sponsor is unable or unwilling to reimburse the University for expenses incurred. When the Sponsor does not pay the amount due, the department may be responsible for covering the cash deficit. Examples include:

1. The sponsor filed for bankruptcy or went out of business;

2. The PI/PD performing the work failed to complete the project in accordance with the terms and conditions of the agreement;

3. The PI/PD began the work prior to receiving the award; however, the award was not funded.

The Executive Vice President for Research and Innovation and/or Vice President for Finance will review any unresolved instances on a case-by-case basis.

6.10 Service Center Costs

Allowable direct costs generally include charges from University facilities that provide specialized services. Please view the University of Louisville Service Center Policy.

11/25/2020

Chapter 7: Administrative/ Non-Financial Management of Awards

7.1 Post-Award Changes and Approvals

Personnel within the Office of Sponsored Programs Administration (OSPA) assist in obtaining Institutional and Sponsor approval (if required) of administrative and budgetary changes to a sponsored project. Such changes may include but are not limited to the following:

1. A change in the scope or the objectives of the project;
2. A change in the amount in funding;
3. A change in the PI/PD, other key personnel, or the addition of a Subrecipient;
4. A change that is not covered by the authority granted by the Sponsor;
5. A change in the period of performance.

All communications should be drafted by the PI/PD and approved and countersigned by the Authorized Institutional Official prior to submission to the Sponsor (if required). OSPA will coordinate all requests and communications with the Sponsor. Upon approval, OSPA will notify the appropriate parties.

No-Cost Extensions

To assure the successful completion of a sponsored project, a no-cost extension may be requested. Extensions are dependent upon the Sponsor's policies but, with justification, 12 months beyond the original end date can usually be obtained. No-cost extensions do not allow for additional funding but may authorize continued spending of remaining funds. Under Expanded Authority, the University may approve a one-time, no-cost extension of up to 12 months on a sponsored project with notification to the Sponsor. Requests for no-cost extensions should be made in accordance with Sponsor guidelines and submitted to OSPA no later than 30 days prior to the end date of the award.

If the University does not have delegated authority to grant a no-cost extension, requests must be submitted to OSPA at least 60 days prior to the end date of the award. Written requests should be initiated by the PI/PD and include justification for the request, a budget for the no-cost extension period, and the expected project completion date. Upon approval by OSPA, the request will be forwarded to the Sponsor by the respective Authorized Institutional Official (if required).

Change in or Absence of a Principal Investigator/Project Director

If a PI/PD is unwilling or unable to continue to direct a sponsored project, a replacement PI/PD must be proposed and approved by appropriate University officials and OSPA. Following Institutional approval the request and justification will be forwarded to the Sponsor along with the Curriculum Vitae and/or Biographical Sketch of the replacement PI/PD.

If a PI/PD will be disengaged from a project for a period of 3 months or more or is requesting a significant percentage reduction in time devoted to the project, prior approval must typically be obtained from the Sponsor. Note that PIs/PDs can be away from campus and still be considered engaged in a project. Written requests should be initiated by the PI/PD and include justification for the request. Upon approval by OSPA, the request will be forwarded to the Sponsor by the respective Authorized Institutional Official (if required).

Carry Forward of Funds

Allowability of the carry forward of unexpended funds/remaining balances from one budget period to the next varies among Sponsors. PIs/PDs should reference the terms and conditions of the respective award to determine whether or not the carry forward of funds is allowable. Any questions related to carry forward of funds can be sent to OSPA.

7.2 External Resources on Sponsored Projects

External Consultants

Consultants are appropriate if:

1. They will work independently without supervision;
2. They are not employees of the University;
3. They are using their own facilities or equipment to conduct the work;
4. They are eligible for participation on Federal programs.

Subawards

Subawards are appropriate if:

1. A third party is identified in the original proposal to conduct a significant portion of the scope of work and is approved by the Sponsor;
2. The work of the Subrecipient is substantive and independent; the Subrecipient makes programmatic decisions and its performance is tied to the objectives of the project;
3. The need for a Subrecipient is determined during the course of the project.

With Sponsor approval, OSPA will issue a subaward agreement that will include a scope of work, budget, and the appropriate terms and conditions of the prime award. Once the subaward agreement has been fully executed, the Subrecipient can invoice the University for expenses incurred during the budget period. It is the PI/PD's responsibility to monitor the activities of the Subrecipient and to inform OSPA if significant changes are contemplated in the subaward agreement. It is the responsibility of OSPA to obtain and review an annual A-133 or alternate audit documentation from the Subrecipient.

The PI/PD should obtain and process timely invoices for all work performed by a Subrecipient and should determine that the work covered by the respective invoice(s) has been performed satisfactorily and that the costs associated with such performance are appropriate for the work performed. The PI/PD should sign and date each invoice as an indication of approval of the invoice for payment.

Prior to the issuance of a subsequent year's subaward agreement/amendment, the PI/PD must attest that the Subrecipient's work has fulfilled the requirements of the previous year's subaward agreement and that the Subrecipient has submitted all required reports and satisfactory progress has been made. Subrecipients shall maintain reasonable records incident to the performance of a subaward and shall allow the University to access the records upon request.

7.3 Other Award Management Considerations

Property Management/Disposition

Property purchased with sponsored funds is to be used for the sponsored project. Vesting of title and/or reporting requirements vary by Sponsor. In some cases, equipment purchased with sponsored funds remains the property of the Sponsor. The Inventory Control Office is responsible for the University's equipment/asset management system, including inventory, record keeping, sharing, audit, and disposition.

The ownership and transfer rights related to property purchased with sponsored funds is typically defined in the terms and conditions of the award agreement. The terms and conditions may vary by Sponsor and differing circumstances of ownership (title), original cost, source of funds, and current market value.

Questions regarding property management or disposition should be directed to OSPA and to the Inventory Control Office (852- 6131).

Intellectual Property

Questions about intellectual property developed during the course of a sponsored award should be directed to the Commercialization EPI-Center.

If the PI/PD has reason to believe that a potentially protectable invention or discovery has been made during the course of a sponsored award, a disclosure must be submitted to the EPI-Center

in the time frame required by the Sponsor as may be outlined in the proposal/agreement or Sponsor guidelines. The EPI-Center is responsible for submitting any disclosure or other periodic invention reports required to the Sponsor. Prompt disclosure allows the EPI-Center to make a decision about pursuing patenting and licensing in accordance with University and Sponsor policies.

Publications

University researchers and their students need the ability to use data and other research work products for noncommercial educational and research purposes and the right to independently publish. This right can be provided under license, can be limited by a sponsor's right of review or can be delayed for a short period to permit the protection of IP rights. Credit should be given to the source of support for the project through an appropriate acknowledgement and the terms and conditions of the agreement typically dictate.

If a proposed sponsored agreement restricts publication rights beyond what is described above, OSPA will coordinate with the Commercialization EPI-Center and the Office of Export and Secure Research Compliance to negotiate appropriate publication rights.

Research Data

The University of Louisville has developed Guidelines on the Ownership of Data which address faculty obligations and responsibilities regarding access to and retention of research data.

Freedom of Information

Commonwealth of Kentucky statutes guarantee the right of access to information about public agencies. The Federal Freedom of Information Act (FOIA) applies to federally funded projects. University policy documents and funded research proposals must be disclosed to the public upon request. Contact University Archives for assistance on disclosure.

Travel

The University's Travel Policy governs all travel unless Sponsors have additional restrictions. Travel supported with federal funds usually requires the use of an American flag carrier. Section 200.474 of 2 CFR 200 requires that "if travel costs are charged directly to the Federal award documentation must justify that: (1) Participation of the individual is necessary to the Federal award; and (2) The costs are reasonable and consistent with the non-Federal entity's established travel policy." For additional information on travel on sponsored awards please consult with OSPA.

7.4 Reporting and Closeout

Reporting

Sponsors specify the form, frequency and types of reports required, including financial reports, progress reports, case report forms (for clinical trials) and invention disclosure/reports. The PI/PD is solely responsible for meeting all technical and programmatic reporting requirements. The Office of Sponsored Programs Administration-Financial Administration Core is generally responsible for submitting financial reports and invoices. When unique financial reporting requirements are necessary, the PI/PD may need to assist with the development of the report.

The University considers timely reporting essential to the proper stewardship of sponsored funds. Consequences when reports are not submitted in a timely manner include but are not limited to: payment for project expenses may be withheld; pending proposals may not receive favorable consideration; and/or some Sponsors may withhold future awards to the University.

Technical Reports

The PI/PD is responsible for preparation and submission of technical reports. Sponsor-required forms for final technical reports may be provided as part of the application package, with the award documentation, or on a Sponsor's website.

Invention Reports

OSPA, in conjunction with the Commercialization EPI-Center, will work with the PI/PD to complete and submit invention reports.

Financial Reports

Sponsored Programs Administration-Financial Administration Core is responsible for preparing/ reviewing financial reports. The PI/PD or department designee is responsible for reviewing and approving a draft financial report prior to submission to the Sponsor. Final financial reports require that all related expenditures have been posted to the appropriate account. In instances in which the department or program is responsible for preparation of the financial report, the report must be submitted to Sponsored Programs Administration for review and approval prior to submission.

Property Reports

The PI/PD will prepare property reports and submit them to Sponsored Programs Administration for review, approval, and submission to the Sponsor. When title to property acquired under a sponsored agreement vests with the Sponsor, it may be possible to have the title transferred to the University. Contact OSPA for additional information.

Delinquency in Reporting

Delinquent reporting can have an adverse impact on the University's relationship with Sponsors. Upon notification of delinquency, the Office of the EVPRI will inform departmental chairs and the respective deans of the issue. With permission of he EVPRI, OSPA may withhold submission of new proposals and establishment of awards for PIs/PDs who are seriously delinquent in their reporting responsibilities.

Closeout Reporting

OSPA will assist PIs/PDs with closing sponsored projects by ensuring the timely submission of required final reports. Reports may be due 30 to 120 days following the expiration date of the sponsored agreement. Reports required at closeout may vary by Sponsor. As a general rule, Federal sponsors require financial, invention, and technical reports; property reports may also be required.

Closeout Audit

Some Sponsors may request that its designated auditor perform a closeout audit prior to issuance of final payment on a sponsored project. PIs/PDs who are notified that a Sponsor intends to perform a closeout audit must contact OSPA.

Residual Funds on Sponsored Projects

Some Sponsored agreements allow the University to retain residual funds upon completion of the project. If the agreement allows for such retention, the Office of Sponsored Programs Administration-Financial Administration Core will work with the PI/PD or departmental designee to ensure that all expenditures have been posted to the award and to transfer remaining funds to an appropriate residual account.

Award Chartfield/Speedtype Closings

Sponsored awards typically have a specified period of performance. When the award expires, Sponsored Programs Administration-Financial Administration Core (SPFA) will work with the PI/PD or departmental designee to confirm effort, address any deficits and closeout the award. SPFA will obtain confirmation that all charges have been posted to the chartfield/speedtype and are appropriate, allowable, and allocable to the project. The award will then be officially closed in the financial system.

7.5 Record Retention

Maintaining adequate records on sponsored programs/activities is required by Federal agencies as well as most other Sponsors. PIs/PDs and their designees are required to be aware of and meet the requirements of the respective Sponsors, Agreements or as defined by the University's Records Retention Policy.

7.6 Transfer of Sponsored Projects to Other Institutions

If the PI/PD of an active sponsored project moves to another institution, the University of Louisville may agree to transfer the award(s). Such transfer must be approved by the University

and Sponsor. Equipment purchased on sponsored awards may be transferred to the new institution depending upon the nature of the project and the terms and conditions of the award.

7.7 Communications from Sponsors

Letters or other communications from Sponsors to any University employee that suggest or identify the existence of a potential problem with the administration of a sponsored project must be forwarded immediately to a Director in OSPA for review, further communication and resolution.

7.8 NIH Awards: Progress Reports and Carryover Requests

Reason For Procedure

With tighter budgets and increased monitoring of awards by NIH agencies, it is important that both progress reports and carryover requests for non-SNAP (Streamlined Noncompeting Award Process) awards be submitted in a timely and accurate manner in order to avoid loss of funding. This notice clarifies procedures on preparation of progress reports and the submittal/processing of carryover requests.

Progress Reports:

Annual NIH non-Research Performance Progress Reports (RPPRs) should be submitted by the date listed in the federal Electronic Research Administration (eRA) system (normally 60 days before the end date of the budget period). Annual RPPRs for NIH e-snap awards should be submitted 45 days prior to the end date of the budget period. Once uploaded the PI must route the RPPR to the respective Grants Management Specialist for review and approval. Once reviewed and approved, an Office of Sponsored Programs Administration (OSPA) institutional official will submit the RPPR and email the PI and departmental contact accordingly. OSPA must receive the continuation proposal five (5) business days prior to the deadline in order to review, approve, and submit the documents on time. Timely submission of NIH RPPRs is required in order to ensure 1) on-time issuance of the continuation award notice from NIH and 2) approval of requests by the NIH for carryover of unobligated funds.

Carryover Requests:

If it is anticipated that a carryover of unobligated funds to a future year will be required for an NIH non-eSNAP award, the carryover request should be described within the NIH continuation RPPR. As the exact amount of unobligated funds requested for carryover may not be known until the Federal Financial Status Report (FFR) [previously called the Financial Status Report (FSR)] is prepared, the carryover request described in the RPPR should include a best estimate of the amount of carryover being requested.

When the FFR is later submitted to NIH via the Office of Sponsored Programs Administration (OSPA), the exact carryover amount requested should be included in Item 12 “Remarks” of the FFR. Simultaneously, a separate written request must be submitted to NIH (via OSPA) as

detailed in the NIH Grants Policy Statement, Part II, Terms & Conditions. All carryover requests must include a well-detailed justification of the need for the carryover funds and how they will be used for the benefit of the project.

NIH's decision about the disposition of a reported unobligated balance will be reflected in the Notice of Award (NoA) for non- SNAP awards that require formal NIH Grants Management Specialist approval. Upon receipt, OSPA and the PI/PD must review the award notice to ensure that the carryover request has been approved, and if questions arise concerning the carryover amount approved or not approved OSPA will contact the NIH GMS for clarification.

Competitive Renewals for SNAP Awards:

If the request for carryover is related to a competitive renewal and the FFR is accepted and approved, the OSPA will process the budget transfer and notify the PI and departmental contact accordingly.

Transfer Awards:

Following receipt of a transfer award, additional carryover from the previous institution may be released and made available for carryover. In this event, a letter from NIH Closeout or a revised Notice of Award will be issued. Once received, OSPA will process the budget transfer and notify the PI and departmental contact accordingly.

T32 Awards:

These grants have special conditions regarding trainee stipends. When an appointment starts in a budget period, the entire stipend for that appointment must be charged to that same budget period. Trainee appointments may extend beyond the end date of the budget period to accommodate a normal 12-month appointment EXCEPT in the final year of the project. In order for appointments to extend beyond the end date, the grantee must send an e-mail request for an extension to avoid issues with appointments through XTRAIN. If an appointment does extend beyond the end date of the budget period, the Federal Financial Report (FFR) should reflect the portion of the stipend commitment remaining unpaid as of the end of the budget period as an unliquidated obligation. Once the FFR for the previous year is accepted/approved, OSPA will move only the unliquidated stipend amount to the new award year. If the PI identifies a need to retain the unobligated balance, a request for prior approval must be submitted through OSPA for review and approval prior to submission. Approval will result in issuance of a revised NoA, at which time OSPA will process the budget transfer and notify the PI and departmental contact accordingly.

Chapter 8: Industry Awards and Agreements

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 Office of Sponsored Programs Administration 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.

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.

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.

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.

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).

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., eProposal, Proposal Clearance Form (PCF) or Transmit Research Initial Assessment (TRIA)-Multi-Institutional Research Application (MIRA)).

Chapter 9: Research Regulations

Listed below are important policies that help to ensure University compliance with federal regulations governing research.

9.1 Human Subjects Protection Program Office (IRB)

The University's Institutional Review Boards (IRB) are a part of the University Human Subjects Protection Program. An IRB is a group of individuals with varying backgrounds, charged with reviewing proposed research involving human subjects to ensure the protections of those subjects and compliance with federal human subject's regulations. The University of Louisville has two such review boards, each consisting of faculty, staff, and representatives from our affiliated institutions, as well as members of the Louisville community.

The University of Louisville Institutional Review Boards and the Human Subjects Protection Program were accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in 2005. The University of Louisville IRBs operate in compliance with Good Clinical Practice (GCP)/International Conference on Harmonization (ICH) Guidelines insofar as those guidelines are consistent with the U.S. Food and Drug Administration regulations (21 CFR Parts 50 and 56) and the Department of Health and Human Services regulations (45 CFR 46) pertaining to the protection of human subjects in research.

The charge of the Institutional Review Board is:

- To protect human subjects involved in research at the University and its affiliated institutions
- To ensure that human subjects voluntarily consent to their involvement in research
- To protect the investigators involved in research at the University and its affiliated institutions by providing guidance
- To protect the University and its affiliated institutions by providing guidance to the signatory institutions named herein and following the federal, state and local standards for human subject protections
- To protect the volunteer members of the IRB involved in the review of human research studies.

All paid and gratis faculty of the University of Louisville, who conduct human subject's research associated with their appointment, must utilize the University's IRBs for review, approval and continued oversight of the research. In certain circumstances, individual or institutional conflicts of interest may require the utilization of an independent IRB. Requests for use of an independent IRB must be made to the University IRB and approved by the EVPRI.

Prior to implementation of any research involving human subjects, one of the IRBs, one of the IRB chairs or vice-chairs or one of the experienced committee members designated by the IRB chair must review the proposed research and approve it or exempt it from IRB review.

The IRB is guided by three basic ethical principles regarding all research involving human subjects, regardless of whether the research is subject to federal regulation, with whom it is conducted, or the source of support. Those principles, enumerated in The Belmont Report, are:

- Respect for persons
- Beneficence: The obligation to do no harm, maximize benefits and minimize risks
- Justice, equal opportunity for subjects to receive the benefits and bear the risks of research, regardless of gender, race and socioeconomic status.

All faculty and staff involved in human subjects research are expected to be familiar with The Belmont Report. As noted above, there are two IRB's at the University of Louisville.

IRB Medical

IRB Medical meets three times per month - the first, third and fourth Thursday of the month at 12:15 p.m. in Room 230 of MedCenter One, 501 E. Broadway, Health Sciences Center campus.

IRB Behavioral/Social Science/Education

IRB Behavioral/Social Science meets the first Wednesday of every month at 12:30 p.m. Room 230 of MedCenter One, 501 E. Broadway, Health Sciences Center campus.

Protocols are assigned to primary reviewers and are pre-reviewed by board members or Human Subjects Protection Program Office staff to identify items that need the investigator's attention prior to full board review. The investigator should work with the reviewers and staff to address any concerns identified prior to the protocol going to the full board.

Definition of Research and What Types of Research Must be Reviewed

Research is defined in the “Common Rule” (45 CFR 46.102(d) as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Clinical investigation, as defined in FDA regulations (21 CFR 50.3(c) means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Human subjects are defined in the “Common Rule” as “living individuals about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” The FDA regulations define human subjects as an individual who is or becomes a participant in research,

either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. The appropriate definition depending on the type of human research will generally apply to all human research conducted by investigators at the University of Louisville.

If there is any doubt as to whether IRB review for specific research is required, one of the IRB chairs makes the determination for the University of Louisville and its affiliated institutions. Every prospective investigator considering submitting a proposal including human subject research should become familiar with the issues related to human research and with the process by which IRB approval is obtained.

Federal-wide Assurances

The University of Louisville, University of Louisville Hospital, Norton Healthcare and Jewish Hospital Healthcare Services all have Federal-wide Assurances with the Department of Health and Human Services. An FWA is a binding written document that commits these institutions to comply with federal regulations concerning federally-funded human research conducted at the institutions listed below. The Federal-wide Assurance numbers for each of the named institutions are:

Institution With FWQ	FWA Number	Expiration Date
University of Louisville	FWA00002211	08/07/2019
University of Louisville Hospital	FWA00002163	07/20/2016
Norton Healthcare, Inc.	FWA00002217	07/11/2018
Jewish Hospital Healthcare Services	FWA00002167	01/03/2018

The Human Subjects Protection Program Office

The Human Subjects Protection Program Office (HSPPO) helps to ensure that all University of Louisville research involving human participants is conducted in accordance with Federal and State regulations and University and sponsoring agency policies and procedures instituted to protect the rights and welfare of human research participants. HSPPO upholds this commitment to the protection of human participants involved in research regardless of the funding source and regardless of the location of the research. HSPPO supports two duly established and independent Institutional Review Boards (hereby referred to as IRBs), which review and approve protocols for all research involving human participants.

The HSPPO staff is the first point of contact in the human research review process. They will answer questions and provide assistance about the appropriate review path for the particular research protocol. The IRB chairs and vice-chairs work out of the Human Subjects Protection Program Office when conducting IRB business.

The Human Subjects Protection Program Office on the Health Sciences Campus is located in Suite 200 of MedCenter One, 501 E. Broadway. The office is open from 8:00 a.m. to 5:00 p.m. Investigators are encouraged to call 852-5188 with questions.

IRB Policies and/or Procedures

Comments or suggestions regarding IRB policies or procedures are welcome and should be addressed to the Executive Vice President for Research and Innovation, Room 200, Jouett Hall, or to the Director, Human Subjects Protection Program, MedCenter One, Suite 200, 501 E. Broadway, Health Sciences Center.

9.2 Animal Subjects

The Animal Care and Use Program encompasses all use of vertebrate animals by or for the University of Louisville for educational or research purposes. The designated Institutional Official, the Executive Vice President for Health Affairs, has the ultimate responsibility for the Program. Direct oversight of the Program, which has been accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), International since its inception in 1965, is delegated to the Institutional Animal Care and Use Committee (IACUC). No vertebrate animal intended for research or teaching may be purchased, bred, or otherwise acquired by or for University faculty or staff without prior approval by the IACUC. The Research Resources Facilities (RRF) manages the acquisition, husbandry, and disposition of animals. All research and teaching activities involving animal subjects in University facilities must be directed by University of Louisville faculty members or by other personnel meeting University-accepted criteria as Principal Investigators.

The IACUC is responsible for monitoring all aspects of the Animal Care and Use Program and for advising the Institutional Official regarding recommendations for Program requirements and/or changes. Principal IACUC responsibilities include the following:

- Ensuring the humane treatment of laboratory animals
- Establishing policy and procedures to protect personnel from occupational health and safety hazards associated with the use of research animals
- Monitoring the laboratory animal environment by periodic inspection of housing and procedural areas
- Disseminating information related to approved methods for animal care

The IACUC is composed of at least seven faculty members who are experienced scientists, at least one veterinarian experienced in laboratory animal medicine, , and at least one individual not affiliated with the University to represent community interests.

Regulatory authority for the Program, including IACUC responsibility and function, include:

- The Animal Welfare Act (AWA), 7 U.S.C. 2131-2157, 2.17, 2.51, and 371.2(g)

- U.S. Department of Agriculture (USDA) Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Chapter 1, Subchapter A – Animal Welfare, parts 1, 2, 3, and 4 (and subsequent amendments).
- Public Health Service, Policy on Humane Care and Use of Laboratory Animals
- Interagency Research Animal Committee (IRAC), "Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training

The University of Louisville Animal Care and Use Program also fully endorses the National Research Council, Guide for the Care and Use of Laboratory Animals, which is used as a basis for Program development and AAALAC accreditation.

Principal IACUC activities are as follows:

- Semi-annual review of the institutional animal care and use program and inspection animal housing and study areas
- Prepare and submit written reports of program and facility evaluations, reviewed and signed by a majority of the IACUC, and including any minority views, to the Institutional Official. Recommendations regarding any aspect of the institutional animal care and use program or facilities may be included in these reports
- Review and approve, require changes to secure approval, or withhold approval of "Proposals to Use Laboratory Animals in Research and Teaching" (*Proposals*) prior to the initiation of related research or teaching activities. Re-review is required every three years, or more frequently as determined by the IACUC or regulatory agencies, and prior to modifications of ongoing activities.
- Provide PIs/PDs with written notice of decisions regarding Proposal review
- Suspend previously approved *Proposals* if activities are determined to be contrary to federal, state, local, and University regulations
- Investigate, review, and, if warranted, report public or institutional concerns of animal care and use program noncompliance

Prior to IACUC review, a Proposal t is pre-reviewed by IACUC staff, a member of the Research Resources Facilities Veterinary Care faculty, and representative from pertinent safety offices/committees. This pre-review not only satisfies regulatory requirements for veterinary involvement in project design but also helps ensure that personnel and facilities are available to support the proposed work and that any special safety concerns are met. Following pre-review, the Proposal is submitted to a Designated Reviewer and 0-2 Review Consultants, depending on the nature of the project. Summaries of *Proposals* under review are sent to all IACUC members, which may elect to request full committee deliberation prior to approval. Otherwise, approval is granted after assigned reviewers' concerns are met. Decisions involving *Proposal* disposition are made only after consideration of non-animal models and other research methods that reduce animal number and/or any anticipated pain or distress. Committee objectives are accomplished while preserving the freedom of scientific inquiry...

All research faculty and staff members are required to attend a training seminar that addresses humane methods of animal maintenance and research experimentation. Also discussed in mandatory training are the availability and use of research or testing methods that limit the use of

animals and minimize potential animal pain and distress. This includes the proper use of anesthetics and analgesics. Procedures whereby personnel may report perceived deficiencies in the Animal Care and Use Program are also defined. Issues pertaining to the hazards associated with animals and mandatory enrollment in the Occupational Health and Safety Program for personnel exposed to research animals are also presented. Because of such issues, the IACUC also serves as a liaison for research staff and other important oversight bodies within the University, including the Department of Environmental Health and Safety, Radiation Safety, and the Institutional Biosafety Committee.

Once approval for the use of animals is secured, the faculty and staff of the RRF are responsible for maintaining research animals in a clean and distress-free environment. In maintaining centralized animal holding facilities, the RRF strives to provide investigative staff with physiologically and psychologically healthy research subjects. The University Animal Care and Use Program views the relationship of the IACUC, RRF, and research staff as a partnership in providing the highest quality animal model possible to support the highest quality research data.

For more information regarding the University's policies, see https://louisville.edu/research/iacuc/policies, and/or contact the Health Sciences Center Office of Research Services.

9.3 Institutional Biosafety Committee

In compliance with NIH Guidelines and University policies, an Institutional Biosafety Committee (IBC) has been established at the University of Louisville. UofL's Institutional Biosafety Committee (IBC) reviews all institutional activities involving the use of biohazardous agents, and recombinant and synthetic nucleic acid molecules that require approval for "biosafety activities" as described in current governmental regulatory requirements. These regulatory requirements include, but are not limited to, the National Institutes of Health (NIH) Recombinant DNA Guidelines, the Centers for Disease Control and Prevention (CDC) Guidelines, and the Occupational Safety and Health Administration (OSHA) regulations and compliance directives as adopted and adhered to by KY OSHA.

All principal investigators that want to use one of the following biological agents must complete and submit at IBC application/registration form:

- Biological agents as specified in the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories web site.
- Recombinant DNA and human gene therapy, as outlined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) web site.
- Human blood, body fluids, tissues, other clinical specimens are regulated through the OSHA Bloodborne pathogen standard: See information on the Department of Environmental Health and Safety (DEHS) web site for all the regulatory requirements that principal investigators and clinical supervisors must meet.
- The possession, transport and acquisition of Select Agent and other than permissible quantities of toxins requires registration with Health and Human Services (HHS) Centers

for Disease Control (CDC) and USDA Animal and Plant Health Inspection Service (APHIS) prior to possession. If you possess Select Agents or any amount of Select Toxins OR intend to perform future research or work involving any Select Agent or Toxins, you must immediately inform the Biological Safety Officer, or call 852-6670, so that appropriate arrangements can be made

- When laboratories are to be relocated, renovated, vacated or closed, all chemical, radioactive, biological or other hazardous materials must be removed and disposed, in accordance with applicable EPA, OSHA, NIH, CDC and other regulations. Equipment and items that may pose a potential danger to people or the environment must be removed and properly disposed. Failure to comply with the policy below may result in sanctions. Policy For Laboratory Decommissioning

The IBC application/registration form is available on-line at the iRIS web site. Completed application/registration forms must be submitted by the principal investigator. In general, approval from the IBC is needed for work with Risk Group 2 and 3 biological agents; recombinant and synthetic nucleic acids (unless it is specifically exempt per the NIH guidelines); and human and primate materials; biological Toxins.

The IBC's charge is to ensure that all procedures and facilities involving the use of biological agents, recombinant DNA and large scale activities meet the best interests of laboratory safety, effective research, as well as the environment and general public. The IBC is appointed by and reports to the Executive Vice President of Research and Innovation. The composition of the committee meets the requirements as specified in the NIH Guidelines which includes two community members that are not affiliated with the University of Louisville. The IBC has standing monthly meetings, which are generally scheduled the first week of each month. The Department of Environmental Health and Safety provides the administrative support for the functions and business of the IBC.

9.4 Radiation Safety

The University of Louisville’s radiation safety program encompasses approval of Authorized Users and uses of radioactive materials, worker training, laboratory surveys, purchasing and inventory control of radioactive materials, bioassay, personal dosimetry, radioactive waste disposal, survey instrument calibration and emergency response. The Radioactive Materials User Guide is the policy and procedure manual for all authorized users of radioactive materials and the personnel under their direction that handle radioactive materials. The Department of Environmental Health and Safety’s (DEHS) Radiation Safety Office writes and maintains the University’s radioactive materials licenses. These licenses are issued by the Kentucky Radiation Control Branch of the Cabinet for Human Resources under the authority of the Nuclear Regulatory Commission. Additionally, DEHS’s Radiation Safety Office coordinates the activities of the Radiation Safety Committee, which meets quarterly. Under UofL’s radioactive materials licenses, the Radiation Safety Committee has full authority to govern radioactive materials usage within the university. In accordance with our licenses and state regulation, the Committee is charged with the following duties and responsibilities:

- Reviewing the training and experience of a proposed Authorized User to determine their qualifications to use radioactive material and approving all requests to use radioactive material.
- Prescribing special conditions and monitoring techniques for all proposed uses of radioactive material to insure safety.
- Reviewing the Radiation Safety Officer's summary reports on radioactive material uses including training records, lab surveys, incidents, misadministrations, occupational radiation exposure records that are submitted to the committee on a quarterly and annual basis.
- Establishing a program to insure that all individuals working with radioactive material are properly trained prior to commencing work and annually thereafter.
- Recommending remedial actions to correct any deficiencies in the radiation safety program.

In order to obtain authorization to procure and use radioactive material at UofL, an individual must: be a full-time faculty member; have prior training and experience in the types of radioactive material and uses requested; and complete an "Application for Authorization to Use Radioactive Material" form. The first point of contact in the application process is the Radiation Safety Office, which is located in Room 102 of the Library/Commons Building. Applications are available on-line or by calling 852-5231. Once the application is completed, it should be submitted to the Radiation Safety Office so that the Radiation Safety Officer can perform a preliminary review. The application will then be routed to appropriate members of the Radiation Safety Committee for ultimate approval or disapproval.

All authorized users of radioactive materials must comply with the conditions and possession limits of their authorization and UofL's radioactive materials license as follows:

- Assuming responsibility for their own safety and the safety of all personnel under their direction working with radioactive material.
- Notifying the Radiation Safety Officer of newly hired or transferred personnel who will be working with radioactive material.
- Ensuring that all individuals requiring radiation dosimetry to monitor exposure are assigned film badges which must be
- ordered through the Radiation Safety Office.
- Ensuring the security of radioactive material in the laboratory and clinical areas to prevent accidental loss or theft. Ensuring that all radioactive waste is properly disposed of through the Radiation Safety Office.
- When laboratories are to be relocated, renovated, vacated or closed, all chemical, radioactive, biological or other hazardous materials must be removed and disposed, in accordance with applicable EPA, OSHA, NIH, CDC and other regulations. Equipment and items that may pose a potential danger to people or the environment must be removed and properly disposed. Failure to comply with the policy below may result in sanctions. Policy For Laboratory Decommissioning

Additionally, the Authorized User is responsible for assuring that all individuals under his/her direction that handle radioactive materials have received adequate instruction in radiation safety

principles applicable to specific practices of that particular laboratory. It should be noted that many handling and radiation safety procedures pertain to circumstances in a particular lab or institution; therefore, it may not be assumed that instruction has necessarily been adequately provided by prior occupational training, board certification, etc.

Completion of the initial orientation radiation safety training course offered by the Radiation Safety Office is mandatory for all individuals using radioactive materials. This course is generally offered the second Thursday from 11 AM – 12PM. Locations are specific on the DEHS web site. Group or individualized training can be arranged on a case-by-case basis. All users and workers that require this training must contact the Radiation Safety Office at 852-5231 to register. Annual refresher training is also mandatory for all users of radioactive material. This training is now available on-line on the Department of Environmental Health and Safety web site.

X- Ray Units and Other Radiation Producing Machines

Machines that produce ionizing radiation, such as x-rays from fluoroscopes, analytical x-ray units, must be registered with the Kentucky Radiation Control Branch as required by state law. Department Chairs are responsible for review and approval of proposed uses of all ionizing radiation producing machines within their jurisdiction. Such approval signifies that the department will provide the resources including facilities and equipment necessary to control hazards. Prior to departmental approval, the Radiation Safety Office must be notified of any new ionizing radiation producing equipment in the event that revisions to UofL's

licenses and permits are required. All individuals working with x-ray units or machines that produce ionizing radiation must be trained by the Principal Investigator or Clinical Supervisor in the appropriate safety practices and must wear dosimetry.
Compliance surveys of radiation producing machines are conducted by the Radiation Safety Office on a pre-set time frame
consistent with the license issued by the Kentucky Cabinet for Human Resources' Radiation Control Branch.

9.5 Laser Safety

Lasers are utilized in research and clinical applications throughout the university. The laser's high degree of coherence of the light beam makes it an ideal tool for many different applications. However, this coherence also makes the light beam (direct or reflected) a serious threat for damage to the human eye. For that reason, the American National Standards Institute has developed a guideline entitled "Standards for the Safe Use of Lasers" (ANSI z136.1) which is the laser industry's standard for all persons who operate Class II, Class III, or Class IV laser products. The Radiation Safety Office has produced a Laser Safety manual that can be found online on the DEHS website. Adhering to this manual will satisfy the recommended requirements for laser safety. Additionally, the Occupational Safety and Health Administration (OSHA) issued a directive to its compliance officers entitled "Guidelines for Laser Safety and Hazard Assessment" since citations for safety problems with lasers can be issued under OSHA's general duty clause. This directive provides detailed information on laser types, hazards,

classifications, control measures, and personal protective equipment. In addition to the operations and maintenance manual for each laser, this directive contains useful information that can serve as the basis of training for users of lasers.

All Principal Investigators and Clinical Supervisors that have lasers are responsible for the training and safety of personnel under their direction that may use the laser. Laser Safety training can also be found online at the DEHS website. This includes ensuring that protective eyewear is available and utilized and that beam stops or other engineering safety features are not defeated or removed. Principal Investigators and Clinical Supervisors must notify the Radiation Safety Office of any existing class IIIB or IV lasers as well as any purchased in the future. All injuries involving lasers must be reported to the Radiation Safety Office as well as UofL's Worker's Compensation representative in the Risk Management department.

OSHA Directive Publication 8-1.7 "Guidelines for Laser Safety and Hazard Assessment" is available at
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1705

When laboratories are to be relocated, renovated, vacated or closed, all chemical, radioactive, biological or other hazardous materials must be removed and disposed, in accordance with applicable EPA, OSHA, NIH, CDC and other regulations.
Equipment and items that may pose a potential danger to people or the environment must be removed and properly disposed. Failure to comply with the policy below may result in sanctions.
Policy For Laboratory Decommissioning

9.6 Chemical Agents

The use and storage of hazardous chemicals are highly regulated by federal, state and local agencies such as the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the National Fire Protection Association (NFPA), and the Metropolitan Sewer District (MSD). An overview of environmental, health and safety regulations applicable to laboratories is available on the DEHS web site. This information source, Regulatory Requirements and Standards of Care for Laboratories, provides compliance basics on various aspects of chemical safety, including keys to compliance, training information, common problems to avoid, as well as University contacts for additional support and resources.

This section of the Research Handbook will not attempt to duplicate that web-based resource, but will instead emphasize one of the major regulations impacting research laboratories using hazardous chemicals: the OSHA Laboratory Standard. This standard

regulates laboratory use of hazardous chemicals. Compliance with this standard centers on each laboratory having its own written Chemical Hygiene Plan with the following major elements:

- Standard operating procedures.
- Control measures such as fume hoods, special work practices, and personal protective equipment.
- Training of laboratory personnel, including access to Safety Data Sheets.

- Circumstances under which prior approval of a laboratory operation is required.
- Provisions for medical consultations and examinations in case of exposure to hazardous chemicals.
- Designation of persons responsible for implementing the Plan.
- Designation of a Chemical Hygiene Officer/Committee to provide technical guidance.
- Additional precautions for working with select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity.
- Measures to ensure fume hoods function properly.

Policies and procedures for chemical safety are incorporated in the University **Laboratory Safety Manual and the Laboratory Chemical Hygiene Plan.**

- Lab personnel interested in performing self-inspections of labs should contact the DEHS Laboratory Safety Coordinator for guidance. DEHS also conducts periodic laboratory safety inspections. Faculty or laboratory managers are also encouraged to request a DEHS lab safety inspection, particularly if a highly hazardous chemical or procedure has been introduced to the lab.

In addition to inspections of laboratories, DEHS also provides review of research proposals requiring institutional health and safety approval. IACUC policy requires health and safety review of animal research proposals involving hazardous chemicals. If the hazard assessment indicates the need for hazard controls, DEHS determines that appropriate procedures and equipment are in place prior to approving the proposal. Granting agencies such as the American Heart Association and the Department of Defense also require this institutional review and approval. Researchers should be aware they will be required to have approved, written safety procedures for use of select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity, such as cytotoxic drugs, in place prior to grant application deadlines.

Other responsibilities of the Principal Investigator related to the use of chemical agents are:

- Maintaining an accurate and current chemical inventory of all chemicals used and/or stored in areas under his/her responsibility (i.e. labs and cold rooms).
- Maintaining current copies of Safety Data Sheets (SDS) for each hazardous chemical used in the laboratory. If SDS are accessed on-line, all laboratory staff must be informed regarding the procedures to obtain them.
- Assuring that the proper personal protective equipment is provided to all laboratory staff which includes but is not limited to lab coats, aprons, eye protection, face protection, gloves, etc. The DEHS web site contains useful information on the selection of personal protection equipment in labs.
- Assuring that training is provided for hazards and procedures specific to their laboratory, the DEHS web site contains a Laboratory Safety and Hazardous Waste classroom training schedule. All new laboratory staff must attend a Laboratory Safety and Hazardous Waste classroom training session. Online refresher training must also be completed every 3 years.

Finally, if principal investigators use large quantities of solvents or other flammable liquids, storage requirements and the allowed volumes are specified by the National Fire Protection Association (NFPA) standards and the Occupational Safety and Health Administration (OSHA) regulations. Also, there are carcinogens and other chemicals that are regulated by OSHA through substance specific standards so that additional requirements may apply. Refer to the DEHS Laboratory Safety Manual for information.

When laboratories are to be relocated, renovated, vacated or closed, all chemical, radioactive, biological or other hazardous materials must be removed and disposed, in accordance with applicable EPA, OSHA, NIH, CDC and other regulations.
Equipment and items that may pose a potential danger to people or the environment must be removed and properly disposed.
Failure to comply with the policy below may result in sanctions. Policy For Laboratory Decommissioning

9.7 Hazardous Chemical and Infectious Waste

The disposal of hazardous chemical waste, as well as infectious, waste, are both highly regulated activities due to the potential for environmental harm if not properly handled. The University has a very restrictive policy regarding the sink disposal and regular trash disposal of chemically hazardous and infectious waste. As such, DEHS has developed a Disposal Guide to provide assistance to faculty and staff on the required procedures to handle and dispose of these types of waste. This manual is available on-line. In addition to providing the requirements for proper disposal of chemical and infectious waste, it also includes information on disposal requirements of gas cylinders; empty containers; used batteries and lamps, controlled drugs and used oils since these are all potential issues that principal investigators in labs may encounter.

Completion of the hazardous waste training course offered by DEHS is mandatory for all persons who manage hazardous waste in laboratories. It offers information about the basics of complying with hazardous waste regulations and instructs university personnel in the procedures for having hazardous waste picked up by DEHS. University personnel can view the DEHS training schedule located on the DEHS web site for session dates. Most all chemical wastes from laboratories are presumed to be a regulated hazardous waste. If the chemical waste exhibits one or more of the following EPA four hazardous characteristics or is listed, the waste is determined to be a regulated hazardous waste.

- **Ignitability** - Ignitable wastes can create fires under certain conditions, are spontaneously combustible, have oxidizing potential, or have a flash point less than 60 °C (140 °F). Examples include ethanol and acetone wash solutions, hexane, diesel fuel, used solvents, nitrates, perchlorates, and chromates.
- **Corrosivity** - Corrosive wastes are liquid wastes, such as acids or bases (pH less than or equal to 2, or greater than or equal to 12.5) that are capable of corroding metal containers, such as storage tanks and drums.
- **Reactivity** - Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water. Examples include n-butyl lithium, silane, lithium-sulfur batteries, and explosives.

- **Toxicity** - Toxic wastes are harmful or fatal when ingested or absorbed (e.g. contains heavy metals such mercury, lead, cadmium, chromium, barium, silver, selenium, arsenic, pesticides, carcinogenic organics, etc.). When toxic wastes are land disposed, contaminated liquid may leach from the waste and pollute ground water. Toxicity is defined through a laboratory procedure called the. The TCLP helps identify wastes likely to leach concentrations of contaminants that may be harmful to human health or the environment.

Additionally, by definition, EPA determined that some specific wastes are hazardous. These wastes are incorporated into lists published by the Agency. These lists are organized into three categories:

- **The F-list** (non-specific source wastes). This list identifies wastes from common manufacturing and industrial processes, such as solvents that have been used in cleaning or degreasing operations. This includes common used waste solvents such as xylene, toluene, acetone, ethyl acetate, methylene chloride, trichloroethane.
- **The K-list** (source-specific wastes). This list includes certain wastes from specific industries, such as petroleum refining or pesticide manufacturing. Certain sludges and wastewaters from treatment and production processes in these industries are examples of source-specific wastes.
- **The P-list and the U-list** (discarded commercial chemical products). These lists include specific commercial chemical products in an unused form. Some pesticides and some pharmaceutical products become hazardous waste when discarded.

Although the chemical may not be determined to be a regulated hazardous waste, it could still be toxic to human health, animal health, and the environment if not disposed properly. These include chemicals that have acute or chronic carcinogenicity, mutagenicity, and teratogenicity. Moreover, some chemicals could be deemed hazardous or a nuisance to our city's waste water treatment plants. These include chemicals that contain concentrated dyes, emanates a strong, offensive odor, any oxygen demanding pollutant, detergents, surface active agents, or other substances which might cause excessive foaming to the POTW.

All laboratories that generate hazardous chemical waste are considered "satellite accumulation areas" by the EPA. Colleges and universities across the country are not immune from EPA inspections, it is essentially important that all principal investigators and research personnel that generate hazardous chemical waste comply with the following **Satellite Accumulation Area Requirements:**

- Hazardous chemical waste container(s) must be kept at or near the process generating the waste and under the control of the operator. An inspector typically interprets this as the same room the hazardous chemical waste is generated.
- Any container used to collect hazardous or chemical waste must be marked with the words "*Hazardous Waste*" or "*Chemical Waste*".
- Any container holding hazardous chemical waste must be in good condition. This means no cracks, no rust, and no leaks.

- Any container holding hazardous chemical waste must be compatible with the waste and any waste mixtures in that container must also be compatible.
- Any container holding hazardous chemical waste ***must be closed at ALL TIMES***. The only exception to this is when waste is being added to or removed from the waste container.
- Accumulation of hazardous waste in any satellite accumulation area cannot exceed 50 gallons or 200 pounds at any time. If the area accumulates acutely hazardous waste (EPA P-Listed Waste), one quart (1 kg) is the maximum amount allowed to be accumulated. A list of EPA acutely hazardous wastes is available in Chapter 3 of the Disposal Guide.

NOTE:

Laboratories may be subject to unannounced hazardous waste inspection by State and/or Federal regulatory agencies. These inspections routinely include ensuring that chemical hazardous waste containers are prominently marked as "Hazardous Waste", chemical hazardous waste containers are closed, and chemical waste is kept in the same room the waste is generated. Any fines assessed against UofL laboratories will be paid by the home department or lab itself.

Regulations imposed by local, state, and federal agencies dictate that infectious (medical, biological waste) must be segregated, packaged, and disposed of in a specific manner. The primary purpose of the regulations is to limit on-the job exposure to blood and other potentially infectious materials. It is the responsibility of every unit, or laboratory generating infectious waste to ensure that all wastes listed in this section are segregated from other wastes, packaged, and disposed of in accordance with University policy, following packaging and disposal guidelines. These wastes include the following:

- Microbiological waste - i.e., stocks and/or cultures of etiological or infectious agents, including culture plates, test tubes, swabs, etc. contaminated with these agents.

- Human Pathological Waste - i.e. all human, tissues, muscles, parts, organs, etc.

- Animal Pathological Waste – i.e. animal carcasses, tissues, parts, etc.

- Transgenic Plant Material - plant's genetic material that has been altered by the introduction of genes from another organism.

- Sharps - i.e., syringes, needles, and scalpel blades, glass and plastic pipettes, plastic pipette tips, and vials All needles and syringes regardless of their use are to be handled in accordance with this guide. Approved sharps containers are hard-sided, biohazard labeled and puncture resistant. Sharps containers should be sealed when ¾ full and discarded in a red biohazard bag- lined burn box.

Contaminated protective gloves and disposable lab coats should also be disposed of as biohazardous waste. Laboratories and other areas that generate infectious waste must use the medical waste red bag liners and containers provided by University custodial services. Infectious waste must be packaged and prepared for disposal by laboratory or clinical staff. Full securely

closed, marked, and labelled medical waste containers should remain in the laboratory or clinical space. When U of L laboratories are housed in a non-University facility, disposal of infectious waste must follow the policies of the organization where the laboratory is located. Policy conflicts or questions about safety should be directed to DEHS.

The detailed requirements for pickup of hazardous chemical waste and infectious waste are available on the DEHS Waste Disposal web site. (Chapters 3 and 5, respectively, of the Disposal Guide). For further information regarding the University's chemical waste and infectious waste management programs, contact the DEHS Hazardous Waste Coordinator at 852-2956 or Cathy Price.

When laboratories are to be relocated, renovated, vacated or closed, all chemical, radioactive, biological, or other hazardous materials must be removed and disposed, in accordance with applicable EPA, OSHA, NIH, CDC and other regulations.
Equipment and items that may pose a potential danger to human health or the environment must be removed and properly
disposed. Failure to comply with the policy below may result in sanctions. Policy For Laboratory Decommissioning

9.8 Conflict of Interest in Research

A conflict of interest is any situation that may compromise or appear to compromise a covered individual's (employee's) professional judgment in carrying out their institutional activities because of an external relationship/interest of the employee or their immediate family. The University of Louisville has developed policies and procedures for promoting objectivity and responsible conduct of research by managing, reducing, or eliminating conflicts of interest.

The Attestation and Disclosure Form (ADF), available in iRIS must be completed, at least annually by:

1. All University of Louisville Employees.
2. All individuals participating in research under the auspices of U of L, regardless of compensation. This includes all individuals with a research appointment.

Effective August 24, 2012, a current ADF must be on file for each named researcher at the time of proposal submission. The ADF is located on the iRIS web site. Directions for completing the ADF are located on the COI web site (under the COI requirements link). Additional information regarding conflicts of interest can also be found at this site.

If you have a question or concern regarding research misconduct, feel free to email Research Integrity.

9.10 Research Activities Performed by Outside Organizations

The University of Louisville recognizes that from time to time it may be appropriate for an outside organization to perform research activities, including human subject research, at the

University. The University will consider requests for such activities based on the following guidelines:

- University faculty research must have priority over all private-sector research with respect to all resources including facilities, equipment, services, and personnel.
- The services that are to be provided to the outside company should be for stated periods of time rather than permanent.
- The research being conducted in University facilities must be within the research mission of at least one of the University's departments.
- If the research involves human subjects, then the guidance subscribed to by the university must be followed. This includes review by the appropriate University of Louisville IRB and continued oversight by the IRB for the length of the project.
- The University will receive reimbursement for all costs associated with each individual project. Such reimbursement shall include incremental costs incurred by the University as a result of the use plus the appropriate indirect cost for sponsored projects.
- The University will not make its facilities available for services that are available from the private sector in the Louisville area. This guideline would apply to the basic purpose for which facilities are used and not to all ancillary services.
- All companies must have a sponsoring department that is willing to certify to at least the following:

    1. The department has the space available for the outside company to perform the project.
    2. The project will not take away from any of the department's functions or activities.
    3. The department will be responsible for all administrative details relating to the proposed company's use of the facilities, such as obtaining temporary parking permits through University Police, arranging for keys, etc.
    4. If University resources for which it has an obligation to a third party are to be used, the sponsoring department will appoint a faculty member who will be responsible for the conduct of the outside company relating to those resources.
    5. All such arrangements should be subject to a business agreement to be negotiated by the Office of the Executive Vice President for Research and Innovation upon the recommendation of the sponsoring department and the appropriate dean, with final approval by the President.

9.11 Responding to Instances of Non-Compliance

The University has taken steps to manage compliance risk, but in the event that an instance of non-compliance occurs, the University has policies and procedures through which instances of non-compliance with federal, sponsor, or University regulations will be investigated. Findings of such investigations will be reported, as required by regulation and contractual requirements.

9.12 Committee Information

Application deadlines, meeting schedules, procedures and forms for each of the University of Louisville's research regulation committees can be found at the following points of contact:

Committee	Phone	Website
Animal Care (IACUC)	852-7307	Animal Care (IACUC)
Institutional Biosafety Committee (IBC)	852-6670	Institutional Biosafety Committee (IBC)
Human Subjects Protection Prog. Office (IRB)	852-5188	Human Subjects Protection Program Office
Radiation Safety Committee	852-5231	Radiation Safety Office

11/25/2020

Chapter 10: Service Centers

Core scientific facilities support innovative research by providing highly specialized services, equipment, and staff. Please see the links below and contact the core facility directly for more information. If you have any questions, please email the Office of the Executive Vice President of Research and Innovation.

Research Core Laboratories

Service Center Policy

Research Centers & Institutes

11/02/2020