CENTER FOR HEALTH SCIENCES

Research Handbook

I. Introduction

A. Sponsored Projects at OSU-CHS

At Oklahoma State University Center for Health Sciences (OSU-CHS), our mission is to educate and train osteopathic physicians, research scientists, and other healthcare professionals, emphasizing service to rural and underserved areas of Oklahoma. In support of this mission, involvement in sponsored programs is crucial. Active participation not only enhances research capabilities, but also addresses healthcare challenges in underserved regions. Sponsored projects are externally funded research, service, and scholarly activity.

The Office of Research assists the Principal Investigator (PI) in the administrative processes of sponsored projects: preparation, approval, and submission of proposals, adherence to compliance regulations, and negotiation and acceptance of awards.

When awards are executed by the Office of Research, they are handed off to the Office of Grants, Contracts and Post Award Administration (or simply Post Award), who assist PIs in the financial and administrative management of their projects. Post-Award Administration is responsible for ensuring that the business interests of the University are protected throughout the operation of such agreements. The Post-Award Administration maintains auditable records of direct and indirect charges to contracts and grants and prepares fiscal reports required by sponsors. Post-Award Administration is also responsible for billing and collecting costs incurred on cost reimbursement contracts and for requesting funds related to contracts.

B. Purpose of Handbook

To ensure that funds provided from external sources to support research and other projects are administered in accordance with OSU-CHS policies and those of the sponsor, all externally sponsored projects for research or other purposes will be administered through the Pre-Award, Post-Award and the Office of Clinical Research following established University policies and procedures. External sources include both governmental and private organizations.

Faculty and staff members who conduct sponsored projects under OSU-CHS auspices have an important public and personal responsibility to manage those projects carefully. The Sponsored Projects Handbook is a crucial tool that will guide and support research investigators in fulfilling that responsibility. Its purpose is to acquaint new investigators with the research policies and procedures of OSU-CHS, inform them of the various services available to them, and serve as a reference and guide to further information and assistance for all investigators and administrators.

This handbook is designed to aid Principal Investigators (PIs) and their respective departments in navigating the administrative facets of sponsored projects, ensuring they derive maximum value from their work. In doing so, PIs can devote their attention to advancing knowledge, nurturing the next generation of scholars, and service both the State of Oklahoma and the global community.

Where appropriate, specific reference is made to OSU-CHS policies on Sponsored Projects. Investigators and administrators should be mindful that portions of this Handbook may be superseded by policy memoranda, or changes in sponsors' policies and regulations. While every attempt will be made to keep the materials herein timely, the most current information will ultimately be found in specific sponsor documentation and award documents.

The three main goals of this Handbook are:

1. **Facilitate Effective Sponsored Project Development and Administration** – provide comprehensive guidance for Principal Investigators on the development and administration of sponsored projects.
2. **Clarify Roles and Responsibilities in Sponsored Projects –** Inform Principal Investigators about their roles and responsibilities in sponsored projects administration and compliance, emphasizing the collaborative support of staff.
3. **Centralize and Enhance Accessibility of Information –** Collect, organize, and present pertinent information related to sponsored projects administration in a unified document, ensuring accessibility for all stakeholders involved in the sponsored programs process.

This handbook is an overview of the activities required for researchers to prepare, submit, and manage externally funded projects at OSU-CHS. The handbook is divided into five main parts: 1) introductory material, 2) pre-award activities, 3) post-award management of the project, 4) compliance, 5) clinical trials and 6) miscellaneous matters.

The introductory material (sections I-III) covers an overview of Sponsored Programs at OSU-CHS their nature, and the staff, services, and contacts involved. There are two distinct pathways provided by the Office of Research to help investigators conduct research at OSU-CHS investigator-initiated and industry- sponsored. Sponsored Programs and OSU-CHS support both investigator-initiated research and industry-sponsored clinical trials.

The pre-award (section IV) provides an overview of the activities required to initiate a funding proposal and prepare it for submission. Sections V-VIII cover post-award project management. Research Compliance (e.g., responsible conduct of research, conflicts of interest, human subjects, and animal care and use) and Clinical Research are covered by sections IX and X.

In addition to the University's policies, scholarly activity conducted at OSU-CHS is governed by federal, state, and institutional rules. Policies that apply to OSU-CHS generally (e.g., Conflicts of Interest) are detailed in the OSU-CHS Faculty Resource Manual and OSU-CHS's Sharepoint web site. Other funding-agency specific policies apply to a subset of projects (e.g., National Science Foundation, National Endowment for the Humanities) and should be consulted as necessary.

II. Nature of Sponsored Programs

Sponsored programs at OSU-CHS encompass scholarly, professional, and creative activities conducted by OSU-CHS personnel with support from external funding instruments. This includes grants, contracts, cooperative agreements, clinical trial agreements, or other arrangements. Sponsored programs are characterized by the presence of formal proposals, progress and final reports, specified performance periods, compliance terms, and the testing/evaluating of proprietary products.

Financial and institutional involvement in sponsored programs includes external audit oversight, billing requirements, reimbursement contingencies, cost sharing, budgeted indirect costs, and the disposition of property resulting from the activity.

While project funding is granted based on the professional expertise of the PIs, the formal award is conferred in the name of Oklahoma State University Center for Health Sciences. Upon acceptance, the PI assumes the responsibility for executing and completing the technical work and for overseeing project administration in compliance with State and Federal regulations. In the case of Clinical Research, the PI can collaborate with the OSU-CHS clinical research office to support the conduct of clinical trials per state and federal regulations. This collaboration is mutually beneficial, as it allows the PI to access the necessary resources to expertise while OSU-CHS benefits from the PI's professional knowledge and skills. OSU-CHS provides the essential infrastructure for project execution. Consequently, there exists a shared interest between the PI and OSU-CHS in successfully executing the sponsored project.

The award for sponsored programs is made to Oklahoma State University Center for Health Sciences (OSU-CHS), reflecting the University's commitment to the project. **All proposals, awards, and contracts must undergo thorough review and approval by the University, facilitated by the Office of Research.** This process ensures compliance with the sponsor, OSU A&M Board of Regents, and OSU-CHS policies, underscoring the mutual interest of the Principal Investigator and OSU-CHS in successfully executing the awarded project.

A. Gift vs. Sponsored Programs

A gift to OSU-CHS is defined as any item of value given by a donor with no significant expectation of tangible or economic benefit, other than recognition. Gifts lack contractual requirements and expectations of deliverables or rights in property or data. In contracts, sponsored programs involve external funding and a contract with specific terms, conditions, and scope of work, requiring monitoring and compliance. Contact the Office of Research for clarification on distinguishing gifts from sponsored programs. This distinction ensures that OSU-CHS maintains the proper oversight, compliance, and commitment to transparency in managing both sponsored programs and philanthropic gifts. Refer to Distinguishing Between Gifts, Grants, and Contracts policy# 3-70252.

B. Contractual Agreements

All contractual agreements (whether a contract, subcontract, clinical trial agreement or

consulting agreement) under which OSU-CHS faculty or staff will provide services or perform research for an external sponsor are subject to the same internal review process as standard grant proposal submissions.

1. *Policy*

The Office of Research is authorized to review, negotiate, and execute contractual agreements on behalf of OSU-CHS. This includes incoming and outgoing awards. The process requires reconciling issues and concerns; and ensuring compliance with the contracting agency, the OSU A&M Board of Regents policies, Federal Laws, State Statutes, International requirements, and OSU-CHS policies. All agreements processed through the Office of Research are signed by the Vice President for Research or named designee. *Faculty/staff are not authorized to sign grants, contracts, or other agreements on behalf of OSU-CHS.*

2. *Procedures*

Faculty/Staff are encouraged to seek collaborative projects with external sponsors, including industry. Contracts typically involve technical discussions and the provisions of informal quotes

- ***Investigator-Initiated Research***

Faculty/staff are encouraged to engage in collaborative projects with external sponsors. Faculty/staff are strongly encouraged to contact the Office of Research before providing any quotes or data or engaging in contracts. Contracts typically involve technical discussions, feasibility, confidentially and informal quotes. PI must formalize the quote and a contractual agreement through the Office of Research prior to formal engagement with the sponsor. Procedures for submitting a proposal routing form and finalizing contracts are the same as those for grant proposals. See Sections IV and V of this manual for specifics.

- **Industry-Sponsored Clinical Trials**

There are frequent opportunities to engage with corporate sponsors for the conduct of clinical trials. The Office of Clinical Research is responsible for the negotiations of these agreements. Further information on specific policies governing corporate-sponsored research, including corporate-sponsored clinical trials, can be found in the Clinical Research Sharepoint site.

C. PI Eligibility

The Principal Investigator on a project is the lead researcher who assumes primary responsibility for designing, conducting, and supervising sponsored projects. The PI serves as the key individual accountable for the scientific, technical, and administrative aspects of the project. PIs guide the project's direction, ensure compliance with regulations and policies, manage fiscal responsibilities, and report directly to the sponsoring agency. The role demands a commitment of time proportional to the scope of work and proposal submission, emphasizing the PI's pivotal role in advancing knowledge and contributing to the success of sponsored projects.

1. *Policy*

OSU-CHS Policy on PI Eligibility can be found here.

The right to lead projects rests with Principal Investigators (PIs), individuals who, by their educational backgrounds, work experiences, and position responsibilities, have demonstrated the project management skills needed to assure compliance with applicable regulations. Eligibility to serve as a PI for sponsored funding administered through OSU-CHS and projects requiring compliance committee approval depends on an individual's position classification. Below is a summarization of PI eligibility by classification, however, some sponsors may impose stricter regulations. Additionally, some colleges, centers, institutes, or departments also may enact stricter regulations. For all position classifications, maintenance of the right to serve as PI is contingent upon responsible performance of duties as PI. Regulatory compliance committees are charged with determining whether the individual has adequate expertise and training to serve as the PI.

2. PI Eligibility for Various Position Classifications

Tenured, Tenure-Eligible, and Research Track Faculty (Category 1)
Tenured, tenure-eligible, and non-tenure full-time research faculty are automatically eligible to serve as PIs on sponsored projects and compliance protocols at the time of hire. Such individuals generally have terminal degrees in their field and, by virtue of their training and qualifications at the time of hire, generally have relevant project management skills.

Professional and Scientific (P&S) (Category 2)
Some P&S job profiles are automatically eligible to serve as PIs on sponsored projects and compliance protocols at the time of hire, provided they meet sponsor requirements.

Full-Time Clinical Track, Teaching Track, Practice Track Faculty (Category 3)
Full-Time Faculty who are Clinical Track, Teaching Track, Practice Track are automatically eligible to serve as PIs on sponsored projects and compliance protocols at the time of hire. Similar to Category 1 personnel, such individuals generally have terminal degrees in their field and, by virtue of their training and qualifications at the time of hire, generally have the relevant project management skills.

Part Time Employees, Biweekly Paid Employees, Adjunct, and Lectures (Category 4)
Full-time, biweekly paid individuals and part-time employees are not eligible to serve as principal investigator. They can serve as a co-investigator with a Category 1, 2, or 3 individual.

Emeritus Faculty
Retired faculty who previously served as PIs and who are awarded emeritus status may continue to serve as PIs on existing sponsored projects and compliance protocols, and they are automatically eligible to serve as co-PIs on new sponsored projects or compliance protocols. The use of university resources, such as space, equipment, etc., by emeritus faculty requires the approval of the department chair.

Postdoctoral Associates and Students
Postdoctoral associates and graduate students may serve as PIs on project if the sponsoring

entity requires it and a Category 1 or Category 2 employee serves as Co-PI.

Co-Investigators
All OSU-CHS faculty and professional/exempt staff are eligible to serve as Co-PIs on sponsored projects.

3. PI Waivers

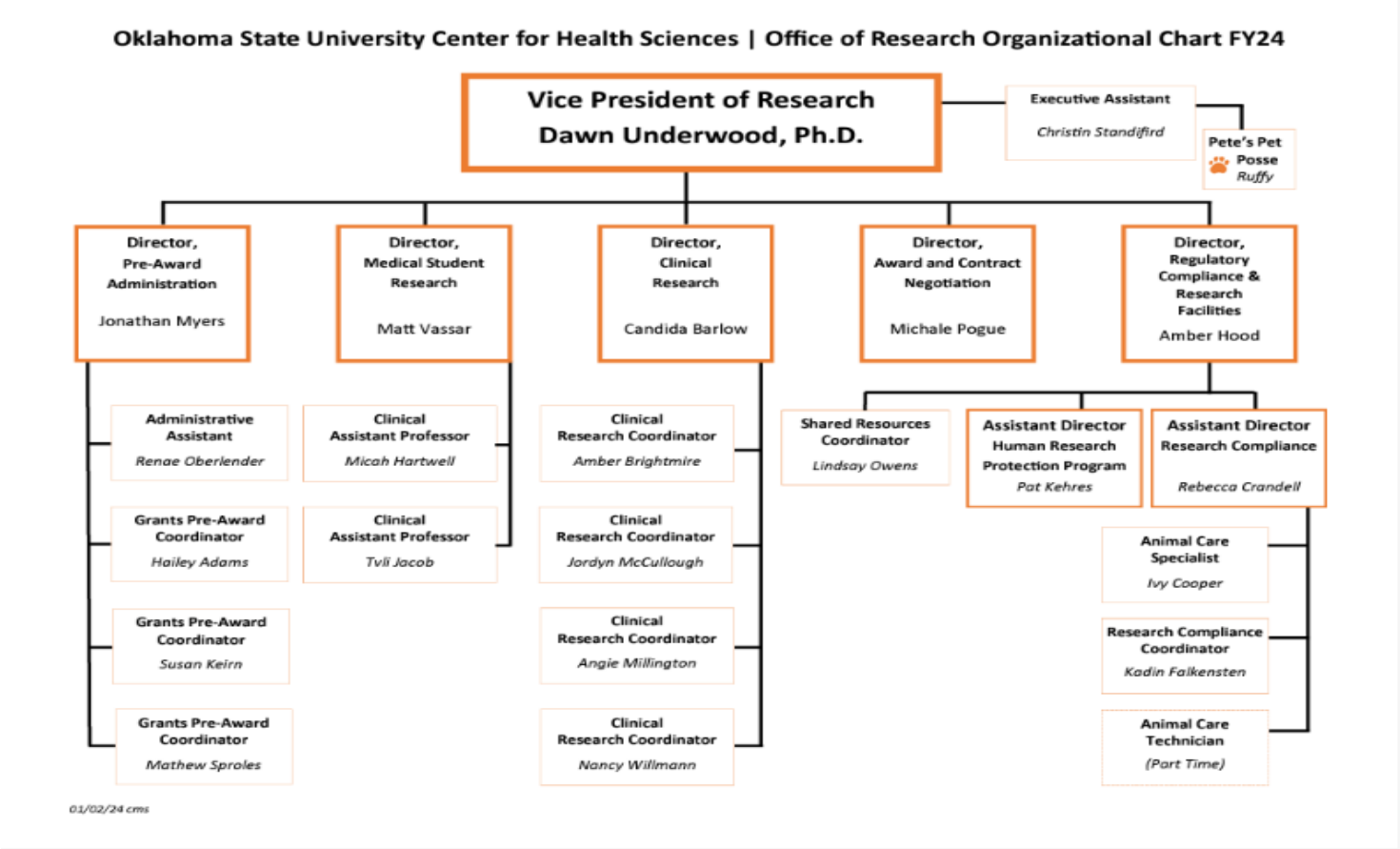
Individuals not eligible to serve as a PI per the above criteria may request a waiver to serve as PI. A request should be sent to the CHS.VPR@okstate.edu email. The VPR's approval to serve as PI on a sponsored project also serves as approval to be on a related compliance protocol. The compliance committee would also be charged with determining whether the individual has adequate expertise and training to serve as the PI. The request should include:

1. a CV,
2. a cover letter describing evidence of prior successful independent scholarship, such as an advanced degree with an extensive record of independent research, and evidence of prior successful grants management, such as service as a Co-PI,
3. documented approval from requestor's supervisor, and
4. explanation of why the individual is the most qualified to serve as the PI

III. Contacts of Sponsored Programs

There are two main offices that assist Principal Investigators with Sponsored Program Administration: the Office of Research and Post-Award Administration.

The Office of Research has several sections housed in it: Pre-Award, Medical Student Research, Clinical Research, Award and Contract Negotiation, and Regulatory Compliance and Research Facilities.



Post-Award Administration is one office with a portfolio model where each project is assigned to a specific team. This team monitors spending, meets regularly with stakeholders, and serves as a resource to connect research and grant directors with administrative support throughout campus.

IV. Proposal Process Overview

Proposing a sponsored project can be a lengthy and complex process of finding possible funding, preparing the proposal and obtaining institutional review and approval. Pre-Award Administration in the Office of Research is tasked with assisting PIs in this process. No submission for external funding should be submitted without prior approval and involvement of Pre-Award Administration or the Office of Clinical Research.

A. Funding Opportunities

Funding Opportunities are the "advertisement" that sponsor agencies use to announce the availability grant funds to the public for investigator-initiated research. There are several key components of a funding opportunity:

- Program purpose/goals
- CFDA number (if federal)
- Type of award
- Due dates
- Reporting requirements
- Application instructions
- Full text of announcement

1. Finding a Funding Opportunity

The Office of Research routinely sends grant opportunities to individuals, departments, and colleges for investigators to identify funding opportunities for research. To set up an appointment to discuss your research interests and possibly funding, email CHS_Proposals@okstate.edu.

Available Resources

- Pivot is a searchable database of funding organizations, funding opportunities and awarded grants, including extensive coverage of governmental and private sources. You can use Pivot by going to the website and setting up an account using your institutional email address.
- Grants.gov – Grants.gov provides a unified electronic storefront for interactions between grant applicants and the federal agencies that manage grant funds. All active and forecasted federal funding opportunities are listed at this site.

2. Communicate Your Intent to Apply

a. Department Chair and Dean

When you have found an appropriate funding source for your project, you need to begin communicating with others about your interest in applying for support. Talk with your department chair first. The chair may suggest that you meet with the dean of your college if your project has broader implications or will involve personnel in more than one department or college, especially if personnel from other colleges will be co-investigators.

Find out what parts of the application package your chair and dean expect to review. In

some cases, they may need just the abstract and budget; in other cases, they may need to see the complete proposal.

Discuss your budget in detail with your department chair and dean as needed. Issues such as course reassignment time, the use of indirect costs for the project, and cost sharing require their approval. If you have not prepared a grant budget before, contact the Office of Research.

Inform your department chair of your proposal deadline and ask about the chair's availability to review and sign documents before the due date.

b. ***Office of Research***

After discussing your project with your department and college, complete the Pre-Award Request Form and notify the Office of Research of your intention to apply for external funding, ideally no later than 14 business days before the sponsor's deadline.

c. ***Foundation or Agency Program Officer Contacts***

Unless the program's guidelines explicitly discourage it, you should always speak with the appropriate program officer at the foundation or agency about your plans and ask for guidance.

d. ***Formal Letter of Intent***

If a formal letter of intent is required, the Office of Research can help you prepare it.

3. *Limited Proposal Submissions*

Funding agencies may limit the number of proposals an institution is permitted to submit for a solicitation. Proposals submitted to these programs must be reviewed and approved by the Vice President for Research.

Faculty and staff who plan to prepare a proposal for a program with a submission limit must notify the Office of Research of their intention by providing a one-page abstract *no less than four weeks prior to the deadline*. If fewer abstracts are received than the number allowed by the agency, all proposals will move forward toward submission. If more abstracts are received than the number allowed by the agency, the Vice President for Research will decide which applications will be submitted. Depending upon the number of competitors and the expertise required for review, the Vice President for Research may appoint *ad hoc* review committees as needed.

If the solicitation requires that the institution be the named applicant, recommendations of the review committee will be forwarded to the Vice President for Research who will make the final decision regarding which proposals will be submitted. When the applicant is an individual, the appointed committee makes the decision. In the event that two or more proposals might be combined and submitted, the committee may make this suggestion to the Vice President for Research.

OSU-CHS uses InfoReady for limited submission postings, review, and approval.

B. Proposal Development

The proposal development process for investigator-initiated research includes reading the guidelines, developing a timeline for completing the proposal, budget development, revision and editing of the narrative and other documents, submission of the final version, and submission of any updates required or allowed by the sponsor. Sponsor instructions should be followed carefully for content, page limitations, font size, file names, etc. The Office of Research staff will provide assistance throughout the process.

1. *Coordinating your Submission with the Office of Research*

Planning is a key element of successful proposals. The Office of Research must know the deadlines of all proposals under development as early as possible. Once you have submitted the Pre-Award Request Form, Pre-Award Administration will schedule a meeting to go over the program's guidelines, to set up a timeline for finishing all the required sections of the proposal, to plan for technical support, to review the budget, and to coordinate the final proposal submission. Research involving foreign nationals or travel outside the United States must follow federal laws restricting the export of technology and information. Proposals with subawards require additional time for the Office of Research to coordinate with the subawardee's sponsored programs office.

One of the goals of the initial meeting is to determine how much support you will need to assemble your application package. Those who are new to the process typically need editorial support, help with budget development, and technical support with electronic proposal submission.

2. *Components of a Proposal*

The structure and necessary documents for a specific proposal are contingent on the sponsor's specifications. Many sponsors impose page limitations, particularly on the narrative section, making it imperative to adhere to all requirements. Failure to align with the sponsor's formatting guidelines may jeopardize the proposal's success. Pre-Award Administration stands ready to aid in proposal budget development and the interpretation of guidelines from various funding agencies. Additionally, they offer support in drafting or editing sections of the proposal text related to administrative or institutional matters as needed. Finally, the department can handle sponsor and institutional forms, provide insight into budgetary issues, and secure the signature of the institutional authorized representative when necessary.

A typical proposal will require, at a minimum, a title page, project narrative/summary, detailed budget, and budget justification. Other documents including, but not limited to, letters of support, curriculum vitae, appendices, etc. can be required for submission.

All proposals will require some legal and financial information from the requesting institution. The Institutional Information Sheet contains commonly needed information such as financial identification and compliance assurance numbers, indirect cost and fringe benefit rates, and authorized institutional representatives. Additional information for applications can be obtained from the Office of Research.

a. *Cover/Title/Face Page*

Almost all applications will have a cover/title/face page with the basic information on the applicant and institution. It could also contain portions that ask for a brief description of the project, funds requests and contact information. This section will sometimes need to be signed by an OSU-CHS Institutional Official.

b. *Abstract*

An abstract is a condensed summary of the proposal, often 200-500 words, written in a non-technical language. Funding agencies usually give specific instructions regarding the abstract's content, length, and order. If no instructions are given, the abstract should identify the applicant institution, establish credibility, state the main objectives and the activities to be conducted, and amount requested. A well-written abstract is critical because some reviewers may read only this part of the proposal.

c. *Narrative or Technical Description*

The narrative describes the scope and objectives of the proposed project in as much detail as is permitted by the guidelines. Most sponsors prescribe the format and limit the length of the narrative. Clarity and focus are essential in a good narrative. If the scope and objectives are too broad, it might not seem possible to complete the project. If it is too narrow, the project can be deemed outside the sponsor's scope. Office of Research staff are available to review agency guidelines with PIs, provide editorial support, and ensure compliance with the sponsor's requirements.

d. *Budget and Budget Justification*

The budget is a comprehensive estimate of projected costs for the proposed project, encompassing standard line items such as salary, fringe benefits, travel, consultants, subcontract, supplies, equipment, and indirect costs. It is a financial plan that must align with the sponsor's range, ensuring a realistic and reasonable request. Costs included in the budget must adhere to the criteria of being allowable, allocable, and reasonable under both University and sponsor policies. PIs receive support from Pre-Award Administration staff to assist PIs in developing budget justification consistent with University policy and sponsor requirements, emphasizing accuracy to prevent underestimated budgets and associated cost overruns.

The budget justification or narrative provides a detailed explanation for each item listed in the budget. This document is crucial for demonstrating to the University and sponsor that the PI thoroughly understands the financial requirements of the project. It explains the need for each cost. Additionally, the budget justification aligns with the methodology described in the proposal narrative, offering clarity on how proposed costs relate to the project's goals.

e. *Facilities and Equipment*

A description of the facilities and major items/equipment available for use on the project should be included in the Facilities section. This includes computing equipment and electronic/machine shops. This information will assist the evaluators in determining the capabilities of the organization to perform the scope of the project.

f. *Curriculum Vita*

A current *curriculum vita* (CV) is typically required for the PI and all co-investigators. Some organizations (e.g., the National Science Foundation) specify the maximum lengths of CVs and what information must be included. PIs must follow the required format if one is specified. Exhaustive *curricula vitae* are rarely expected. In most cases 2-3 pages of the information most relevant to the proposed investigation will be appropriate. The Office of Research has templates available upon request.

g. *Appendices*

Appendices are included only if allowed or required. Appendices are generally used to expand on information in the narrative, not to add information essential to the project. The proposal's table of contents should contain a list of the appendices included.

h. *Attachments*

Most application packages consist of more than the project narrative and budget. Documents such as financial statements, letters of support, and various appendices require time to assemble. The Office of Research can help you gather the required documents, but your timeline must be known in advance of the submission date.

- Tax Exemption Letter
  Many proposals require a copy of a letter from the Internal Revenue Service stating that the OSU-CHS is not subject to federal taxation. Post-Award Administration will provide this if required.

- Annual Financial Report/Audit
  Post-Award Administration will provide the financial information required by sponsors.

i. *General Letters of Support*

Sponsors may require letters of support for projects involving multiple organizations. Program announcements sometimes specify the necessary content of such letters. When not specified these letters should explain the relationship of the sponsor to the PI or the university, why the project is being supported, and specifically what will be done to assist and support the program. Letters of support are usually addressed to the projector's director, not the sponsor or reviewers. Letters of support are *evidence*, not testimonials. Letters of support from the Office of Academic Affairs must be coordinated through the Office of Research.

j. *Letters of Support from the OSU-CHS President*

Letters from the President in support of proposals are arranged by the Office of Research. Requests for these letters must include evidence that the project has the approval of the faculty member's Dean, a draft of the proposed letter of support, and the proposal guidelines. The Office of Research must receive these documents *at least 15 calendar days prior to the submission deadline* in order to refine the draft and receive the President's signature. Exceptions to this procedure are rare.

The draft letter must include the following information:

- The specific information required by the proposal guidelines
- How the project advances the mission of the University

- How the project relates to similar work being done at the University

Letters that do not follow these guidelines will be returned to PI(s) for completion. The Office of Research does not write the letters but will edit them to meet the requirements of the President's office.

C. Budget Development

All budget submitted by OSU-CHS must adhere to federal regulations stated in 2 CFR 200 and state regulations of Oklahoma.

Creating an effective budget is a collaborative effort between the PI and Pre-Award Administration. It is crucial to submit a compelling proposal that is set up for success when awarded. Adherence to cost principles is critically important at the proposal budget development stage, as expenditures in the award phase must follow what was proposed. The heart of cost principles is allowability. That means that a cost is:

- **Reasonable** A prudent person would pay for the goods or services obtained for the cost it was charged at and it is necessary for the performance of the project.
- **Allocable** The project that pays for the cost is the project that benefits from it.
- **Consistently Treated** The University consistently designates a type of cost as either direct or indirect when incurred for the same purpose in similar circumstances.
- **Not Unallowed** Costs must not be explicitly excluded by the federal or sponsor guidelines. A cost could meet all the above criteria but is not allowed by the sponsor.

Budgets are broken down into two main categories: direct and indirect costs. These and other budgetary considerations are discussed below:

1. Direct Costs

Direct costs refer to allowable budget items that are directly charged to a specific project and are essential for the completion of the project. They are specifically identifiable and easily allocable to the sponsored project with a reasonable high degree of accuracy, ensuring their direct contribution to the project's objectives. Examples of direct costs include the following:

a. Personnel

Personnel costs include salaries and wages for faculty, staff, and student workers who are employees of OSU-CHS.

Payments for work performed on sponsored agreements by faculty members are based on the person's regular rate of compensation. This figure is stated in the individual's annual contract letter as the base salary and excludes any salary supplements or overloads paid during the contract period, whether or not they are listed in the initial contract letter or an addendum.

OSU-CHS faculty members have either a 9-month appointment or a 12-month appointment. For most members of the faculty, the period that constitutes the basis of their salary is for the academic year (a period of 9 months). For 9-month faculty, the

monthly rate is the base salary divided by 9. (Their pay may be distributed among 10 checks, but this does make them 10-month faculty.)

Most administrative appointments (e.g., department chairs, deans, associate deans) and some special faculty appointments are given 12-month fiscal-year contracts. For 12-month faculty, the monthly rate is their contract amount divided by 12.

Exceptions to this principle involve consultation across departmental lines or work in a separate or remote operation. If the work performed by the individual is in addition to the person's regular departmental load, payments beyond the base salary may be allowable provided that the arrangements follow the procedures for overload compensation in the OSU-CHS Faculty Resource Manual and are specifically provided for in the agreement or approved in writing by the sponsor. Only the Office of Research may approve such payments.

Salaries for projects funded by the Department of Health and Human Services are capped at a specific amount, currently $221,900. This applies to all grants, cooperative agreements, and contracts. This is not a limit on the employee's salary, but what can be requested to be funded by the project.

b. Fringe Benefits

Fringe benefits are additional compensation provided to employees beyond their base salary, typically covering various non-wage perks such as health insurance, retirement contributions, paid time off, and other supplementary offerings. Fringe benefits must be included if there is salary on the budget. It is calculated by a percentage of the salary. These rates change annually and can be found here.

c. Capital Expenditures (Including Equipment)

Capital expenditures include individual items of equipment, new buildings, and alterations and renovations of the existing physical plant. All capital expenditures are not subject to indirect cost allocation.

- Construction, Alterations, and Renovations – Projects that include new construction involve planning at the institutional level and are beyond the scope of this handbook. However, alterations or renovations of existing space are often required for the installation of new equipment or the creation of new laboratories or other special purpose rooms. The costs of these changes are considered as capital expenditures. Such projects require coordination with the offices of the Vice President for Research, Information Technology Services, Environmental Health & Safety, and/or Facility Management. When renovations or alterations are required, the appropriate offices should be consulted early in the budget planning process.

- Equipment – **The federal government and the University define equipment as tangible, nonexpendable property having a useful life of more than one year. As of October 1, 2024, the federal government identifies equipment as have an**

acquisition cost of $10,000 or more per unit. The University, operating under the current federal negotiated indirect cost rate, defines equipment as having an acquisition cost of $5,000 or more per unit (including tax, shipping, and installation). Because the prior approval policies of sponsoring agencies vary, listing equipment in an award does not necessarily provide approval to purchase the equipment. Budgeted equipment must comply with the specific rules and regulations of the sponsoring agency. Before requesting any new equipment, the Principal Investigator must determine that equipment already available to the University either will not meet the project's needs or is not available for use when required. Proposals should specify the manufacturer and model number, or specifications of the instrument(s) required for the project. The amount budgeted for each item should include the cost at time of purchase and any installation and shipping costs, usually documented by a price quotation from an appropriate source. Maintenance and repair costs to keep project-specific equipment in operating condition are allowable if they are within the period of performance of the project.

d. Travel

The costs of travel for personnel to conduct work for the project or attend conferences, presentations, or workshops in performance of the project are an important component of many budgets. For travel within the state of Oklahoma, follow the state's travel regulations. For domestic travel outside Oklahoma, use the lodging and per diem rates established by the U.S. General Services Administration. For travel outside the United States, use the lodging and per diem rates established by the U.S. State Department. Special rules often apply to travel outside of the United States. Note that all federally funded air transportation is generally required by the "Fly America Act" to use U.S. flag air carriers. All business travelers should review OSU-CHS's travel regulations. Employees must travel by the most direct route and use the most economical mode of transportation available considering travel time, costs, and work requirements. Meals while in travel status may be reimbursed by per diem only. Employees cannot receive per diem for same day travel. Documentation must be maintained for all expenses incurred while in travel status on a sponsored project.

Typically Allowable Travel Expenses	Typically Unallowable Travel Expenses
Economy/Coach Airfare	First Class/Business Class Airfare
Travel Agent & Airline Baggage Fees	Upgrades & Ticket Change Fees for Personal Convenience
Car Rental, including gas	Parking Tickets or Traffic Fines
Ground Transit – shuttle/train/taxi/bus	Rental Car for Personal Use
Lodging	Late Check-Out, Room Guarantee, Entertainment
Conference Registration Fees	Late Registration or Cancellation Fees
Per Diem	Actual Cost of Meals Purchased
Tolls, Parking and Reasonable Tips	Hotel/In-Flight Internet Access

e. Participant Support Costs

Participant support costs are defined in 2 CFR 200.75 as "direct costs for items such as

stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects." Participants are not OSU-CHS employees and are not part of the project implementation team. Costs for transportation, per diem, stipends, and other expenses for participants or trainees should be budgeted as participant support costs when there is a category for participant support costs in the funding opportunity budget guidelines. Many agencies do not allow institutions to charge indirects on participant support costs, such as NSF.

Of particular note:

- Participants are not OSU-CHS employees and don't perform any work or services for the program.
- Prior approval may be required for budget reallocation from participant support costs to other items of expense.
- Indirects are not charged on participant support costs.
- PIs will need to provide participant selection documentation, as well as documentation of actual attendance (sign-in, attendance sheets), to Post-Award Administration.
- Participant support costs are not Research Participant Incentive Payments (human subject pay).

Eligible Participant Activities	Eligible Participants	Allowable PSC Expenses
Meetings	Students and Teachers	Stipends
Workshops	National scholars, scientists	Travel Support
Conferences	Private sector reps	Meals
Seminars and Symposia	Agency reps	Other participation-related expenses
Other Training Activities	Other non-working participants	

f. Other Direct Costs

- Materials and Supplies – This expense category includes all expendable materials to be used during the course of the performance period. Special purpose computers costing less than $5,000 are included in this category.

- Publication, Documentation, and Dissemination Costs – The costs of documenting, preparing, publishing or otherwise disseminating the findings of the project are included in this item. Examples of dissemination expenses are page charges, illustrations, indexing of data, and archiving sample collections.

- Consultants – Each individual's expertise, primary organizational affiliation, normal daily compensation rate, and number of days of expected service should be included. A description of consultants' qualifications should be included if these individuals have not been identified. Please see the Office of

Budget and Finance for information on hiring consultants.

- Computer Services – Computer services include the cost of software, hardware and leasing of computer equipment. Note that the cost of general- purpose computers is included in the University's Indirect costs.

- Space Rental – In some cases a University department, school, or center may require rental space to house a sponsored project. If off-campus space is required, the Office of Research must be contacted early in the proposal stage to assure that University and State regulations are followed.

- Tuition Remission – Budgets that include support to Graduate Assistants must include tuition support for those graduate assistant under OSU policy 3-0421. A tuition remission rate is applied to the Graduate Assistant stipend. The rate can be found here.

- Human Subject Pay – Projects involving human subjects may provide payments to the subjects for their involvement. Payments to human subjects/research participants must be approved by the Institutional Review Board (IRB). Refer to OSU policy 4-70401.

g. Subawards & Contractors & Consultants

Under 2 CFR 200.92, a **subaward** is an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of an award received by the pass-through entity. The subaward has responsibility for programmatic decision making and contributes to the scholarly/scientific conduct of the project as described in the statement of work.

A clear description of the work to be performed, the basis for selection of the sub-awardee, and a separate budget and budget justification for the subaward should be included as part of the proposal, along with a completed Subrecipient Commitment Form or a letter of participation from the subawardee's sponsored programs office. The letter should state that the subaward organization has reviewed the budget and scope of work and agrees to participate in the proposal.

Subawards must be approved by the sponsor in advance. Subaward documents must also be approved by the sponsor prior to finalization of any such agreement. Financial commitments or arrangements must be coordinated with and approved by the Office of Research during any programmatic discussions with potential sub-recipients.

All subaward costs are considered a composite direct cost by the University and should always be shown in the subaward cost line of the proposal. Subaward costs must be broken out and supported in the subawardee's proposal to the University. Subaward costs should never be intermingled with OSU-CHS cost elements. Subawards that include Indirect charges as part of the budget must provide a copy of

the institution's most recent federally negotiated Indirect costs rate agreement.

A **contract or fee for service agreement** provides goods or services within normal business operations and operates in a competitive environment providing similar goods and services to a variety of customers.

Consulting is when an independent contractor provides advisory services related to the project.

2. *Indirect Costs*

In addition to the direct costs of conducting a project, most proposals will include an amount to cover Indirect Costs (previously called Facilities and Administrative Costs), often referred to as indirect costs or overhead. F&A costs are those that are incurred for common or joint objectives, and therefore, cannot be identified readily and specifically with a particular sponsored project, but are essential to the completion of the project. These costs include: laboratory and office space, utilities, administrative services (e.g., purchasing, accounting, research administration, personnel, security), custodial services, library services, and building, grounds, and street maintenance. In summary, Indirect costs cover the institutional infrastructure essential to support sponsored programs that cannot be allocated and directly charged to a specific grant or contract.

OSU-CHS collects F&A costs based upon a *federally negotiated rate* that is applied to the Modified Total Direct Costs (MTDC) of the project. MTDC is calculated by removing Capital expenditures (including items of equipment costing more than $5,000), the portion of each sub-grant or sub-contract in excess of $25,000, most participant support costs, and facility rentals from the total direct costs of the project.

The University has separate Indirect cost recovery rates for projects performed on and off campus.

- On-Campus Rate – OSU-CHS's negotiated rate with federal agencies is **41.3%** of MTDC.

- Off-Campus Rate – OSU-CHS's federally negotiated Indirect off-campus rate is **26%** of MTDC. In general, if 50% or more of the project will be conducted off-campus (in facilities not owned by OSU-CHS), the off-campus rate should be used for the whole project. If there is any question about which rate to use, investigators should confer with Office of Research staff.

- Industry Sponsored Research Rate – research sponsored by an Industry partner that is to their benefit, rather than a philanthropic action, uses the appropriate Indirect cost rate with an **additional 10% included**.

Some sponsors limit Indirect cost recovery or prohibit it altogether. If a sponsor prohibits or

limits F&A charges, a copy of the sponsor's F&A rule must be attached to the Proposal Routing Form. If the sponsor does not have a rule on F&A costs, but there is a compelling reason to waive or reduce the charges, the PI must complete the Request for Facilities and Administrative Waiver form. Without documentation of the sponsor's limit or a VPR approved waiver request, the University applies the standard F&A rate to all proposals.

Uniform Guidance states that salaries of administrative and clerical staff should normally be treated as F&A costs. However, direct charging of administrative and clerical salaries and other administrative items may be appropriate when it can be demonstrated that they meet Uniform Guidance standards for classification as a direct cost:

- Administrative or clerical services are integral to a sponsor project.
- Individuals involved can be specifically identified with the sponsored project.
- Such costs are explicitly included in the budget and budget justification or have the prior written approval of the Federal awarding agency.
- The costs are also not recovered as indirect costs.

3. Cost Sharing

Cost sharing or matching is the portion of the project expenses covered by OSU-CHS or another third party and not by the main program sponsor. Some sponsors will require cost sharing of the project expenses. In accordance with Uniform Requirements, the sponsor must state if cost share is required in the funding opportunity. Cost share can be expressed as a percentage of effort, number of hours, percentage of the total sponsor-funded costs or an absolute dollar amount. Generally, OSU-CHS will contribute direct labor and fringe benefits, plus indirect costs, to meet cost share requirements. The PI is responsible for identifying resources for cost sharing at time of proposal. Refer to OSU policy 1-70113.

Cost share contributions must meet certain criteria:

- Verifiable from the recipient's records
- Not included as contributions for any other federal award
- Necessary and reasonable for accomplishment of project objectives
- Allowable under applicable cost principles
- Not paid by the Federal government under another award
- Provided for in the approved budget when required by the sponsor
- Incurred within the performance period of the award

Cost share should only be done to the extent required by the program or offered when it is a condition of receiving an award. If the award is made on the basis of a proposal that includes excess cost sharing, the proposed cost sharing in excess of the required amount becomes a legal obligation that must be recorded, tracked and reported to the sponsor. PIs are encouraged to not include cost sharing language or quantifiable cost sharing amounts in a proposal or proposal budget/budget justification unless the sponsor explicitly requires the cost share.

As part of the proposal review process, when a Principal Investigator plans to include either OSU-CHS's resources or external entities' resources as cost sharing, this information must be specifically identified on the routing form. Proposals for cost sharing constitute a formal commitment to the sponsor by the department chair, dean of the academic unit, director of the center or institute, the Vice President for Research, and/or the Provost. In cases where the matching involves external entities, a letter of commitment from each entity and a detailed budget must be submitted with the proposal. If subcontractors are providing cost sharing, their budgets need to identify these commitments.

The four types of cost sharing are:

- *Mandatory cost sharing* is required either by federal statute or by the established policy of the sponsor. Time and effort reports are required.
- *Voluntary committed cost sharing* is volunteered to demonstrate the University's commitment to a project. Voluntary contributions specified in proposals become required financial commitments if the proposal is funded, even if the amounts are not included in the budget but are quantified in the proposal narrative. Time and effort reports are required.
- *Voluntary uncommitted cost sharing* is defined as effort over and above that which is committed and budgeted for in a sponsored agreement. More specifically, this is either additional time or resources provided by the applicant, which were not quantified in the budget or in the narrative of the proposal.
- *In-Kind Contributions* are contributions of time, talent, or resources by third parties. This includes real property, equipment, supplies, and other expendable property.

4. Budget and Justification Templates

Investigator-Initiated Research
Pre-Award Administration can supply the PI with budget and budget justification templates that have all the applicable rates and formulas to assist the PI with budget creation.

Industry Clinical Trials
The clinical research trials unit negotiates the clinical trial agreement budget on behalf of the PI and the Office of Research for industry-sponsored clinical trials. Budgets are developed in alignment with Medicare Coverage Analysis (MCA) and clinical trial billing compliance guidelines. They are created by collaborating with the PI, practice administrators, and billing compliance and in accordance with fair market value rates in clinical research.

D. Compliance at the Proposal Stage

Further explanation and policy references of Compliance in Sponsored Programs are covered in Section IX.

1. Institutional Review Board and Animal Care and Use

For projects involving human subjects, most sponsors require the investigator to provide specific information about protection of human subjects at the time of proposal submission. However, most sponsors do not require certification of Institutional Review Board (IRB) approval or evidence of training until they are ready to recommend an application for funding. Instructions for submitting a protocol for review can be found here.

Similarly, proposals involving the use of vertebrate animals normally require some description of the animals, proposed procedures, care and use; however, certification of the Institutional Animal Care and Use Committee (IACUC) approval is usually not required until the agency is considering making an award. This is known as the "just-in-time" concept. Thus, investigators should expect to describe their proposed use of human subjects or animals as part of their proposal and should be prepared to certify that approvals are in place later, as a condition of receiving an award. Instructions for submitting a protocol for review can be found here.

2. ***Conflict of Commitment and Interest***

Conflict of interest is when an individual has interests in the outcome of the project that may lead to personal advantage, financial or otherwise, and that might compromise the integrity of the project, regardless of whether this influence is real or merely perceived. Interests can include salary, equity interests, intellectual property rights, and/or appointment to a position. Sponsor agency requires investigators submitting proposals to disclose any significant financial interests at the time of proposal submission. To meet this requirement, OSU-CHS requires all principal investigators who will be submitting proposals to complete a Conflict of Interest Disclosure Form before submission and every year thereafter, regardless of the existence of a conflict. Any changes in financial circumstances related to Conflict of Interest must be updated within 15 days of the change. Conflicts of Interest do not constitute wrongdoing; however, any such potential conflict of interest must be disclosed to OSU-CHS and managed.

OSU-CHS utilizes the COI-SMART online system for the COI questionnaire completion. Conflict of Interest information, forms and COI login can be found here.

3. ***International Relationships and Export Control***

The federal government has expressed concerns regarding inappropriate influence by foreign entities on federally funded projects lead by principal investigators failing to disclose their relationship and activities with foreign governments, institutions, and funding agencies. While OSU-CHS encourages international collaborations, it is still important that PIs be transparent about their foreign relationships and activities. To mitigate this risk, OSU-CHS abides by the Export Control laws related to the Federal laws and regulations that deal with the distribution of strategically important technology and information to, and certain financial transactions with, foreign nationals in the US and entities in foreign countries. In the proposal stage, there may be special review and approval for certain activities that fall under Export Control laws before submission can take place. This includes, but is not limited to projects involving foreign nationals, travel outside of the U.S., transporting items to or from the U.S.

4. ***Lab Safety and Biosafety***

Principal Investigators are responsible for the safety of all lab personnel in a Sponsored

Project. Any factors that might present a lab safety and/or biosafety issue, must be identified and disclosed in the proposal stage. These are documented in the routing form and may require additional documents or information to be reviewed by the Compliance Office. These include, but are not limited to:

- Hazardous Materials
- Select Agents and Toxins
- Potential Biological Hazards
- Research Activities Involving Minors
- DEA or OBN Controlled Substances
- Chemical Hazards

5. *Intellectual Property*

Intellectual Property is the ideas, information, and knowledge that come from the results and outcomes of project. This includes subject matter, methods, and tools. At the proposal stage, it must be identified if there has been any disclosures to the Innovation Foundation at OSU, if the project involves any patents, or involves material transfer agreements. Refer to the OSU Intellectual Property policy #1-0202.

E. Proposal Approvals and Submission for Investigator Initiated Research

1. Proposal Approvals

Before a proposal is submitted to an external sponsor, the application must be approved through the University's established procedure called routing. Routing is the process of the basic information of the grant proposal or contract being reviewed and approved by all pertinent parties and is required for every grant proposal or contract submitted to the Office of Research.

a. Cayuse Research Suite

Cayuse gathers information and documents required for processing a grant or contract and electronic signatures showing the University's support and approval. All Cayuse records are initiated by Pre-Award Administration and should not be started by a PI or other staff members. By electronically approving the proposal in Cayuse, each signatory accepts accountability for the roles and actions assigned to them by the University.

b. Required Documents

The following information and documents are required for routing:

1. The Cayuse Routing Form section includes information on the Principal Investigator (PI) and Co-Principal Investigator(s), the project type, proposal due date, name of sponsoring agency, basic budget information and proposal title. Questions regarding conflict of interest, involvement of human subjects, and cost sharing are addressed.
2. The Budget Justification explains the detailed budget in a narrative format. This and the budget must be final before routing.
3. The Detailed Budget explains the costs of the project that are being requested by the sponsor.
4. The Abstract is a brief description of the work of the project and can be in draft form for routing.
5. Other applicable documents may be necessary depending on the project being

proposed: subaward documents, human subject documents, animal documents, etc.

c. *Routing*

Once the above information and documents are completed, routing can be initiated. Electronic approval is required from the PI, co-PIs, and the department head(s) and the next level of oversight of the PI and co-PIs. Depending on the scope of the project, other approvals (see below) may be necessary. All the required approvals must be obtained before the proposal will be submitted to the sponsor. Each individual who signs a routing is assuring that the proposal is true and accurate and will comply with all University policies and procedures and sponsor requirements. It is highly important that everyone signing thoroughly read and review every proposal.

d. *Principal Investigator, Project Director, and Co-Principal Investigators*

The e-signatures of the principal investigator and all co-principal investigators are required. By electronically approving the proposal, the PI and co-PIs understand and certify that:

- The information submitted within this application is true, complete, and accurate to the best of my knowledge.
- Any false, fictitious, or fraudulent statements or claims may subject the University, and the investigators to criminal, civil or administrative penalties.
- I am responsible for the scientific, fiscal, and ethical conduct of the project and to provide the required progress reports if an award is granted.
- I will adhere to all relevant state and federal regulations, University policies, and contractual obligations in administering the resultant award.
- I have reviewed applicable U.S. Export Control requirements and University policy on Export Controls and will comply with the export control requirements.
- I will work to ensure that my relationship with the sponsor of this project is either free of conflict of interest or consistent with a previously disclosed conflict of interest management plan.
- I will adhere to intellectual property policies, including the management of proprietary information and collaboration agreements.

e. *Other Committed Personnel*

“Other committed personnel” means OSU-CHS faculty or staff who are either paid from the grant or committing time to the project as specified in the proposal but are not involved in the implementation or development of the project. Routing approval from other committed personnel (OCP) is not required, but the proposed effort should still be discussed with and approved within their department. It is the OCP’s responsibility to confirm availability (e.g. course releases) for a project with their department head. If other committed personnel would like internal approval on file with the OR, they can complete and submit an optional paper routing form.

f. *Department Head*

The department head of the Principal Investigator and all Co-Principal Investigators must

approve all sponsored activities prior to proposal submission to the next supervisory level of oversight. The department head's electronic approval in Cayuse indicates acknowledgement of, but is not limited to, the following:

- The individual serving as PI on the project is eligible to serve in this role.
- Approval of the budget and any cost share commitments.
- The scope of work aligns with the short or long-term objectives of the department/center.
- Understanding of the needs of the proposal's requirements, including space, materials, staffing, or health and safety hazards associated with the scope of work.
- Commitment to fulfill any necessary requirements if the proposal is funded.
- Approval of release time (if any) for designated faculty.
- Agreement to cover any over-expenditure or disallowed expenditures from departmental funds.
- Adherence to all applicable department, college, and university policies and procedures.
- Confirmation of the PI's competence to conduct and manage the proposed project.

The next supervisory level of oversight's electronic approval in Cayuse indicates acknowledgement of, but is not limited to, the following:

- Approval of the budget and any cost share commitments.
- The scope of work aligns with the short or long-term objectives of the university/college Understanding of the needs of the proposal's requirements, including space, materials, staffing, or health and safety hazards associated with the scope of work.

g. Other Approvals

The application is also routed to Pre-Award Administration for review by the Pre-Award Director, the Compliance for review by the Director of Compliance, and finally the Vice President for Research. Once all approvals are obtained, the proposal is ready for submission.

2. Proposal Submissions

It is the responsibility of the PI to submit the proposal documents to Pre-Award Administration for timely submission to the sponsor. For proposal submission made less than three (3) business days prior to the sponsor's deadline the PI accepts the risks of the proposal missing the deadline or being rejected for errors.

a. Standard Process

In nearly every instance, the Office of Research is responsible for submitting the final proposal, usually in an electronic format. If the application is to be submitted electronically, the Office of Research will provide technical support (including uploading documents, if necessary) and obtain the electronic signature. For many electronic submissions, there are parts that must be completed by the PI and parts that must be completed by the Office of Research. Plan to be available on agreed upon submission date to answer last minute questions, especially for electronic submissions. Occasionally questions arise that are not covered in the application guidelines. If a paper application is required, the Office of Research will manage copying and shipping. In most cases, sponsors will not consider proposals that miss a deadline.

b. *Multiple Proposal Submissions*

In some cases, identical proposals may be submitted simultaneously to more than one sponsor provided each sponsor is advised that this has occurred. Careful attention must be given to sponsor restrictions on the submission of identical proposals to multiple sponsors. Please consult the Office of Research well in advance of any deadlines.

3. Submission Timeline

1. *Notify the Office of Research > 2 weeks prior to deadline:*

- Submit the Pre-Award Request Form.
- Meet with Pre-Award to discuss deadlines and review funding opportunity.
- Start proposal development.
- Proposal is started in Cayuse by Pre-Award Administration

2. *Acquisition of Signatures and Approval > 1 week prior to deadline:*

- Start circulating Cover Pages, Letters of Support/Commitment or other program-specific documents that require signatures from you Chair, Dean, President, etc.
- Electronic routing through Cayuse is started. Even if your proposal is not final, starting routing early will allow plenty of time for circulation. You will still be able to edit your proposal while it is going through the approval process. If your Chair/Dean requires a final draft for approval, make sure they are aware of the approval process so it can be completed in a timely manner.

3. *Review (Office of Research) > 3 days prior to deadline:*

Office of Research will perform a complete review, including:

- Send all required documents for review to Pre-Award. Pre-Award will do the following:
    - Comparison of proposals to sponsors' guidelines (e.g. forms and formatting).
    - Review of budget (calculation, rates, relevance to project description, cost-sharing).
    - Confirm Cayuse information.
    - Send a preview of the entire application back to PI to review.

4. *Submission*

Proposal development and routing should be complete 3 business days prior to the application deadline. The Office of Research cannot guarantee successful submission if final documents and routing are not complete before this time. However, the Office of Research will still do its best to submit proposals that are completed less than 3 days before the deadline.

The 3-day window affords time for corrections to be made to the application if necessary. It also allows time for any difficulties that might arise with the electronic submission, such as the sponsor website being down.

F. Feasibility and Proposal Industry Study

OSU-CHS Office of Research and Clinical Research Unit assumes responsibility for the conduct of clinical research along with the PI and will, therefore, oversee the conduct of each clinical study. These studies are conducted according to GCP and comply with applicable regulations, guidelines, and institutional policy for conducting human subject research and using investigational products. The OSU-CHS Clinical Research Unit supports the business and clinical operations regarding study conduct, supporting the investigator and clinical units for which the research is conducted.

For additional study start-up information, reference the OSU-CHS Clinical Research standard operating procedures. For study feasibility and/or clinical research support, please submit the sponsor a request to chs_clinresearch@okstate.edu

These responsibilities include:

Conducting research according to

a. The clinical trial agreement

b. The signed investigator statement

c. The study plan/protocol

d. Applicable regulations

Support for the conduct of research

a. Provide clinical research staff

    a) Leadership, clinical research coordinators, research nurses, business financial analysis, regulatory specialists

b. Financial oversight oversees federal and state regulations for clinical research

c. Clinical Trial Agreement

d. Clinical trial billing compliance

e. Liaison with the study sponsor

f. Training and education for research staff

g. Dedicated central unit to house staff, investigational drugs and study-related specimens

h. Monitoring and audit support and oversight

V. AWARD NEGOTIATION, ACCEPTANCE, SETUP

After the sponsor receives your proposal, a comprehensive review process begins to analyze your proposed project by a peer group. If your project is selected for funding, a Notice of Award will be sent to the Office of Research or the Principal Investigator. The Notice of Award is the notification from the sponsor indicating that the proposal was funded. Contact the Office of Research if you receive a notice of award, all notifications of award must be submitted and reviewed by an authorized University official in the Office of Research.

A. Types of Awards/Agreements

There are several different types of awards or agreements that can be received from a sponsor. Some of these are listed and described below:

- Grant – a grant is a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used when there is no substantial programmatic involvement with the University during the performance of the activities. Grant award agreements are generally a short, pro-forma document referencing a standard set of accepted regulations.
- Cooperative Agreement – an agreement similar to a grant but used when substantial involvement is expected from the sponsor. Typically, a cooperative agreement will require University Signature.
- Contract – a mechanism for procurement of a product or a service with specific obligations for both sponsor and recipient. Typically, the scope of work is specified in detail by the sponsor, although some sponsors award contracts in response to unsolicited proposals.
- Fellowship – support for predoctoral or postdoctoral training of individuals to undertake research.
- Memorandum of Agreement or Memorandum of Understanding – written agreement to identify the working relationships and guidelines between two entities. It contains common understandings, clarifies the type of support provided, and defines the rights and responsibilities of each party.
- Research Services Agreement – type of contract used by sponsors for services to be provided by the University for which the Sponsor provides a specific protocol to be followed, to which the PI did not contribute creative/intellectual input.
- Gifts – Gifts, though not typically considered formal agreements like grants or contracts, can also be received from sponsors. These are contributions made by sponsors to support the activities of the recipient entity without the expectation of a direct benefit or deliverable in return. Gifts may include financial assistance, equipment, supplies, or other resources. All gifts must be first given to the OSU Foundation where the funds can be used by the Principal Investigator.

- Clinical Trial Agreements, often referred to as "CTAs," are legally binding contracts that outline the responsibilities of each party involved in conducting the clinical research trial. OSU-CHS and the Office of Research enter into a contractual agreement with the study sponsor and the PI. The Office of Research supports the negotiation of the CTA in alignment with federal, state, and local policies and procedures.

B. Award Mechanisms

Awards can be made in different ways to the University:

- Cost-Reimbursable Award – the sponsor agrees to pay for all allowable costs incurred by the University in the process of doing the project to an agreed upon amount. If the project costs less to complete than the original amount budgeted, the sponsor is obligated to reimburse the University only up to the allowable costs of the project.
- Fixed-Price Award – commits the PI to a defined scope of work for a set sum, where the sponsor pays the University a fixed amount to complete specific deliverables, regardless of actual cost. The PI is obligated to perform the work specified in the award and to complete that work within the negotiated period of performance.
- Purchase Order – mechanism used for buying goods and services. Usually this will contain terms and conditions that must be reviewed, revised, and agreed upon.
- Flowthrough – contracts or grants issued under a larger agreement where a portion of the scope of work is delegated to OSU-CHS with terms and conditions flowed down from the prime award.

C. Award Negotiation

Before an award is accepted, negotiations concerning the terms and conditions (e.g., scope of work, budget, intellectual property) of the award are sometimes necessary. These negotiations must be coordinated through the Office of Research and the Director of Contract and Award Negotiations. Direct communication between the OSU-CHS and the sponsor on matters affecting contractual agreements must also only be carried out by the Office of Research. Technical communications can be done by the PI and the Sponsor. The Cayuse proposal number or the grant number assigned by the agency should be referenced in all written correspondence.

Contracts or any bi-lateral agreements requiring institutional signature with terms and conditions, require a robust review by the Office of Research before execution. The University follows standard practices when negotiating award terms. Some sponsor agreements contain terms which create risk for the PI and the University. It is the Office of Research's practice to try to remove or edit these terms to align them with University policy. Some of the most important terms to look for are indemnification, governing law and jurisdiction, arbitration, disclaimer of warranty, publication, confidentiality, insurance, intellectual property, and export control. These terms will likely cause a negotiation of the award to be necessary and is completed by the Director of Contract and Award Negotiation.

D. Award Acceptance

Once the Notice of Award is agreed upon, it will be accepted by the Office of Research. Because OSU-CHS, not the PI, is the legal applicant, the Office of Research legally accepts all awards. The Office of Research will obtain the signature of the authorized institutional official to accept the award. ***Faculty/staff members may not sign contracts that obligate the University in any way.*** A signature by the contracting institute must be completed by a legally authorized signatory.

E. Award Setup

The University understands the tight schedule that the PI is under once a project is awarded and does its best to minimize the amount of time it takes to set up a fund for expenditures. Banner cost centers and funds are set up by the Grants and Contract Financial Administration (GCFA) in Stillwater once the award is fully executed and a corresponding budget is submitted to GCFA.

1. Early Fund Set-Up

It may be necessary to set-up a fund to capture expenditures for a potential externally-sponsored project prior to the award's final execution or when a modification of an existing award is awaiting the next installment of a multi-year/incrementally funded project.

If these situations occur and are beyond the control of OSU-CHS, a principal investigator may formally request an expedited approval of a fund to initiate grant-related work/expenditures prior to final execution of the award. Though an "Early Fund Set-up" process is outside the normal policy and procedures of the University's operations and requires multiple levels of administrative approvals prior to activating the fund, if approved, a grant fund with an available budget will be established to initiate the project and to capture appropriate costs.

The benefits of an early fund set-up could reduce salary redistributions and/or retroactive cost transfers, improve timely effort reporting and billing.

It is important to note that a clinical trial agreement does not meet the criteria for an early fund setup and cannot be charged against until an executed CTA has been obtained by the Office of Research.

2. Pre-Award Spending

For Federal awards, approval may be granted for expenditure of funds up to 90 days prior to the expected start date of a new award, known as pre-award costs. To qualify for advance funding the expenditure must be necessary for the effective and economical conduct of the project and approved by the sponsor. Pre-award costs will not be approved unless a department head guarantees to reimburse the University if the award is not received. Requests for pre-award expenditures are made to Post-Award Administration. Please contact Post-Award Administration for additional information.

VI. Project Financial Management

Sponsored projects rely on external funding, understanding the intricacies of financial management is crucial for ensuring compliance and effective utilization of resources. This section offers guidance on navigating the financial aspects of sponsored projects, ensuring transparency and accountability throughout the process.

OSU-CHS is the official recipient of grant and contract awards from government agencies and other sponsors and is required to comply with numerous rules and regulations. The Federal Office of Management and Budget establishes broad policies governing grant and contract financial administration. Every government agency that awards grants and contracts (e.g., the National Institutes of Health and the National Science Foundation) has its own regulations for administering grants and contracts as do most non-governmental sponsors.

Although Post-Award Administration assists the PI in carrying out administrative activities related to the grant or contract, the PI must provide guidance and oversight. The Principal Investigator best understands the scope of the project, the effort committed to it by faculty and staff, and the relationship of that project to other projects with which resources may be shared. Therefore, PIs are ultimately responsible for all direct costs that are charged to their grant. In this usage, direct costs are expenses that can be identified specifically with a particular sponsored project or expenses that can be assigned to a project with a high degree of certainty. Deans, directors, and department heads have a corollary responsibility for assuring that all sponsored programs conducted within their units conform to the applicable guidelines.

For project financial management of the clinical trial for industry-sponsored clinical trials, refer to the standard operating procedures for the OSU-CHS Clinical Research Unit.

A. Getting Started

As soon as possible after notification that a proposal has been approved for funding, the Grants and Contracts Financial Administration in Stillwater will create accounts for the award, and Post-Award Administration at OSU-CHS will schedule a meeting with the Principal Investigator(s) to review appropriate University and sponsor regulations and receive budget information for the new award.

1. Principal Investigator(s) Responsibility

The Principal Investigator's most important responsibility is to pursue and complete the scope of work described by the funded proposal within the specified time frame. The award document will outline the rules and guidelines that govern the project and specify the required technical and financial reporting. The PI(s) must understand the award agreement and execute the work under these guidelines. The PI is also responsible for the programmatic direction of the project and for initial authorization of all expenditures charged to the award budget. The PI is ultimately responsible for making prudent use of the award by ensuring that expenditures are appropriate and directly relate to the budget and intent of the award and comply with applicable University, state, federal, and sponsor regulations.

Before an externally funded project is undertaken at OSU-CHS, the PI(s) must familiarize themselves with and agree to comply with all applicable policies on issues governing the conditions of the award including:

- Responsible conduct in research (see Section IX.A.)
- Conflict of interest (see Section IX.C.)
- Use of human subjects (see Section IX.D)
- Use of vertebrate animals (see Section IX.E)
- Biohazardous materials (see Section IX.F)
- Radioactive materials (see Section IX.F)
- Other controlled substances (see Section IX.F)
- Export controls (for projects involving foreign nationals or travel outside the United States see Section IX.G)
- Laws and University regulations dealing with intellectual property and patents.

University policies are located here. Regulations governing other issues should be consulted as necessary.

2. Responsibilities of Post-Award Administration

Post-Award Administration has the primary responsibility for providing the Principal Investigator(s) with financial information necessary to manage a sponsored project effectively and to ensure that the project complies with the financial terms of the agreement. The following list covers many of the activities included in that responsibility:

- Issue invoices to sponsor
- Prepare financial reports for the awarding agencies
- Refer the PI(s) to other University offices, as needed
- Remain current on federal, state, and University policies related to sponsors
- Train project directors and staff in administration regulations and procedures
- Serve as a liaison with auditors on financial matters
- Implement approved internal budget revisions
- Review and approve transactions
- Process draw downs for federal Letter of Credit awards

B. Cost Principles

The University has a responsibility to ensure that costs incurred on sponsored projects are compliant with Federal regulations, sponsor policies, award terms and conditions, and University policies. This means that all costs must be allowable if they are to be incurred on the project.

1. Cost Allowability

In order for costs to be allowable, sponsors require that they be reasonable, allocable, consistently treated, and permitted according to the terms of the award. When dealing with multiple grants or contracts, neither the availability of funds nor a project's expiration date allows discretion in which project may be charged for a particular expense. All expenditures, whether for personnel, equipment, supplies, or other categories must be properly allocated to the grant or contract benefiting from the expense. The PI, not the sponsor, is responsible for ensuring that expenses budgeted and/or charged to an award are allowable. Definitions of expense allowability are established by the University, the sponsor's policies, the project's

Notice of Contract or Grant Award, and by federal policy. In general, to be allowable, costs must meet the following tests.

- Expenses must be *reasonable*:
  - Necessary for performance of the sponsored agreement
  - Do not impose on the restraints and requirements of federal and state laws and regulations, and sponsored agreement terms and conditions incurred by individuals who exercised due prudence
- Expenses must be *allocable*:
  - The expense must benefit the grant directly
  - The expense must be necessary to the operation of the grant
  - The expense must be assignable to the grant
  - If the expense benefits more than one sponsored project, the expense should be allocated to the different projects in proportion to the benefits received by each.

- Expense treatment should be *consistent*:
  - With policies applied to other federal and non-federal funds of the University
  - In treatment in like circumstances regardless of the funding source.

- Expenditures must conform to any limitations or exclusions established by the University, the State, the deferral government per 2CFR200, or in the specific sponsored agreement as to the allowability of a cost, whichever is the most restrictive. Any expense that does not meet these criteria cannot be charged to an externally sponsored project.

2. Unallowable Costs

Most federal and non-federal sponsors issue policy guidelines defining acceptable expenses for their programs. Federal guidelines are contained in 2 CFR 200 Subpart E. Despite a great deal of commonality in content, variations in policy make it impractical to maintain a policy compendium. Individual agency or organization directives must be consulted for authoritative guidance; however, the following items are almost universally treated as unallowable expenses:

- advertising (recruitment of study subjects may be allowed)
- alcoholic beverages (unless the subject of the project)
- alumni activities
- commencement and convocation expenses
- entertainment expenses
- personal use of goods and services

PIs are ultimately responsible for tracking expenditures to prevent disallowable costs and overdrafts. If unallowable costs are erroneously charged to a sponsored project, the PI must notify Post-Award Administration immediately. If the issue is not resolved, the PI's home department will be charged with disallowed expenditures and overdrafts. If Post-Award Administration finds the erroneous charge first, they will communicate the proper process to remove the charge with the relevant department.

3. *Procurement Cards*

The Principal Investigator is responsible for verifying that all procurement card purchases charged to the project are in compliance with the award or contract. Additionally, the PI is responsible for following the procurement card policies of OSU in Tulsa Budget and Finance Repeated violations of these policies will result in the revocation of procurement card privileges.

PIs are responsible for all charges to their project with procurement cards regardless of who holds the card. If invalid or unauthorized purchases are charged to a grant using a procurement card, the PI's departmental budget will absorb the expense. Charges that cannot be paid by the department (i.e., expenses cannot be paid with state funds) will be the responsibility of the PI. The Office of Finance and Accounting will create a receivables account in the PI's name to collect funds that cannot be absorbed by the PI's home department.

C. Spending Funds

Funds should be expensed in accordance with the budget that is awarded by the sponsor. The following are the processes and procedures for expensing funds and categorical explanations for expenses.

1. *Purchase Orders*

Purchase Orders for goods and services are generated via a requisition through OKCorral. OKCorral requisitions must be approved by the PI. This approval certifies that the cost is allowable and solely allocable to the grant.

2. *Effort Reporting*

Effort reporting is how OSU-CHS assures that faculty and staff have met their commitments to sponsored projects and that salaries charged to projects are reasonable in relation to the work performed. It is a federally mandated process by which the salary charged is certified and applies to all sponsored projects. Salaries and wages are allowable as a direct cost to the extent that they are reasonable and conform to established University salary and wage policies.

a. *General Policy*

All personnel involved in a sponsored project effort, whether faculty, professional staff, clerical staff, or students (research assistants), must be paid in accordance with University and state guidelines. Budgeted amounts contained in a proposal do not in any way supersede University policies. The salary and wage categories and job or position classifications on sponsored projects must be congruent with those established for other employees of the University. Salary rates and increments are, therefore, subject to the regulations applied to all other University employees of the same classification. Exceptions may result in audit disallowances.

Federal cost principles allow the direct charging of personnel services to projects

provided that the following requirements are met:

1. The effort by the employee directly benefits the project.
2. The effort incurred is reasonable and necessary to project objectives.
3. The personnel services costs are treated consistently and accurate to established policies.
4. The terms of the agreement or Federal cost principles do not otherwise prohibit charging the personnel services costs.

Effort is not based on a 40-hour work week or any other standard workweek or predetermined number of hours. 100% effort is the total number of hours actually spent on work within the scope of employment.

b. Time and Effort Reporting

OSU-CHS uses an after-the-fact system of documenting time and effort charged to federal grants and contracts. The University's payroll distribution system meets the United States Office of Management and Budget (OMB) standards. OMB, 2CFR, Part200.430, paragraph (i) states that charges to federal awards for salaries and wages must be based on records that accurately reflect the work performed.

Post-Award Administration prepares and distributes effort certification reports via email to the PI for salaries and wages charged to federally sponsored grants and contracts either as a direct charge or as a cost shared commitment. These reports are based on payroll records. OSU-CHS distributes effort reports per financial quarter.

At OSU-CHS, the Principal Investigator, or person with direct knowledge of the employee's workload, must certify the report. Post-Award Administration accepts original signatures returned via campus mail and scanned reports via email.

The important point is that salaries and wages charged to a project must represent the proportionate share of effort that directly benefits the project, the work on the project justifies the salary charged to the project, and the actual time spent on the project is consistent with what was originally proposed.

3. Travel

As budgeted in the project's award, travel expenses are allowable if they are in direct support of the project. All travel reimbursements, both to University and non-University employees, are subject to state and University travel policies except when more restrictive policies and limitations may be imposed by a specific award. Federal travel regulations apply when required by federal awards. For more information refer to the part of this handbook dealing with travel budgeting. Additional travel information is explained in the Proposal Process Review section.

4. Equipment Management

The Office of Research and the Office of Finance and Accounting are responsible for establishing and maintaining accountability for equipment acquired under grants, contracts, and subcontracts for sponsored programs in accordance with sponsor directives and

University policy. The acquisition cost threshold for what is considered non-expendable equipment may vary among sponsors. Most federal sponsors use the definition contained in 2CFR200, i.e., an acquisition cost of $5,000 or more per unit or the institution's definition, whichever is lower. The threshold amount at OSU-CHS is $5,000 and a useful life of over 1 year. Equipment must be requested in the original proposal application, or a prior approval request may be required before acquisition.

There are 3 types of equipment:

1. General Purpose Equipment – equipment which is not limited to research, medical, scientific, or other technical activities. Examples are office equipment and furnishings, modular offices, air conditioning equipment, etc.
2. Special Purpose Equipment – equipment that is used only for research, medical, scientific, or other technical activities. Examples are microscopes, x-ray machines, surgical instruments, and spectrometers.
3. Fabricated Equipment – an item fabricated or made within the University.

If your project includes funds for equipment, please contact Post-Award Administration for assistance in obtaining quotations (bids) from vendors and placing orders. Questions about these policies or equipment purchased on a federally sponsored award should be directed to the Office of Research and Post-Award Administration. If the equipment is purchased to support multiple projects the cost must be allocated specifically to each.

a. Receiving Requirements

The Principal Investigator is responsible for assuring that equipment received is as ordered and in good condition. Any discrepancies or damage should be immediately reported to the Procurement Department.

b. Maintenance

Responsibility for maintaining physical control of all equipment acquired under an award and safeguarding it against loss, damage, or unauthorized use rests with the Principal Investigator. Subcontractors or sub-grantees are also responsible for compliance with equipment policies and requirements as described in sub-award documents.

c. Equipment Transfers

The terms and conditions of the award will state where the equipment vests. Equipment owned by the federal government or other sponsors is subject to transfer to another institution when approved and directed by the sponsor agency. A request for transfer of such property can originate with a researcher transferring to another institution and requiring the equipment in the pursuit of continuing research or with the sponsor itself. A transfer originated by a PI requires the advance approval of the appropriate department head, Vice President for Research, and, in some instances, the sponsor.

Sponsor-originated disposition or transfer instructions do not require such approval. However, if sponsor- directed or contemplated transfers are likely to impair continuance of the project at the University, such considerations should be brought to the attention of the sponsor promptly through the Office of Research in an attempt to dissuade the sponsor from making the transfer. Much of the property acquired from awards becomes University (State of Oklahoma) property upon acquisition or by subsequent vesting of title.

Disposition or transfer of such property is subject to University and state policies.

d. Equipment Records

Equipment records shall be maintained accurately and shall include the following information:

1. A description of the equipment
2. Manufacturer's serial number, model number, Federal stock number, national stock number, or other identification number
3. Funding source of the equipment, including the sponsor award number
4. Whether title vests in the University or the Federal Government or the sponsor
5. Acquisition date and cost
6. Split funding information, if more than one source of funding
7. Location and condition of the equipment and the date the information was reported
8. Unit acquisition cost
9. Ultimate disposition data, including date of disposal and sales price or the method used to determine current fair market value where a recipient compensates for the Federal awarding agency for the Federal share

5. Consultants and Contractual Services

Costs of professional and consultant services rendered by persons who possess a special skill and who are *not* officers or employees of the University are allowable.

- Hiring – The Office of Research is the only unit on campus authorized to execute an agreement with consultants when sponsored funds are to be used. Requests to hire a consultant require the Consultant or Contractor Form– Sponsored Funds Only. Requests must be approved by the Office of Research prior to a consultant commencing work on a project.

- Named Consultants – If a consultant is not specifically named in a grant and the agreement is $5,000 or greater, but a statement of work is stated in the grant/contract, then a Sole Source Form must be completed by the PI and submitted with the Office of Research Consultant or Contractor Form and a CV/resume.

- Payment – To initiate payment of a consultant/contractor, an OKCorral requisition should be submitted along with a quote and a copy of the signed contract. PIs should consult with their Grants Manager for assistance.

6. Subawards

Most, but not all, sponsors require prior approval before the University can transfer substantive programmatic work to a third party, known as a subaward. Generally, an award based on a proposal budget with a line item for the named subrecipient constitutes documentation of sponsor approval. Sometimes this approval must be sought after an award has already been issued. In these cases, the PI should work with the Office of Research to ensure that all documentation is complete and submitted in accordance with sponsor requirements. Pre-Award Administration in the Office of Research creates, routes, and executes all subaward agreements for externally sponsored projects.

During the life of the project, the PI will review and approve the subcontractor's invoices before payments are made. Invoices should be received and approved quickly, since most sponsors require that a subaward invoice is paid within 30 days of receipt. The PI should ensure:

- Dates match the correct period of performance.
- Charges are reasonable and allowable.
- The charges fall within the subaward budget and statement of work.
- Required deliverables have been received.
- Progress to date is satisfactory.

7. Other Direct Costs

Other direct costs include materials and supplies, participant support costs, tuition remission, and others. Questions concerning these costs should be directed to Post-Award Administration.

8. Indirect Costs

Indirect costs (also known as Indirect) costs are explained in the Proposal Process Overview portion, Section IV.C.2. In Post-Award, Indirect costs encompass both their allocation as expense and their generation as revenue.

Indirect costs are automatically charged to the fund and the direct costs are incurred. If a project allows indirect costs, when the direct cost is charged to the account, the accounting system incurs the necessary indirect cost to the same account. These costs are used to maintain infrastructure necessary for sponsored programs, such as utilities, facilities maintenance, and administrative support. When a researcher purchases supplies, hires personnel, conducts experiments, or other necessary work for the project, indirect costs are applied to cover the broader institutional expenses associated with supporting the University enterprise. This charging mechanism ensures that the full cost of conducting sponsored projects, including both direct and indirect expenses, is appropriately accounted for and funded.

9. Recommended Purchasing Deadlines for Grants

All grant expenditures must be posted or encumbered on OSU-CHS's financial ledgers prior to the grant end date.

- Last Month of Award – During the last 30 days of the award Project Managers should notify their Post Award Grant Administrator of any purchases (procurement card, OKCorral requisitions, travel, etc.) incurred. On a federal award, there is a liquidation period of 90 days past the end date that expenses obligated will post to OSU-CHS's ledgers prior to the official closeout. In general, supplies and materials purchased for the project should be consumed by the award's end date. Residual inventories of supplies valued at more than $5,000 are subject to specific requirements for their handling.

- Grant-Specific Deadline(s) – You must reference the individual grant/contract for

grant- specific deadlines set by funding agencies (i.e., narrative reporting, etc.). Post-Award Administration is responsible for all fiscal reporting.

10. Post-Award Budget Changes

The budget is an estimate of the spending plan for the project. The actual spending pattern may vary from the categorical budget breakout. The terms of your award will dictate how much actual project expenditures can vary from the cost categories of the award budget.

For sponsored projects awarded under the terms of Expanded Authorities, the investigator is not limited by the categorical breakout of the budget unless the deviation from the budget represents a change in the scope or objectives of the project. As a rule-of-thumb, the NIH Agency-Specific Terms state that a deviation in a budget category of more than 25% of the total award may indicate a change in the scope of objectives of the project.

Some budget changes to sponsored awards require prior approval. Requests for changes are made with Pre-Award Administration of the Office of Research.

D. Cost Sharing or Matching

Cost sharing and matching refer to the portion of the total sponsored project costs that are not paid by the sponsor. Cost share is indicated in the original application to the sponsor. If the application contains cost share committed by OSU-CHS, the University must track and record the cost share. In most cases, this is considered a cash match. In-Kind Cost Share is inclusive of 3rd parties only and is much less common.

1. Fulfillment of Cost Sharing Agreement

Once a sponsor accepts a proposal containing cost sharing, it is considered binding upon the University and the University accepts the same fiduciary responsibilities in expending these funds as for the funds from the sponsor. Written approval from the sponsor is required to change the matching or cost sharing commitment. The Principal Investigator is responsible for ensuring that any cost sharing commitments are met, and that all necessary documentation is provided to the Office of Research and Post-Award Administration. Cost sharing or matching expenditures incurred, or services rendered must occur during the period of the award and are subject to the same sponsor requirements.

If, at the time of award, the sponsor's level of support is less than the University's originally proposed budget, any original matching commitments offered by the University or external entities on behalf of OSU-CHS should be reconsidered for possible reduction or elimination from the award in consultation with the Office of Research and Post-Award Administration. If conditions arise that make it impossible to satisfy the matching requirements, the Principal Investigator should inform the Office of Research immediately. The Office of Research is responsible for renegotiating any reduction in the level of matching required by the sponsor. The Principal Investigator is responsible for eliminating any matching shortfall requirements.

2. Characteristics of Contributions to Shared Costs of Federally Sponsored Projects

2CFR200 definitions of cost sharing and matching contributions require that they meet all of the following criteria:

- Are verifiable from the records of the Principal Investigator.
- Are not being included as contributions for any other federally assisted project or program.
- Are necessary and reasonable for proper and efficient accomplishment of project or program objectives.
- Are allowable under the applicable cost principles.
- Are not paid by the federal government under another award, except where authorized by federal statute to be used for cost sharing or matching.
- Are provided for in the approved budget when required by the federal awarding agency.
- Unrecovered indirect costs may be used as cost sharing or matching only with the prior approval of the federal-awarding agency.

3. Capturing Required Information

To assist the Principal Investigator in capturing the cost sharing information in accordance with University requirements, Post-Award Administration will provide guidance. When an award commits Cost Share, funds are created for each cost-sharing sponsor. Post-Award Administration is responsible for assigning cost share fund numbers for departmental, college, or University funds. They are also responsible for obtaining, tracking, and reporting "in-kind" third party cost share.

E. Cost Transfers

A cost transfer is a reallocation or redistribution of a previously charged expenditure transferred from one University fund to another fund after the charge has been posted. Cost transfers follow the same allowability standards presented earlier. Cost transfers receive careful scrutiny by sponsors, especially federal government contracting officers and auditors, and are exceptional activities that should not occur frequently. PIs are responsible for managing their sponsored projects to minimize the need for cost transfers.

The following accounting activities are *not* defined as cost transfers.

a. Initial Transfers

Initial transfers of charges for supplies or services from an inventory account, cost center, or other similar operations in accordance with established accounting procedures.

b. Corrections Processing Errors

Corrections of processing errors that occur within the Office of Finance and Accounting's accounting systems, such that when the correction is made, the accounting records are in agreement with the documentation that authorized the change.

1. Error Correction by Cost Transfers

Cost transfers required to correct errors or to achieve proper, consistent, and equitable distribution of costs to sponsored projects are allowed, provided adequate justification for the change is furnished and necessary approvals that certify the accuracy of the charges are received. Corrections must be made promptly after the error is discovered. A cost transfer

made within 90 days after the posting date of the transaction requiring a transfer will be considered timely. In other exceptional instances, cost transfers may be required after the 90-day period. The transfer must be supported by a written explanation of how and why the error occurred and a certification of the correctness of the accounting change. An explanation that merely states that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. The Office of Research will approve or disapprove the request for a cost transfer when all requested documentation and justifications have been provided.

2. *Cost Transfers of Personnel Service Expenses*

Cost transfers of personnel service expenses (salary or fringe distribution changes) requests require adequate supporting statements that clearly indicate that the costs being moved to a project are directly related to the project scope and allowable by the project budget and have been incurred in a timely manner to benefit project activities. Justification must always consist of more than simple statement such as "to correct an error" or "posted to the project number." While such statements may be correct, justification must be considered adequate to convince a sponsor or auditor of the accuracy of the charge to the sponsored project. The Office of Research approves the cost transfer as to accuracy of the accounting, the proper authorization, and the adequacy of the documentation.

3. *Unallowable Cost Transfers*

Costs may not be shifted between accounts or from one budget period to the next solely to cover cost overruns. Cost transfers based on funding considerations are prohibited (i.e., cost transfers cannot be done to expend remaining funds). The intentional "parking" of charges on a restricted grant or contract pending transfer to another grant or contract account upon its funding is unallowable.

Parking of charges for any reason is considered a misuse of grant funds.

F. Program Income

Program income is the gross revenue earned from activities for which the direct costs have been charged to an award or counted as a direct cost toward meeting a cost sharing or matching requirement of a grant. The University is required to identify, document and report program income generated on a sponsored project in accordance with Uniform Guidance, awarding agency regulations, and terms and conditions of the sponsored project. Refer to OSU-CHS policy on program income.

1. *Examples of Program Income*

In addition to other possible sources, program income includes:

- Fees for services such as laboratory drug testing or conference fees
- Proceeds from sale of equipment or supplies purchased or constructed with grant funds if title does not vest in the grantee
- Usage or rental fees charged for use of facilities or equipment such as computer use charges
- Funds generated by the sale of commodities such as sale of tissue cultures, cell lines, or research animals
- Third party patient reimbursements for hospitals or other medical services where such reimbursement occurs because of the grant supported activity

- Patent or copyright royalties

All program income must meet the following core principles:

- The program income must be used for the purpose of the sponsored project.
- The program income must be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the sponsored project.
- The program income must be used for current costs unless the sponsor authorizes otherwise.
- Expenses will be assessed indirect costs at the same rate as the associated sponsored project.
- The program income may be used to fulfill a cost sharing or matching requirement with prior approval of the sponsor.

2. Accounting of Program Income

The Office of Research and Post-Award Administration should be contacted at the time the recognized program income will be generated. Post-Award Administration will assist in establishing the proper method of accounting for the income. Because program income has the same accountability requirements as federal grant funds, Post-Award Administration will select a mechanism that will account for program income in accordance with federal requirements and specific award terms. Program income, in accordance with specific agency requirements, will be reported to the sponsoring agency on financial reports that are prepared periodically. If program income is anticipated as part of a sponsored project, it should be disclosed in the project proposal.

Program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award.

Program income may be used in support of the award in one of three methods: deducted from expenditures by the awarding agency, added to the project budget, or used to meet matching requirements. In all cases, program income must be tracked in a dedicated fund and reported to the federal sponsor or Pass-Through Entity.

G. Project Residual Funds

Residual funds can be carried over to the next period of the project, if approved by the sponsor guidelines. The process and information if a project has ended and a balance still remains is presented below.

1. Residual Balances

A residual balance is unobligated money remaining in a fixed-price sponsored project after closeout. Cost reimbursement grants and contracts cannot have residual balances. Projects that have a balance after the period of performance has ended may be permitted to carry that balance forward if allowed by the sponsor under the specific terms of the project.

2. OSU-CHS Funds

If there is a residual balance at closeout and the PI has performed due diligence in ensuring

that all incurred costs have been recorded, Post-Award Administration will transfer the residual funds to a department or center operating fund. The balance in these funds must be used to support OSU-CHS's mission.

Residual funds must be used for a purpose that is related to the project or to enhance programs to which the project is tied within the director's home college. Residual funds may be used to support the project director's professional development or for the professional development of other faculty members in the director's home college. The State of Oklahoma's rules and regulations apply to the use of residual funds.

H. Over-Expenditures

Responsibility for clearing over-expenditures on sponsored projects fund belongs to the PI and department head. For grants awarded under Expanded Authorities, over-expenditures from one budget period may be absorbed by the award of the continuing non-competitive renewal.

VII. Project Administrative Management

Project Administrative Management for Industry Clinical Trials should refer to the Clinical Research Standard Operating Procedures for more in depth policies and procedures.

A. Hiring Personnel

The following sections provide a brief overview of the process and rules for hiring both students and non-student employees. Please contact Post-Award Administration or the Department of Human Resources for additional information and assistance.

1. *Summer and Maymester Payroll*

Summer and Maymester pay is subject to requirements different from those during the remainder of the academic year:

- The project director is responsible for ensuring his/her department chair submits to Academic Affairs the faculty names, amounts, and grant account for those that are budgeted to be paid Maymester and Summer payroll from externally funded grants and contracts.
- Maymester payroll is charged to the current fiscal year (ending June 30). Maymester payroll is paid for work completed during the month of May, not June.
- If work is done during the summer months (June and July), faculty should be paid through summer payroll, which posts in the next fiscal year (which begins July 1). Thus, the grant end date should carry into the next fiscal year in order to support the processing of summer payroll through the award.
- In addition, a Time and Effort report is required as backup documentation for any Maymester or summer payroll charged to federal sponsored awards.
- For specific OSU-CHS submission deadlines for faculty payroll, please contact the Office of Academic Affairs. For OSU-CHS Maymester or summer payroll check dates, please contact the Office of Payroll.

2. *Leave Benefits*

Personnel paid from a sponsored program account receive the same leave benefits as personnel paid from other University funds. Staff and fiscal year appointees are encouraged to utilize accrued vacation before the program's termination date. If the contract or grant does not have sufficient funds to pay the accrued vacation, it is the responsibility of the employing department to provide the necessary funding. The Principal Investigator must ensure that these employees accurately report their vacation time prior to the project's expiration.

3. *Training Stipends*

A training stipend is an allowance granted to an individual to assist with his or her living expenses during a period of training (e.g., while attending a workshop or conference). Training stipends are not considered compensation for the services expected of an employee. Payment to OSU-CHS faculty or staff for work on sponsored projects is paid as salary, not as a stipend.

4. *Time-Limited Appointments*

Normally, positions funded by a sponsored project are time-limited and for a stated definite term. Otherwise, an employing unit has a continuing obligation to the person after the end of the funding period. During the recruitment period, the Principal Investigator will be advised by staff in the Office of Human Resources about how to describe the position to interviewees.

5. Reduction in Force (RIF) Policy

An employee whose position is entirely funded by a sponsored project remains employed by the university as long as the sponsored funds continue to be available. If the grant funding ends, budgets are reduced, or other funding changes occur, the university may no longer be able to support the position. Refer to the Layoff and Reduction in Workforce for Staff policy # 3-70711.

The hiring manager is responsible for notifying the OSU-CHS Human Resources office at least 90 days before funding for a position is scheduled to end. This timeline applies even when there is the potential for the funding to be extended. If funding is continued, the Reduction in Force Policy process can be halted.

The OSU-CHS Human Resources office will assist the hiring manager in following the layoff procedures, including appropriate notification to the employee in writing.

6. Charging Administrative and Clerical Salaries and Staff Benefits as Direct Costs

Salaries and fringe benefits of administrative and clerical staff may be charged as direct costs if a project requires the services of administrative and clerical staff beyond the normal level provided by departmental administrators paid from a department account. The total cost of these services may be budgeted, charged, and reported as a direct cost to a sponsored project when *all* of the following conditions apply.

- The specific type and nature of the services are not provided by the departmental administration account.
- The services are required by the project's scope.
- The cost can be accurately identified to the project.
- The approved project budget narrative clearly describes the need for the service. For example, charging administrative and clerical salaries and fringe benefits as a direct charge to a sponsored project may be permissible for projects requiring:
    - Extensive data accumulation, statistical analysis and entry, database management, surveying, tabulation, cataloging, or literature review.
    - The preparation and production of manuals and large reports or books. (This does not include routine progress and technical reports.)
    - Extensive travel and meeting arrangements for a large number of participants, such as conferences and seminars.
    - The management of a project at locations geographically inaccessible to normal departmental administrative services, such as field-sites remote from campus.
    - Special research security services at a level not normally provided by campus security.
    - Large, complex programs (such as general Clinical Research Units, primate

centers, environmental research centers, engineering research centers, and other federally sponsored projects) that entail assembling and managing teams of investigators from a number of institutions or units. National Institutes of Health R01 Grants do not qualify as complex programs.

These examples are not an exhaustive list, nor do they imply that direct charging of administrative or clerical salaries would always be appropriate for the situations illustrated in the examples.

Furthermore, separate projects cannot be grouped together to meet any of the criteria listed above. The project director must support and justify in the proposal all direct costs to be charged to a sponsored project and are, therefore, strongly advised to discuss such costs with the Office of Research staff.

7. Release Time

If a sponsored project supports a course release, the project director is responsible for notifying the Office of Research via email or memorandum about the course release(s) schedule to charge against the appropriate sponsored project during the semester in which the course release is taken. Reassignment of faculty time from standard teaching responsibilities to a sponsored project may occur by paying a different person to teach one or more of the faculty's courses.

B. Subaward Monitoring

When a project has a subaward, it is the PI's responsibility to monitor the progress of each subawardee to assure that all required deliverables have been received and spending is reasonable and allowable for the work being done. The PI should also monitor the technical progress of a subrecipient's performance as defined in the subaward's statement of work and identify issues or problems in a timely manner. The PI should communicate any concerns, whether programmatic or budgetary to the Office of Research and Post-Award Administration as soon as possible.

C. Reporting

Sponsors generally require reporting during the life of the award, from annual project reports to final equipment reports. Responsibility for these reports varies. All scientific and technical reports are completed and submitted by the PI, unless submission requires an Institutional Official. Patent reports are completed with both the Office of Research and the PI and submitted by the Office of Research. Post-Award Administration prepares financial status reports for sponsored projects, according to the terms of the award.

D. Project Changes

Certain award activities require sponsor approval before being undertaken. The term *prior approval* is used to refer to those activities. All administrative project changes that require prior approval are submitted by Pre-Award Administration in the Office of Research.

1. No-Cost Extensions

Should the PI be unable to complete the project by the end date, they may be allowed to request a no-cost extension. Extensions are not appropriate when the sole purpose is to spend down remaining funds. No cost extensions do not increase the amount of the original fiscal obligation. Most federal agencies allow the institution to have a one-year no-cost extension. For other agencies, prior approval is required from the sponsor.

2. *Change in PI/Key Personnel, Absence from Grant*

Whenever there is a significant change in the level of participation in the approved project by the PI, the University must notify the sponsor as soon as such information is known. Significant change in level of effort is defined as relinquishing active direction of the project either permanently or for a continuous period of more than 3 months or a 25 percent reduction in time devoted to a project. Since approval of a project has, to some extent, been based on the participation and/or qualifications of the named key personnel, the sponsor requires notification and the option to approve or disapprove alternate plans for conducting the activity.

A change in PI requires prior approval and the internal change of PI request form has to be completed before a request is submitted to the sponsor.

3. *PI Transfer to Another Institution*

When transferring a sponsored project, the award must be closed at the original institution and reissued to the new institution. This process can take several months, so it's crucial to notify the Office of Research as soon as possible when a transfer is needed.

4. *Change in Scope or Objectives*

Approval from the sponsor is required for a proposed change in the scope or objectives of the study stated in the proposal. When in doubt, it is best to err on the side of over-communicating with the sponsor.

5. *Procedure for Prior Approval Request*

Any request that requires institutional representative approval must be signed by the Vice President of Research. Documents requiring signature should be sent to Pre-Award Administration to be reviewed, routed, and signed.

E. Intellectual Property

Sponsored projects often generate intellectual property (IP). Intellectual property is any new, novel, and useful product that is created by the mind of individuals through their own research and development. University policy states inventors must submit an invention disclosure before disclosing the information to any party outside the University, to the general public, through publication or for commercial purposes. Furthermore, OSU-CHS owns the IP the PI develops.

The Innovation Foundation at OSU assists faculty and staff members, administrators, and students with intellectual property issues resulting from their scholarly and creative activities. It exists to foster the creation of innovative technologies and to manage those technologies and other IP for the benefit of the University and the public.

The Innovation Foundation is responsible for managing the IP assets of the University. In carrying out this mission, the purpose of the Innovation Foundation is to:

- Assist faculty, staff and students with the invention disclosure process
- Review disclosure with inventors to learn about potential applications
- Perform technical and market assessments to evaluate the commercial prospects of an invention
- Work with patent counsel to assess patentability and to provide appropriate legal protection
- Recruit prospective licensees
- Negotiate licensing agreements
- Disburse royalty fees to colleges, departments, and inventors
- Advise inventors regarding germane policies and procedures, including conflict of interest
- Facilitate confidentiality agreements
- Review and assist with collaboration agreements as needed
- Facilitate material transfer agreements for biological materials.

VIII. Post-Award Process

A. Closeout of Project

It is the responsibility of the University to close out completed sponsored projects in compliance with Federal regulations, sponsor policy, and award terms and conditions. Uniform Guidance requires that final financial, progress, technical, and other reports be submitted within 120 days after the project end date. Terms and conditions of the award prescribing otherwise, will prevail to standard practice. Non-compliance may cause adverse consequences for the University including, but not limited to, forfeiture of final payment, delayed or reduced future funding, less favorable award terms and conditions, and audit finding risks. This responsibility is shared by the Principal Investigator and the University, especially Post-Award Administration.

1. Early Termination

A project may be terminated by the sponsor, the University or by mutual agreement of both the sponsor and the University. The award agreement and/or sponsor guidelines specify the process for terminating a project before the end date. If the PI receives a notice of project termination, the PI should contact the Office of Research and Post-Award Administration as soon as possible.

2. Transfer to Another University

If a PI moves from OSU-CHS to another institution, the project they oversee can be transferred to the new institution. OSU-CHS initiates the process by relinquishing its interests in the project, usually facilitated through a formal form, and estimating the remaining unobligated funds. Upon confirmation by the Office of Research, in collaboration with Post-Award Administration, and department head concurrence, the sponsor terminates the grant with OSU-CHS and establishes a new grant with the new institution. This process remains consistent for both Federal and non-Federal sponsors, although for modest remaining project time and funds, a subaward may be issued to the new institution with sponsor and replacement PI approval. Equipment purchased with sponsored funds can also be transferred to the new institution with the appropriate approvals.

3. Closeout Process

To ensure compliance, a formal project closeout consists of the following steps:

- In order to explain the closeout process, Post-Award Administration will contact the Principal Investigator 60 days prior to the end of the project. For any expenditures in this time, the PI should consider lead time required in ordering goods; items must be delivered and used for the benefit of the project before the end date. Supplies should not be “stockpiled” for other projects when excess funds remain in an account at the end of a project.

- The Principal Investigator is responsible for initiating requests for extensions by the sponsor via the Office of Research. Prior to requesting the extension, an assessment of the budget status and the timeframe in which to complete the expenditures should be addressed with the Office of Research and Post-Award Administration. This will help

ensure that all fiscal matters, including matching, are appropriately considered in the request for extension.

- Funds will be made inactive after the project termination date. The Principal Investigator will work with Post-Award Administration to ensure that all transactions are completed and charged to the accounts prior to the prescribed sponsor deadline. Post-Award expenditures are charges that post to the account after the end date. These costs will be reviewed and approved for validity by Post-Award Administration. This includes, but is not limited to:

    - Payroll worked prior to the end date, but posted after the end date
    - Service charges incurred in the project period and post after the end date
    - Liquidation of valid purchase orders
    - Expense transfers and correction of errors that either move expenditures, or transfers allowable expenditures to the account

4. Reporting Requirements

Programmatic reports due to the sponsor at the close of the sponsored project are the responsibility of the PI with the assistance of the Office of Research and Post-Award Administration. This includes:

- Final Cost Sharing Certification
- Property Report
- Final technical/Progress/Programmatic Report
- Final Invention Statement
- Final Patent Certification

B. Clinical Trial Closeout Process

The OSU-CHS Clinical Research Unit oversees the clinical trial close-out process in collaboration with the PI. After all study subjects have completed the trial and the study sponsor gives final data lock confirmation, the site will begin engagement to close out the study with the sponsors. Prior to the final study close-out, all accounts are reconciled, and the coverage analysis is reviewed internally in accordance with the clinical trial agreement. For a complete list of study close-out procedures, archival, and long-term storage, please refer to the Clinical Research Unit SOP.

C. Audits

An audit is the systematic examination of financial records, procedures, and compliance with regulations to ensure accuracy, integrity, and adherence to institutional and sponsor requirements. All sponsored projects awarded to the University are subject to audit. Audits may be performed at multiple levels including the:

- Board of Regents, Office of Internal Audit
- Office of the State Auditor
- Federal Auditors
- Public Auditors

1. Focal Point for Audit Matters

Grants Contracts Financial Administration (GCFA) in Stillwater is responsible for coordinating all audit matters related to sponsored projects of the University. Federal, state, and public firm auditors must make their initial contact with Post-Award Administration. Subsequent contacts by auditors with other University departments will be preceded by advance notice from Post-Award Administration. The purpose of the advance contact is to identify the auditors, outline the general purpose of the visit, and facilitate the audit. Questions concerning the official status of an auditor should be referred to Post-Award Administration.

2. ***Grants Accounting Administration Representation***

Depending upon the nature of the audit or subject matter, Post-Award Administration may elect to be represented in audit discussions at the departmental level. Should departmental personnel require guidance at any time, Post-Award Administration should be contacted without hesitation. Post-Award Administration participates in and coordinates the exit audit briefing as deemed necessary by the significance and nature of the audit findings and recommendations.

3. ***Right of Access***

Under the legal terms of sponsored projects, auditors have the right of access to all official University records associated with an award. The University is obligated to make such records readily available for examination.

4. ***Exit Conference***

At the conclusion of an audit and prior to the issuance of the formal report, auditors normally conduct an exit conference. The purpose of this meeting is to review audit findings and tentative conclusions, exceptions, and recommendations. At this meeting, the University has an opportunity to comment on the audit findings and to provide additional information where appropriate.

5. ***Audit Response***

Post-Award Administration is responsible for coordinating the University's response to audits of sponsored projects. This responsibility in no way relieves the Principal Investigator or department concerned from providing necessary input in a timely manner or from resolving financial liability, which may ultimately be assessed as a result of audit exceptions. The University's response must be coordinated through established channels. Under no circumstances may a department or individual initiate a direct response to an audit.

6. ***Cost Disallowance***

Financial responsibility for audit findings rests with the Principal Investigator, department, and college having primary responsibility for the project on which costs are questioned. Disallowances cannot be charged to any federal or state-funded accounts. Personal liability may be considered and assessed when an audit disallowance stemmed from gross negligence or malfeasance on the part of an employee.

IX. Research Compliance

OSU-CHS is dedicated to fostering research initiatives guided by ethical principles, integral to the responsible conduct of research. Under the auspices of Research Compliance in the Office of Research, key compliance programs are implemented to uphold ethical standards in areas such as research misconduct, human subjects research, animal welfare, and biosafety protocols. Through centralized coordination, education, and training, Research Compliance supports faculty, staff, and students in complying with federal, state, and university regulations, thereby fostering a culture of responsible research practices. Responsibilities include ensuring compliance with regulations, promoting a culture of ethical conduct, and providing assistance and training to ensure compliance throughout the proposal submission and award execution phases.

A. Scholarly Misconduct

OSU-CHS is committed to equipping its advanced degree recipients, faculty, and research staff with a comprehensive understanding of responsible research practices. At a minimum, these include: proper citation of other work, plagiarism, research misconduct, intellectual property and copyright, falsification and unwarranted editing of data, management of conflicts of interest, authorship on manuscripts, and cultivation of effective mentor-mentee relationships.

1. *Background*

Federal regulations define Research Misconduct "as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results." Research Misconduct does not include honest errors, differences of opinion or authorship disputes. Faculty, staff, and students of OSU-CHS are expected to conform to the highest standards in research and creative activities including ethical, legal, and regulatory standards of the University, funding agencies, and regulatory agencies. Refer to the policy #4-70125 Compliance of Research Misconduct Policy.

2. *Training Plan*

Prior to submission of a PHS or NSF grant proposal, personnel to be involved in the project must complete the "Responsible Conduct of Research" course at www.citiprogram.org. Refer to policy #4-70201 Requirements for Training in the Responsible Conduct of Research. FAQs can be found on the Research Integrity webpage.

3. *Training for Students*

All degree seeking students and postdoctoral fellows will complete the CITI online RCR training for their respective discipline and forward the curriculum completion report to their research mentor. This training must be completed before commencing paid research with PHS or NSF funding. In addition to this online training, students will complete a face-to-face training segment with the faculty member under whose direction they are conducting research. Office of Research staff will work with the faculty member on this segment. Possibilities include having students read *On Being a Scientist* or *The Immortal Life of Henrietta Lacks* and then discuss it with the faculty member. Face to face training must be documented.

B. Conflicts of Commitment

Conflict of commitment is the situation where an investigator's external commitments or activities interfere with their primary obligations to OSU-CHS, potentially compromising their ability to fulfill their research responsibilities effectively. This could include engaging in outside activities that conflict with their duties, such as consulting for a competing organization or committing insufficient time to research endeavors. To prevent conflict of commitment, investigators should transparently disclose external commitments via COI-SMART and seek approval from OSU-CHS when necessary. Additionally, maintaining clear communication and actively managing time commitments, disclosing external activities, seeking approval for certain engagements, or recusing oneself from conflicting situations can help mitigate conflicts.

C. Conflicts of Interest

1. Policy

OSU-CHS complies with federal regulations ensuring that sponsored activities will not be compromised by investigators' financial interests that could be reasonably expected to bias the design, conduct, or reporting of the research. In accordance with these regulations, the University has the responsibility to disclose, manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. This policy and the implementation procedures apply to research, educational, or service projects funded by federal agencies either directly to OSU-CHS or through another institution or organization by a subaward. Refer to policy # 9-70003 Conflict of Interest.

a. Definitions

1) Conflict of Interest – A conflict of interest exists when the university reviewer(s) reasonably determines that a significant financial interest could directly and significantly bias the design, conduct, or reporting of the federally-funded research, educational, or service activities.

2) Investigator – The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. Interests of the investigator that would constitute a conflict of interest include interests of the investigator's spouse and dependent children.

3) Institution – Any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

4) Research – A systematic investigation designed to develop or contribute to knowledge. The term encompasses basic and applied research and product development.

5) Significant Financial Interest – Significant financial interest means anything of

monetary value, including but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options or other ownership interests); or
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

b. *Exclusions*

Conflict of Interest does not apply to the following:

- Salary, royalties, or other remuneration from the applicant institution;
- Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation in Research program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that when aggregated for the investigator and the investigator's spouse and dependent children, (1) does not exceed $5,000 in value, as determined through reference to public prices or other reasonable measures of fair market value, and (2) does not represent more than a five percent ownership interest in any single entity (both conditions must be met); or
- Salary, royalties, or other payments that, when aggregated for the investor and the investigator's spouse and dependent children over the next 12 months, are not expected to exceed $5,000.

2. *Procedures*

Compliance with the federal regulations requires that investigators disclose a listing of significant financial interests (and those of his/her spouse and dependent children) that would reasonably appear to affect the research or educational activity funded, or proposed for funding, or in entities whose financial interests would reasonably appear to affect such activities.

a. *Disclosures*

Disclosures must be made to the designated university official prior to the submission of a proposal for funding. This official will review the disclosures and determine which, if any, financial interests could directly and significantly affect the design, conduct, or reporting of the research. The institution must, prior to any expenditure of awarded funds, comply with the conflict of interests reporting requirements of the funding agency.

b. *Disclosures Process*

Financial disclosures must be updated at least annually during the award period and more frequently as new reportable significant financial interests are obtained. The procedural steps for this policy are as follows:

1) Investigators applying for funding are required to complete the disclosure questionnaire at https://okstate.coi-smart.com.

1) The disclosure questionnaire is reviewed by the Conflict of Interest Review Committee (COIRC). A management plan is developed to minimize or eliminate any actual,

potential, or perceived conflict of interest. Examples of conditions or restrictions that might be imposed include, but are not limited to:

- Public disclosure of significant financial interests;
- Monitoring of the research or project by independent reviewers;
- Modification of the research or educational plan;
- Disqualification from participation in all or a portion of the research or educational activity;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.

2) After a grant application has been submitted, and prior to the acceptance of an award, the Office of Research representative that serves on the COIRC confirms whether a management plan is in place.

3) Should the investigator disagree with the proposed conditions or restrictions, he/she may appeal the decision as delineated in the OSU CHS Conflict of Interest Policy #9-70003.

4) Prior to expenditure of any funds under an award, the university will comply with reporting requirements of the sponsoring agency concerning the existence of a conflict of interest. The investigator will update any financial disclosures at least annually throughout the period of the award or more frequently as new reportable significant financial interest is obtained.

5) For any interest that the institution identifies as conflicting subsequent to the institution's initial report under the award, the report will be made, and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within 60 days of that identification.

6) Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the university for at least three years beyond the completion of the grant or longer if required by the agency.

7) The university agrees to make information available, upon request, to the sponsoring agency regarding all conflicts of interest for the specified PI identified by the institution and outlining how those interests have been managed, minimized, or eliminated to protect the project from bias.

8) If an investigator violates the OSU-CHS COI policy, the COIRC will recommend appropriate sanctions to the President of the university. If failure to comply has biased the design, conduct, or reporting of the funded research or educational activity, the institution will promptly notify the awarding agency of the corrective action taken or to be taken. The awarding agency may take action or refer the matter to the institution for further action.

9) Collaborators/sub-recipients/subcontractors from other academic/not-for-profit institutions must either comply with this policy or provide a certification from their

institutions that they are in compliance with federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.

D. Research Involving Human Subjects

OSU-CHS is required to safeguard the rights and welfare of human subjects involved in sponsored projects. Any project which utilizes human subjects for research should be submitted for review to the University's Institutional Review Board. This includes projects related to the investigation of new drugs; medical, radiological, engineering, physiological, behavioral, sociological, and nutritional studies; projects involving human tissues or blood; as well as images, questionnaires, interviews, and other intervention or interactive procedures. The PI takes ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of the study, and the ethical performance of the project.

1. *Role of the Institutional Review Board*

An institutional review board is a committee established to protect the rights and welfare of all human subjects who volunteer to participate in research studies conducted under the auspices of a university, research institute, or hospital.

The OSU-CHS Institutional Review Board (IRB) oversees all research sponsored by the University involving human subjects. This includes the collection and/or analysis of data from participants intended for publication or presentation or dissemination to an external audience. The IRB ensures that potential research-related risks (physical, social, emotional, financial, etc.) are minimized and fully disclosed so that participants can make an informed decision about participation. To provide appropriate oversight and protection:

- All research conducted at OSU-CHS involving human subjects must be reviewed and approved by the IRB and the research must be conducted according to relevant university, state, and federal regulations.
- The university charges the IRB with determining whether an activity conducted or supported by OSU-CHS faculty, staff, or students, is research involving human subjects. OSU-CHS policy does not authorize investigators to make a determination of exemption for their own.
- Furthermore, all researchers not affiliated with OSU-CHS must request permission to recruit research participants on the OSU-CHS campus. Instructions for requesting permission can be found here.

For assistance and additional information contact the IRB at chsirb@okstate.edu.

2. *Review Process*

Instructions for submitting an IRB application for review can be found here. IRBManager is a web-based IRB application submission, tracking, and management system. This system allows researchers to securely submit their IRB applications for processing by the IRB Office. You can log into IRBManager at https://osu-chs.my.irbmanager.com. The IRB has an Investigator Manual to provide guidance on the IRB application and review process.

Prior to conducting or assisting with research, each investigator (including faculty, staff and students) *must* complete a training course in human subjects' protection. Training can be completed at Collaborative Institutional Training Initiative (CITI). The program consists of a basic course of modules for biomedical research, social/behavioral research, and research with data or laboratory specimens (only). Training instructions can be found here. Refresher training is required every three years.

E. Research Involving Animals

The Institutional Animal Care and Use Committee (IACUC) oversees campus-wide animal care and use research, testing, or teaching activities) to ensure adherence to humane and ethical principles, as outlined in the Animal Welfare Act, Institute for Laboratory Animal Research "Guide for Care and Use of Laboratory Animals," and all other applicable public laws and local policies which are found on the OSU-CHS Animal Care and Use webpage. Federal laws and regulations define and prescribe rules for obtaining, maintaining, transporting, and using animals for research purposes. Failure to comply with these rules and regulations can result in significant monetary fines and penalties, including the loss of federal funding for the university.

1. ***Role of the IACUC***
   OSU-CHS is committed to providing an animal care and use program that provides a humane and compliant environment for all animals involved in research, teaching, and testing activities. Every effort is made to adhere to all federal, state, and local laws and regulations that govern the care and use of animals. All research, teaching and testing activities involving live, vertebrate animals must be approved by the IACUC.
2. ***Review Process***
   Instructions for submitting an application can be found here. The Institutional Animal Care and Use Committee (IACUC) meets bimonthly in the months of February, April, June, August, October, and December. In order to have an animal care and use protocol (ACUP) reviewed at a particular meeting, it must reach the IACUC office at least two weeks prior to a meeting.

   Prior to conducting or assisting with animal research, each investigator (including faculty, staff and students) *must* complete a training course in animal care and use. Training can be completed at Collaborative Institutional Training Initiative (CITI). The program consists of courses relevant to the animal model you are working with. Training instructions can be found here. Refresher training is required every three years.

F. Biosafety

OSU-CHS required Institutional Biosafety Committee (IBC) approval for all activities involving recombinant DNA, biohazardous agents, human blood or tissues, human gene transfer, select agents, and transgenic animals or plants prior to acquisition and research commencement. Projects involving transgenic animals require IACUC approval, contingent on IBC approval, while human gene transfer projects necessitate IRB approval, also contingent on IBC approval. Application to the IBC and training requirements can be found here. One component of the IBC approval process is satisfactory completion of an inspection of laboratories/facilities that are classified as needing biosafety containment.

G. Export Controls

The federal government has recognized *fundamental research* as "*basic and applied research in science and engineering where the resulting information is to be shared broadly within the scientific community*" (National Security Decision Directive 189). Restricted or classified research produces results that are not shared broadly. Fundamental research is not subject to export controls when conducted within the borders of the United States. However, fundamental research of any kind occurring abroad is subject to export controls if restricted equipment, software, or information is shipped outside the United States.

Export controls are restrictions imposed by the federal government by the Department of Commerce – Export Administration Regulations, Department of State – International Traffic in Arms Regulation, and the Department of Treasury Office of Foreign Assets Control on access to, dissemination of, and transfers of some equipment, software, and data. Providing access to restricted technology or information to non-US persons (i.e., those who are not either American citizens, legal residents, and other protected persons) while in the United States or while abroad may be considered as an export, re- export, or deemed export. For this purpose, export is "the shipment of tangible items and the transmission or transfer of software code or information to another country, while a 'deemed export' is the disclosure of controlled software code or information to foreign nationals."

Principal investigators of projects involving foreign nationals or travel outside the United States must consider whether or not their work is subject to export control restrictions. The implications of federal law governing restricted technologies and the involvement of foreign nationals in research should be discussed with the Office of Research during the early stages of proposal planning.

Violations of export controls can result in major fines against the institution and individuals found guilty and imprisonment of those held responsible.

H. Foreign Collaboration

External collaborations, including international partnerships, are integral to research and scholarship at OSU-CHS, with PIs encouraged to foster such collaborations to advance intellectual goals. However, as relationships develop, transparency obligations arise. PIs must disclose any support, partnerships, or involvement that could introduce bias, conflicts of interest, or conflicts of commitment, aligning with OSU-CHS standards and federal funding agency requirements. Research Compliance offers guidance on disclosing foreign collaborations to both OSU-CHS and sponsors. The University is committed to safeguarding research from foreign government influence while fostering an inclusive research environment, ensuring adherence to the highest ethical standards.

I. Research Records

The preparation, sharing, and retention of appropriate records are essential components of any

research endeavor at OSU-CHS. The University, its faculty, and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, shared, and retained. Original records may be required to:

- protect the University's intellectual property rights,
- answer ongoing questions regarding the management of a research program,
- address possible questions that may arise regarding the propriety of research conduct, and
- comply with the data sharing requirements of many sponsors (e.g., NIH).

Most importantly, it is essential that original research records be mutually available to all the collaborators on a research project.

Research records include, by way of example but not limitation, material contained in research notes, in laboratory notebooks, and in other media, such as computer disks and instrument printouts. Significant research materials or products generated by any research are also part of the record and should be retained and available.

Research records must be available to collaborators (co-investigators, supervisors, and their trainees). In collaborative projects, all investigators should know the status of all contributing research records and have access to them consistent with confidentiality restrictions. Investigators also should be aware if their research records are subject to specific data sharing requirements of a sponsor.

PIs have the obligation to ensure that, for all aspects of their research programs, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation. This practice does not create an obligation to retain the research records of an unfunded project unless it results in publication or involves the use of animals or human subjects. The original research records should be archived for a minimum of five years after final reporting or publication of a project, or longer if required by an external sponsor, law, rule, regulation, or OSU-CHS Policy #3-70190. In addition, the records should be kept for as long as may be required to protect any patents resulting from the work. If questions regarding the research are raised during the required retention period, the records must be retained until all the questions are fully resolved. In the event an investigator leaves OSU-CHS for any reason, the original research records must be retained at the University and the investigator's department and collaborators notified as to their location. See guidance here.

OSU-CHS is the primary owner of research records. The University has the right of access to the supporting records for all research carried out through the University with the understanding that information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. In addition, extramural sponsors providing support for research at the University may have the right to review any data and records resulting from that extramural support. Refer to policy #3-0602 Data Stewardship.

A data management plan (DMP) is a formal document that outlines what you will do with your data during and after a research project. DMPTool is a free, open-source, online application that helps researchers create data management plans. DMPs are now required by many funding

agencies as part of the grant proposal submission process. The DMPTool provides a click-through wizard for creating a DMP that complies with funder requirements. It also has templates, direct links to funder websites, help text for answering questions, and resources for best practices surrounding data management.

J. Material Transfer Agreements

All research materials that are transferred in or out of the University must be accompanied by a Materials Transfer Agreement (MTA), which will be reviewed and executed by a representative in the Office of Research.

The purpose is to implement a process for the transfer of research material. This policy is designed to make sure that the University has an opportunity to review the terms that may accompany materials that are transferred in or out of the institution. MTAs are agreements between a supplier and a user of research materials. They govern the use of the transferred material and are necessary to protect the rights of both the provider and recipient. Many MTAs include provisions that can cause the provider or recipient to lose the rights to their creations or inventions. Additionally, these agreements may include language that can be used to prevent the recipient from publishing or even continuing his/her research.

PIs must complete and submit a Materials Transfer Agreement Questionnaire to the Office of Research. If OSU-CHS is providing material to another institution, the forms package must also include a copy of OSU-CHS's Materials Transfer Agreement template or, if OSU-CHS is receiving material, the provider's MTA, together with the contact information for the representative at the other institution who is responsible for negotiating the Materials Transfer Agreement.

The Office of Research will review the MTA questionnaire and agreement.

After the Office of Research approves the terms of the MTA, the Office of Research will obtain the necessary signatures.

As soon as all the requisite signatures are obtained, the Office of Research will provide the PI with a copy of the fully executed MTA, and the faculty member may send or receive the material.

X. Clinical Research

Further explanation of Clinical Research at OSU-CHS can be found in the Clinical Research SOP document.

A. Overview

The NIH defines clinical trials as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

The FDA defines a clinical trial as a voluntary research study where people volunteer to answer questions about the safety or effectiveness of drugs, vaccines, or other therapies. They are also known as clinical research. There are many types of clinical research, treatment, prevention, diagnostic, screening, quality of life, genetics, epidemiological and clinical trials. Clinical Trials are often conducted in four phases, each with a different purpose and help scientists answer different questions.

Clinical Trial refers to studies conducted on humans to determine the safety and efficacy of new drugs, devices, treatments, or preventive measures by comparing two or more interventions or regimens. The federal government or private companies may sponsor such activities. The scope of work (also known as the protocol) can be designed by the sponsor or solely in collaboration with the sponsor and by the PI.

Clinical Research is considered a sponsored project. This means it must be reviewed in accordance with OSU-CHS policy and approved by the Director of Clinical Research, Director of Compliance, and Vice President for Research before being agreed upon and executed. Review and approval are done identically to other Sponsored Projects through the Cayuse platform.

All Clinical Research is performed under the terms of a formal clinical trial agreement which has been executed or accepted on behalf of the University by the Office of Research. Additionally, all externally funded clinical research is accounted for in a sponsored project fund established by Post-Award Administration.

B. Responsibilities

The Principal Investigator is responsible for managing the clinical trial in accordance with her terms of the clinical trial agreement or grant and protocol, University policies, and applicable Federal laws and regulations. It is also the PI's responsibility to submit required reports and other appropriate information to the sponsor.

The Director of Clinical Research negotiates and executes clinical trial contracts with industry sponsors.

C. Regulations

Depending on the research study type and the specific funding agency or sponsor, multiple levels of regulatory and compliance oversight may be involved, including federal regulations, state laws, institutional policies and guidelines, and funding agency or sponsor policies and guidelines.

Understanding the levels of oversight for a study will ensure the appropriate procedures are in place. Most clinical research studies that take place at an Academic Health Center are regulated by one or more Department of Health and Human Services (DHHS) agencies: National Institutes of Health (NIH), Food and Drug Administration (FDA), and Office for Human Research Protection (OHRP). Though all these agencies are part of DHHS, they function under different sets of regulations. OHRP is the federal office that creates and enforces the regulations for all types of human subjects research, not just clinic research. NIH funds studies that are regulated by 45 CFR 46, the Common Rule, and the stipulations of the funding grant and institute or center within the NIH. The FDA is responsible for regulation and oversight of all human subjects research that involves drugs, devices, biologics, and/or vaccines.

D. Sponsor Types

A study sponsor is an individual, company, institution, or organization with the responsibility for the initiation, management, and/or financing of a clinical trial. There are several types of study sponsors, but there are two main categories: industry and federal.

1. ***Industry Partner***

   An industry-sponsored study is one that is initiated by a company or organization. They develop the protocol and approach a site or an investigator at a site to participate in a study. This is usually a pharmaceutical or biotechnology company. This organization assumes the sponsor responsibilities. Clinical Trial Agreement to an industry partner must be reviewed and approved by the Direct of Clinical Research, then go through the routing process in Section IV.E.

2. ***Federal***

   A federally funded clinical research study is a peer-reviewed activity sponsored under a board charter by a government agency. Government or federal agencies that provide funding for research include, but are not limited to: The National Science Foundation, the Department of Defense, the Department of Energy, the National Institutes of Health. These studies must go through the standard routing, review, and approval process outlined in Section IV.E.

E. Project Managements

1. Assessing Study Feasibility
   a. The sponsor may request that the study site complete a feasibility evaluation form providing site specifics; however, the site must also complete an internal feasibility evaluation to determine whether it is interested in being considered for and selected for the study in question. Please note that data may not be shared with the sponsor until the appropriate contacts are in place for pre-study activities.
2. Billing Compliance
   a. Routine Care **(also known as "Standard of Care")**, is care that is medically reasonable, necessary, and ordinarily furnished (absent of any research programs) in the treatment of subjects by providers under the supervision of physicians as indicated by the medical

condition of the subjects per Center for Medicare Services. By this definition, the appropriate level of care criteria must be met for the costs of this care to be reimbursable. Such care may be diagnostic, therapeutic, rehabilitative, medical, psychiatric, skilled nursing and other related professional health services. The terms synonymous with routine care are usual subject care or standard care. A coverage analysis is required to be in place prior to study subject enrollment, along with a billing compliance plan to oversee regulatory compliance regarding clinical care visits and third-party payors.

b. The Clinical Research Unit prepares the Coverage Analysis (MCA) in collaboration with the billing and coding teams to oversee reimbursement for routine care in alignment with a clinical research study subject visit per the protocol.

3. Study Start Up Activities
   a. See Clinical Research Unit SOP
4. Investigational Product Management
   a. See Clinical Research Unit SOP
5. Source Documentation
   a. See Clinical Research Unit SOP
6. Monitoring and Auditing Visits
   a. See Clinical Research Unit SOP
7. Study Completion
   a. See Clinical Research Unit SOP

F. Definitions

- Human Subjects – a living individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient.
- Clinical Research – the NIH defines clinical research as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
- Prospectively Assigned – a pre-defined process specified in an approved protocol that stipulates the assignment of research subjects to one or more arms, cohorts or groups of the clinical trial.
- Intervention – a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints.
- Health-Related Biomedical or Behavioral Outcome – the effect of an intervention on the study subjects.
- Common Rule – the basic standard of ethics to which any government-funded research in the US is held.
- Drug – a substance recognized by an official pharmacopoeia; created using a chemical process; intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease; and intended to affect the structure or any function of the budget.
- Biologic – wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

- ICH-GCP: International Conference on Harmonization and Good Clinical Practice guidelines is to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.

XI. Appendix