SPONSORED RESEARCH HANDBOOK

Policies and Guidelines

2018
School of Nursing Sponsored Projects Website
Business and Finance Office Website
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I. INTRODUCTION

Welcome to Sponsored Projects at the Johns Hopkins School of Nursing (JHSON)

JHSON Mission — To improve the health of individuals and diverse communities locally and globally through leadership and excellence in nursing education, research, practice and service.

This handbook contains the policies, procedures and guidelines relating to sponsored research, service, and training at the JHSON. It covers the development of proposals, review of proposals, submission of proposals and the establishment and administration of sponsored project accounts.

The purpose of this handbook is to guide the user through the necessary steps and to provide guidance concerning the rules and regulations that apply when submitting a proposal or administering a grant.

- How is a "sponsored project" (or "sponsored program"), distinguished from a "gift" or "grant" provided by a donor? The term "sponsored project" relates to a research, service, or instruction project that is conducted with support provided by some entity outside the campus (SPONSOR).

- A sponsored project grant or contract is based on a commitment from the JHSON to carry out the project in keeping with terms agreed upon by both parties. The sponsored project will always require some use of JHSON resources, and the sponsor will receive some benefit (which could range from a single technical and financial report through substantial material benefits).

- By contrast, a gift or grant from a donor may carry a stipulation as to its use, but there can be no expectation of benefit back to the donor, including the technical and financial reports common to sponsored project grants and contracts; it is donative in its purpose.

The differences are based on the purpose of the funds provided and are completely independent of the source of funding. This distinction is important because project directors, departments, and the campus are required to administer the agreements and account for the funds in different ways. Gifts at JHSON are handled by the Development and Alumni Relations (DAR) office.
II. OFFICES HANDLING SPONSORED PROJECTS FOR JHSON

The aim of the sponsored projects teams is to provide exceptional support for the JHSON research community in proposal development, submission and award management. Our goal is to be a critical resource for faculty and students in all stages of the Grant/Contract Process.

Sponsored Projects Administration at JHSON is coordinated between 3 offices:

- Office for Science and Innovation (OSI)
- Finance and Administration, specifically the Sponsored Projects Group (SPG) that includes Grants and Contracts Analysts (GCA).
- Johns Hopkins University Research Administration (JHURA)

A. Office for Science and Innovation

The Office for Science and Innovation (OSI) was developed to facilitate excellence in nursing research. The goal of OSI is to assist faculty and students by offering programs and resources to support the development of proposals, conduct and publication of research; and by providing the needed information technology to foster research.

1. OSI oversees Intent to Submit (ITS) processing which starts the sponsored projects life cycle.

2. All proposal projects must begin with an ITS. PIs should not submit proposals on their own. The Purpose of the ITS is to provide sufficient detail about a proposal for all kinds of funding, external and internal. An ITS should also be submitted if you are collaborating on a proposal submitted by another Hopkins division (SOM, BSPH) where an SON faculty is key personnel or a Co-I. The ITS alerts OSI and the SPG about the upcoming submission and allows us to properly workflow the proposal and plan the correct resources to assist. Please reach out to OSI should you have questions about the ITS.

3. Once the ITS is received, OSI sends out a detailed response email to the PI in response to the ITS which includes critical timelines and available resources.

4. One of the critical pieces of information needed in the ITS submission and addressed in the subsequent response is a scientific internal review. Scientific internal reviews are required for all proposal submissions to external sponsors. The review is coordinated by OSI on behalf of the PI.

5. OSI provides coordination across other teams within the SON where needed:
   - Biostatistics and Methods Core
   - Development and Alumni Relations
   - Marketing and Communications
   - Multimedia Services
6. OSI can also connect faculty and students with support services both external to and within the SON including (but not limited to):
   - REDCap
   - Biostatistics support
   - JHU Data Management Services- If your proposal requires a data management plan.
   - JHU ICTR Resources
   - JHU Central Development and Alumni Relations Team
   - Malone Center for Healthcare Engineering
   - School of Medicine IRB
   - Welch Medical Library
   - Johns Hopkins University Population Center
   - Johns Hopkins University Urban Health Institute
   - Epidemiology Research Group in Organ Transplantation (ERGOT)

7. Specific services that OSI provides include:
   - Editorial consultations with an author editor
   - Coordination of required scientific internal reviews for proposal submissions
   - Facilitation of specific aims speed reviews
   - Assistance with biosketch development, formatting, and compliance
   - Assistance with tables and graphic design for sponsored projects submissions
   - Guidance and administration of the Dorothy Evans Lyne Fund (internal pilot project funding mechanisms)
   - Workshops and trainings on timely and strategic research methods, resources, and updates
   - Coordination of writing retreats and the Annual Research Retreat
   - Dissemination of funding opportunities and evaluating opportunities with faculty - OSI sends out weekly newsletters regarding upcoming training events and funding opportunities. OSI also distributes weekly and monthly Limited Submissions guides from the Research Development Team and the Vice Provost of Research office.
   - Guiding faculty through the process of disclosing outside activities (eDisclose)
   - Assistance, where appropriate, with grant writing.

B. Finance and Administration

The SPG (Sponsored Projects Group) within Finance and Administration handles both pre- and post-award for sponsored projects.

The GCA is responsible for ensuring complete and timely submissions as well as ensuring that grant funds are spent and monitored properly and seeing that required financial and technical reports are timely provided to the agency.
Each faculty member and doctoral student who submits a grant has an assigned GCA. If you do not know who your GCA is, please contact the Sponsored Projects Director.

Only your GCA can submit proposals into COEUS (JHU’s system of record for tracking agreements) and into JHURA’s contract tracking system (JAWS) for JHURA’s review. The SPG is also responsible for post-award activities including account reconciliations, effort reporting, and contract management. The group stewards your proposal through submission, account set up, and award administration, submitting any subaward requests via JHURA’s Subaward Checklist System.

**PRE-AWARD:**
- Assisting faculty and students with developing proposal budget and budget justification
- Determining allowable vs. unallowable costs during budget preparation
- Ensuring that each proposal is fully compliant with sponsor and federal/state regulatory requirements. The funding announcement is read in detail with the faculty member.
- Submitting into COEUS—JHU’s system of record which tracks proposals and awards—which routes proposal to JHURA for final review
- Creating proposal in System to System programs: Assist for NIH and Workspace for all other federal proposals
- Preparing documents on subawards, if included in proposal
- Submitting contracts into JHURA’s contract system, JAWS
- Facilitating a complete and timely submission
- Regular interface with JHURA on proposal submissions

**POST-AWARD:**
- Monthly (face-to-face meeting with PI not required) and quarterly (face-to-face meeting with PI required) account reconciliations, projections
- Pre-reviewing effort for faculty in the ERS system
- Entering Cost Transfers when needed
- Interfacing with SPSS (Sponsored Projects Shared Services), AP (Accounts Payable), and Purchasing
- Submitting Subaward requests into JHURA’s sub checklist system
- Monitoring and paying Subaward invoices
- Holding monthly meetings with JHURA
- Working with Budget Analysts on non-sponsored spending
C. Johns Hopkins University Research Administration

Johns Hopkins University Research Administration (JHURA) is the central research administration office for most divisions at JHU and submits most federal proposals electronically through either ASSIST or WORKSPACE to the funding agency on behalf of JHSON. JHURA negotiates grant agreements and contracts and is the authorized signatory on sponsored agreements. JHURA’S ADMINISTRATIVE GUIDES.

For most non-governmental proposals, JHURA reviews and approves the proposal but the GCA or faculty member can submit to the funder.

JHURA’s responsibilities:

1. Draft and negotiate agreements
2. Provide the authorized signature on agreements
3. Submit proposals to the government
4. Workflow fully executed awards to SPSS for account setup
5. Identify and manage export control issues
6. Manage and maintain COEUS
7. Draft and negotiate subawards and obtain required signatures
8. Provide grant, contract and compliance guidance to SPG team when needed
D. Useful Contact Information

1. Contacts for OSI: (OSI-- son-innovation@jhu.edu)

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2. Contacts for Sr. GCAs and SPG:

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III. PROPOSAL DEVELOPMENT

In this section, you will find information and resources that can help guide you in the development of a proposal.

A. General Principles

The SPG reviews each proposal in light of the related funding opportunity notice. They check for accuracy, completeness, and compliance with JHU and sponsor policies and procedures.

Complex proposals—such as those that involve the use of human subjects, animals, subrecipients, or pose possible conflict of interest—should be started well in advance of the agency deadline.

B. Finding Funding Opportunities

There are numerous websites for finding funding opportunities. OSI regularly sends out funding opportunity announcements to the school. If a PI finds an excellent research opportunity which he/she would like to pursue, they should notify OSI as soon as possible.

Apply to funding opportunities that are current and are most appropriate for the type of research you are conducting. When thinking of applying to a sponsor, you should always feel free to reach out to your Department Chair, Associate Dean for Research, Director of Sponsored Projects or OSI for advice and direction.

An excellent source of funding information for federal resources is Grants.gov. For foundations: the Foundation Directory Online. For a wider array of funding opportunities, use Grant Forward. Pure Elsevier can help you to help build a research team and Pivot can assist in finding additional funding opportunities.

Limited Submissions are grant programs which accept only a fixed number of applications or nominations from a given institution. Many funding agencies have programs that place limits on the number of applications they will accept. Please note that an ITS form is required for Limited Submissions. Limited Submission applications must be approved by the Provost’s office before submitting to the agency. Limited submissions are coordinated through the University Research Development Team.

After you have identified the appropriate agency or sponsor, it is advised to speak with the assigned Program Officer at the agency about the appropriateness of your proposal, the availability and likelihood of funding, and any other program-specific questions you might have before submitting your proposal.
C. General Considerations

The format and content of any proposal or application will vary due to the requirements of the potential sponsor. For example, an unsolicited grant proposal will differ from a proposal submitted in response to a competitive contract bidding situation, while new, renewal, or continuation proposals will differ from each other. The SPG and JHURA are available for assistance in these matters.

Most sponsoring agencies provide instructions for proposals, while others require the use of specific electronic submission systems, and some have few prescribed rules. Applications or proposals submitted to some sponsors must meet certain deadlines, other sponsors will accept proposals at any time. Please note, it is vital to read the announcement. Each one is different, even if the Sponsor is the same. Often, there are limitations for page length, type size, title length, and supporting documents. Your GCA will provide you with detailed checklists to assist you in gathering the required documents.

D. What does a proposal require?

A proposal requesting support from an external sponsor will most often consist of the following:

Title Page—For those sponsors that do not provide application forms or have other specific requirements, the PI must construct some form of title page. Generally, the title page will contain:

• Title of proposed project
• Name and title of the PI(s)
• Time period of the proposed project
• Total support requested
• Name of sponsoring Agency and Program Announcement Number
• Signature line for JHU’s Authorized Official’s signature

Cover letter—For NIH, cover letters are not recommended for most applications. Instead there is a new form called the Assignment Request Form which lets NIH Receipt and Referral know which agency your application should be directed to for review.

A cover letter is recommended in 4 cases:

1. When you are submitting a late application
2. When you need to submit a video as part of your proposal
3. When your application includes science, which will generate large scale genomic data
4. When you need pre-approval for your submission, e.g. when direct costs are over $500,000 or when submitting an NIH R13 conference grant.
Table of Contents—with page numbers.

Abstract/Project Summary—A brief description covering the purpose, important features, and significance of the project.

Narrative/Research Plan—The detailed description of the project may contain many or all of the following:

- Project Rationale
- Introduction
- Statement of the Needs and Problems
- Goals and Objectives of the Project
- Relation of the Project to the State in the Field
- Significance of the Project
- Project Schedule
- Statement of Approach
- Means by Which Objectives will be Met
- Problems that are Anticipated
- Evaluation
- Management
- Organization of the Project of Knowledge
- Project Staff and Roles

Budget & Budget Justification—Documentation of how requested funds will be spent

Biosketches: Like a CV; contains a personal statement, list of positions and honors, professional memberships, publications. See sample biosketch on SPG website. Ask your Sr. GCA for a sample biosketch if you need one. The OSI is happy to review your biosketch for compliance prior to submission.

E. Cost-sharing

When the SON is donating time or money to a project, this constitutes cost sharing. This should be included only where absolutely required by the Sponsor. Before agreeing to cost share, please send your Sr. GCA an email documenting approval from the Department Chair, Business Unit Manager or the Dean of JHSON. There are several ways to document cost share in a proposal, so work with your Sr. GCA to pick the best way. Reducing indirect costs is a form of cost sharing.

F. Appendix Rules

For proposals which are clinical trials: you may include clinical trial protocols and an Investigator’s Brochure from a new Investigational Drug. For all applications: you may include: blank informed consent forms, Blank surveys,
questionnaires, and/or data collection instruments. Other items may ONLY be included in the appendix if they are specified in the funding announcement as allowable.

**Note that applications submitted with the wrong Appendix materials will be withdrawn and not reviewed.**

G. Principal Investigator Involvement

1. Review the program announcement and any subsequent notices, revisions, or updates. Note that neither an Adjunct Professor nor a Visiting Professor may serve as PI on a grant. Should this be absolutely necessary, approval must be obtained from the Dean.

2. Key things to identify:
   - Due Date
   - Budget limitations/Requirements (reduced F&A rate, cost-sharing, limits or caps on direct & indirect cost amounts)
   - Formatting and Text requirements, including page limitations
   - Allowable costs
   - Method of Submission
   - Human subject requirements
   - Specific access to agency/sponsor websites

   **As soon as you’ve decided to submit, please fill out an Intent to Submit (ITS) form on the OSI website!**

3. Meet with your Sr. GCA, as early as possible, to discuss your proposal’s requirements, including budgetary information, prior approvals, and timelines for submission of final proposal documents. He/she will help clarify any questions specific to the program announcement.

4. If you have Subawards on your proposal, ensure you have a scope of work and budget from the subrecipient as well as a support letter. If the Subrecipient is new to JHU, you will need to fill out a Subrecipient Determination form which your Sr. GCA will provide to you.

5. Complete ALL required JHU training (see Section VIII, Compliance).

6. Complete and certify the COEUS Research Compliance Questions, Yes/No questions (which are attached to the OSI response email). Please note that the COEUS questions
are ONLY required when submitting to an outside sponsor; they are not required for internal submissions. Complete subaward determination form (if applicable) and all other certifications required of the submission. Provide your Sr. GCA with the complete proposal for submission to JHURA.

H. SPG Responsibilities

- Reading and interpreting the program announcement and answering any questions the Principal Investigator or student might have. Providing faculty and students with a detailed checklist on what’s required for particular submission.

- Meeting early with the PI to discuss the proposal, including, but not limited to, budgetary information, responsibility for document collection, and timelines for submission of final proposal documents.

- Reviewing the contents of the proposal for adherence to agency/sponsor guidelines, department and JHU policies, and all other required criteria.

- Gathering all the appropriate documents in order to create and upload to the COEUS record and ASSIST or WORKSPACE.

- Providing the PI a final review of the proposal before routing to JHURA for review.

- Submitting the FINAL version of the proposal to JHURA, including a completed COEUS record, at least three (3) business days before the submission due date. If a proposal requires system-to-system submission, JHURA submits electronically through either the ASSIST program or WORKSPACE program directly to the sponsor. If submission is not done system-to-system, JHURA reviews and approves the proposal and then either the PI or the SPG will submit to the sponsoring agency. If the PI submits, please make sure to give your Sr. GCA a full copy of the proposal.

Special Note to PhD and DNP/PhD students: Always consult with your advisor as you consider submitting a proposal for tuition support or research project funding. Some Sponsors have funding programs especially for students, e.g. F31 for Phd students. It can take more than one submission to be successful. Thus, start early if you are interested in applying for a sponsored project to support you.

I. Deadlines

Most sponsoring agencies have specific deadlines for proposal submission. These deadlines are strict and cannot be modified; this information is always in the RFP application package. A strict deadline is a hard stop; if the deadline for submission is 11.59 pm; a proposal submitted at midnight would not be accepted.

The Sponsored Projects Group requests that the PI submit all proposal materials to his/her Sr. GCA no later than five (5) business days before the program’s due date. This will give the Sr. GCA time to do a thorough review of all proposal documents.
and time to make changes with the PI, if errors are identified. This also allows the Sr. GCA to get the proposal into JHURA for its final review according to their time requirements, namely, three (3) days before sponsor due date.

**IV. BUDGETS**

Every proposal to a sponsor generally includes some type of budget outlining the intended use of the funds. The total cost of the project should be made up of direct and indirect costs. Direct costs are those costs directly associated with and essential to the completion of the project. Indirect costs are not necessarily directly attributable to a specific project, but rather are included to address general administrative, personnel, and facilities-related expenditures related to the project.

For budgets submitted to federal sponsors, Uniform Guidance (UG) establishes cost principles for determining costs applicable to grants, contracts, and other agreements with institutions of higher education. JHU applies these Uniform Guidance Principles to nearly all sponsored projects, federal or otherwise. See 45 CFR Part 75, Subpart E (cost principles for Institutions of Higher Education or IHE).

**Note on Fixed Price Agreements**: A fixed Price agreement is set up very differently than a Cost Reimbursable contract. A Fixed Price is characterized by payments of predetermined amounts by Sponsor to support a project. Payments are NOT on an expense reimbursement basis but on a predetermined lump-sum project cost, without further accounting. If the project costs are actually less than the award, the excess revenue is retained by JHU. If the work costs more than anticipated, JHU would have to either eat that cost or the agreement would have to be modified to add funds and the Sponsor would make that final decision. Fixed price increases require an increase or change in the scope of work.

**A. Allowable vs. Unallowable Costs and Direct vs. Indirect Costs**

All charges to awards must be: Allowable, Allocable, and Reasonable and consistently treated the same across JHU.

A cost is allowable if it is REASONABLE, ALLOCABLE AND CONFORMS to the cost principles and the sponsored agreement and is not prohibited by law, regulation or terms of award.

Examples of **Allowable** Costs:

- Salaries & wages
- Equipment
- Materials & supplies
- Routine maintenance & repair of physical plant or equipment
- Audit services
- Travel
- Computer use/data storage
- Publication costs
- Duplication services
- Photographic/graphic services
- Service contracts
- Data analysis
- Subawards & space rental
- Purchases of data periodicals & books subjects/research participants
- Patient reimbursement
- Value Added Tax (Vat)

Examples of **Unallowable** Costs:

- Advertising & public relations costs (with some exceptions)
- Alcoholic beverages
- Alumni activities
- Bad debts
- Commencement costs
- Entertainment
- Licensing costs, profits & fees
- General office supplies (JHU provides)
- Honoraria (Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, is allowable.)

**Direct Costs**: Costs that can be identified specifically with a particular sponsored project.

**Salaries**: all personnel, the percentage of time each will devote to the project, the rate of pay, and amount requested from the sponsor to support each person per year (or for the budget period). Unless otherwise noted in Program Announcement instructions, time should be expressed as percent effort. You may express time as number of hours for student workers and consultants.
Multiple year budgets should include estimated salary increases. A 1.5-3% increase may be projected unless the sponsor specifies that no salary inflation is allowed. PIs are required to include at least 1% effort on every proposal.

Please note, NIH has a salary cap of $189,600, effective 1/7/2018.

**Other professional research** staff and technicians may be compensated for periods during which their services will benefit the project.

**Administrative Personnel and clerical staff** are sometimes treated as F&A costs; however, direct charging may be appropriate if ALL conditions are met, as follows:

- administrative or clerical services are integral to the project or activity;
- individuals involved can be specifically identified with the project or activity;
- such costs are explicitly included in the budget or have the prior written approval of the awarding agency;
- the costs are not also recovered as indirects.

**Graduate Research Assistant** may be assigned to research duties with the student's time divided between formal study and research. Tuition remission for graduate research assistants on sponsored projects is to be included as a fringe benefit calculation and requested from the sponsor.

In no case can funds be requested or used to augment salaries of any faculty or staff beyond University-approved rates.

**Fringe Benefits** include JHU’s contributions to Social Security, retirement programs, health insurance, and unemployment compensation. Part-time employees who work less than one-half time, temporary personnel, and hourly employees are entitled only to Social Security and unemployment compensation. A table of applicable benefit rates is updated annually and posted on JHURA’s website. The current fringe rate for full time faculty and staff is currently 34%.

**Permanent Equipment** needs must be itemized and justified. Permanent equipment is defined as an article of nonexpendable tangible personal property used only for research, medical, scientific, or technical activities, which has a useful life of more than one year and an acquisition cost of $5,000 or more per unit. In addition, the PI must determine that the equipment requested is not already available within the University. The cost of equipment generally includes needed accessories, installation, and delivery costs. In some cases, the sponsor may provide the equipment directly rather than provide acquisition funds, or short-term rental may be preferred.

**Consultant fees** may be paid only to experts outside JHU who provide a unique contribution to the project. If payment will be made to a consultant on your project, be sure to include those consultant fees in the budget. Consultant fees are subject to F&A costs (on the full amount).

**Supplies and Expendable Equipment** (<$5,000) items should be identified and justified. Supplies may be charged if they are above and beyond what is incurred during normal
operation. Examples of these items include chemicals, glassware, small electronic components, unusually large quantities of paper supplies as in the preparation and distribution of questionnaires or other brochures and forms. Note** If a PI needs to buy laptops or other electronic equipment for their project, he/she must work with SON IT to coordinate the purchases. These costs must be included in the budget.

**Travel** is an expected practice and accepted cost in most projects if there is a need for the PI to consult with colleagues and disseminate new knowledge through scholarly discourse (i.e. meetings, conferences, symposia, etc.). There must be a correlation between the project and the purpose of the meeting. Such costs may include transportation and room and board.

**Publication costs** include manuscript illustration, costs of reprints, page charges, and any unusual cost encountered in publishing. The routine publication costs of a book or monograph are not generally allowed; special permission should be obtained from the sponsor.

**Marketing:** If you need marketing support, please include marketing costs in your grant proposal. For questions on this, please contact Tammy Berwanger, Assistant Dean of Marketing and Communication, tberwanger@jhu.edu.

**Instructional Design:** If your proposal requires online course development, please contact the Educational Quality and Innovation, Instructional Design Team, Rita D’Aoust, Associate Dean for Teaching and Learning, rdaoust1@jhu.edu. Please meet with the team prior to submitting a budget to obtain their input on costing and time lines. Remember to budget not only development costs but also maintenance costs should the course need to be upgraded or changed.

**Subcontracts with other entities** provide a substantial programmatic contribution to the project and may require specific approval of the sponsor. If not included in proposal, adding a foreign subrecipient requires Gov’t approval. The proposal must include documentation (i.e., statement of work, budget and justification, and endorsement by Subcontractor’s Authorized Official) of the services to be performed. Subcontracts must adhere to applicable federal program compliance regulations.

B. **Facilities & Administration Costs (F&A or Indirect Costs)**

**Indirect costs**—also known as Facilities & Administrative (F&A) costs or IDC—are real costs of university operations that are not readily assignable to a particular project. JHU’s indirect cost rates are determined by an agreement with the federal government and the Johns Hopkins University, in accordance with the federal Uniform Guidance.

The applicable rate to use on a sponsored project is determined by several factors, including activity type, on/off-campus location, and sponsor requirements.

**For federal awards:** F&A costs are calculated based on the project’s

Modified Total Direct Costs (MTDC) x the appropriate indirect rate.
To calculate MTDC take the total direct costs and subtract the following:

- Equipment (over $5,000) Capital expenditures (includes alterations and renovations)
- Patient Care
- Student Tuition remission
- Rental costs of off-site facilities
- The portion of individual Subaward over $25,000
- Scholarships and Fellowships, and student support costs (student aid, stipends, and dependency allowances)

F&A rates with non-federal sponsors vary widely. F&A on private awards should use JHU’s regular indirect rate and be calculated on Total Direct Costs (TDC) which just means we don’t subtract the categories mentioned above.

If you are seeking an IDC reduction or an IDC waiver, please complete the IDC waiver form on the Business. Finance. Sponsored Project website and email the form to the Associate Dean for Finance and copy your Sr. GCA.

**F&A Rate Decision Tree:** There are three different types of activities that may take place on a sponsored award: Organized Research, Instruction & Training, or Other Sponsored Activities. Each activity type has its own associated F&A rate.

**IDC Rate Determination Decision Tree (FY17 Rates)**

- **Organized Research?**
  - YES: On Campus?
    - YES: 63%
    - NO: 26%
  - NO: Instruction and/or Training?
    - YES: On Campus?
      - YES: 50%
      - NO: 26%
    - NO: Other Sponsored Activity?
      - YES: On Campus?
        - YES: 28%
        - NO: 16%
      - NO: Not Sponsored (non funded)?
        - YES: Contact JHURA
- NO: Instruction and/or Training?
  - YES: On Campus?
    - YES: 50%
    - NO: 26%
  - NO: Other Sponsored Activity?
    - YES: On Campus?
      - YES: 28%
      - NO: 16%
    - NO: Not Sponsored (non funded)?
      - YES: Contact JHURA
- NO: Other Sponsored Activity?
  - YES: On Campus?
    - YES: 28%
    - NO: 16%
  - NO: Not Sponsored (non funded)?
    - YES: Contact JHURA

**Organized Research** refers to all research and development activities that are sponsored by Federal and non-Federal agencies and organizations, and that are
separately budgeted and accounted for. This generally means that there is a scope of work, a specific time frame, and deliverables (whether technical or financial) that the JHU is obligated to deliver, a specific budget, and indirect cost recoveries.

This term also includes activities involving the training of individuals in research techniques (commonly called research training) where such activities utilize the same facilities as other research and development activities, and where such activities are not included in the Instruction function. Research activities include rigorous inquiry, experiment, or investigation to increase the scholarly understanding of the involved discipline.

Examples of Organized Research include:

- Awards to JHU faculty to support research activities, such as literature surveys, investigations on efficacy of new vaccines, and disease prevention or therapeutics
- External funding to maintain facilities or equipment and/or operation of a center facility that will be used for research
- External support for the writing of books, when the purpose of the writing is to publish research results
- Research data collection and evaluation, and/or analysis, and
- Corporate drug development/clinical trials

**Sponsored Instruction** is defined as teaching and training activities at JHU funded by grants and contracts from Federal or non-Federal sponsors. Sponsored Instruction includes agreements that support curriculum development, as well as all types of teaching/training activities, whether offered for credit toward a degree or certificate, on a non-credit basis, or through regular academic departments or by separate divisions, summer school, or external division.

Examples of Instruction and Training include:

- Any project for which the purpose is to instruct any student at any location; recipients of his/her instruction may be JHU students or staff;
- Curriculum development projects at any level, including projects that involve evaluation of curriculum or teaching methods. Note that such evaluation may be considered “research” when the preponderance of activity is data collection, evaluation & reporting.
- Projects that involve JHU students in community service activities for which they are receiving academic credit;
- Activities funded by awards to departments or schools for the support of students;
- Fellowship support for pre-doctoral and post-doctoral training activities, which may include grants to fund
dissertation work and travel in relation to a dissertation; and

- General support for the writing of textbooks or reference books, video or software to be used as instructional materials.

**Other Sponsored Activities**

Other Sponsored Activities means programs and projects financed by Federal and non-Federal agencies and organizations that involve the performance of work other than Instruction and Organized Research.

Examples of Other Sponsored Activities include:

- Consultancy projects
- Social and/or community service, or health services projects
- Travel grants
- Support for conferences, seminars or workshops
- Support for student participation in community service projects that do not result in academic credit

Determine On vs. Off-Campus

In order for a project to be considered off-campus, all three of the following qualifications must be met:

- The PI will be away from his or her campus facilities (i.e. office & laboratory) for a minimum of three consecutive months;
- The on-campus facilities will be made available for use by other faculty and/or students during the PI’s absence; and
- The PI will be performing work in accordance with the statement of work of the proposed and funded project while at the off-campus location.

These qualifications are a fiscal determination based upon space utilization, and it is not simply dependent on where some of the project work is being performed. If one JHU employee meets the above standards but the entire project does not, it may be acceptable to split the budget into on and off-campus accounts. If you think the off campus rates apply to your proposal please reach out to your Sr. GCA to assist with the determination.

Off-campus rates can only be used relative to JHU’s effort expended on a project. Performance of work on a project by non-JHSON personnel are handled via a subcontract to another institution, which takes on-campus F&A for the first $25,000, or a consulting agreement, which takes full F&A for the entire amount.

**IF SPONSOR LIMITS F &A RECOVERY:** Many sponsors (both federal and non-federal) limit f & a recovery rates to percentages well below JHU’s negotiated rate of 63.5%. In these situations, faculty should work with his/her Sr. GCA to include direct costs of items that...
would have been covered if we received the full f & a rate recovery. Here are some items of cost that can, if possible, be included in direct costs:

- Legal fees (foreign country registration, employment law compliance)
- Audit Expenses
- Project Compliance
- Subcontract Management Costs
- Accounts Payable Processing
- IRB costs
- Computing charges
- Library costs
- Lease review and execution
- Determining IP requirements
- Business Licenses
- Space usage fees

C. Budget Justification
This document provides additional information in each budget category. For example, for Personnel—you would describe the role of personnel on the project and list effort in calendar months, for Travel, you would include the purpose, destination, dates of travel and number of individuals for each trip. See Sample Budget Justification on website.

D. Final Review of your Proposal Budget:

- Does it add up?
- Does the budget identify the necessary cost elements?
- Did you include an escalation factor for future years?—Anticipate! Make budget adjustments for salary increases in budgets that are longer than one year or that span JHU fiscal years.

<table>
<thead>
<tr>
<th>Budget Category</th>
<th>Items to Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries</td>
<td>Other professional research staff? Technicians, graduate research assistants, hourly personnel</td>
</tr>
<tr>
<td>Fringe Benefits</td>
<td>Ensure you have the proper rate</td>
</tr>
<tr>
<td>Equipment (&gt;5000)</td>
<td>Purchase of vehicles, large refrigeration units</td>
</tr>
<tr>
<td>Equipment (&lt;5000)</td>
<td>Include service agreements for equipment, maintenance/repair, freight.</td>
</tr>
<tr>
<td>Supplies</td>
<td>Questionnaire forms, animals and maintenance, general supplies, chemicals, glassware, electronic components, brochures and announcements, audio and video tapes, film and film processing supplies</td>
</tr>
</tbody>
</table>
Travel

Domestic and foreign, field work, conferences, meal and living costs, transportation.

Subawards

Sub budget including their F and A (foreign subs get 8% only on federal awards), sub audit if necessary

Other Direct Costs

Space rental, equipment rental, human subject participant fees, communications, stipends for participants, vehicle lease

Facilities and Admin. Costs

On or off-campus, research, instruction, other sponsored, does Sponsor limit allowable F and A?

Cost-Sharing

Only where required.

Publication

Additional costs/copies/edits?

Two sample budgets are attached to this handbook as a reference.

E. Proposal Submission Workflow

PI submits ITS form to OSI (on OSI website)

OSI & Sr. GCA review ITS. OSI responds with detailed Email to PI & relevant other parties, giving timelines & offering services.

PI meets with Sr. GCA to review specific proposal requirements & to create the budget & budget justification.

If not system-to-system application, JHURA advises Sr. GCA that proposal is approved & PI or Sr. GCA submits to foundation, company, or institute.

JHURA reviews proposal, approves & submits to federal agency if system-to-system application.

No less than 5 days before proposal due date, Sr. GCA submits complete proposal thru COEUS to JHURA.

V. AWARD REVIEW AND ACCEPTANCE – YEAH!

Awards are made to and accepted by JHU. Once a sponsor confirms that a grant has been awarded, JHURA reviews the terms and conditions. If necessary, JHURA negotiates the terms and conditions with the sponsor.

A grant or contract is awarded to JHU, not to the PI. A PI should never negotiate or sign an award. Only certain officers have been authorized by the Board of Trustees to bind JHU. If someone other than those authorized sign the documents, the award may not be considered valid.
Once all terms are satisfactory, JHURA routes the award to Sponsored Projects Shared Services (SPSS) for account set up. After it has received an account number, charges can be made against that account.

**Process Flow Chart**

- Department submits proposal to JHURA via COEUS
- Grants or Contracts Associate (GA/CA) reviews proposal
- GA/CA submits proposal electronically or dept sends paper copy
- GA/CA reviews award terms and negotiates if necessary
- GA/CA is notified that proposal is awarded
- Proposal file is recorded as pending
- JHURA executes award and collects signature from sponsor
- JHURA prepares award for processing for account setup
- Award is workflowed to Sponsored Shared Services (SPSS) for account creation
- Dept allocates budget, PI can spend
- Award is recorded as active in both COEUS
- SPSS sends email notification of account setup to JHURA and department admin

**Award DEAL BUSTERS**

**Publications:** JHU does not enter into agreements to carry out research if the grant, contract, or other award instrument restrains the freedom of JHU and its faculty to disclose the existence of the grant or contract, the general nature of the inquiry to be conducted, or the identity of the Sponsor.

JHU will not sign an agreement which attempts to restrict JHSON’s right/freedom to publish. JHU will not sign if the Sponsor must approve the publication (review and comment is acceptable) of the article.

**Use of Name:** JHU does not want to dilute its name or reputation by allowing outside entities to trade off our name and reputation. This clause must always be carefully analyzed before JHU agrees to it.

**Intellectual Property (“IP”)** is a common sticking point in contract negotiations. IP means all IP including without limitations, technical information, copyrights, patents, ideas, thoughts, concepts, processes, techniques, data, tools, models, drawings, prototypes, inventions and software that is discovered created or reduced to practice.
**Background IP** is the intellectual property the PI/JHU brings to the table prior to the agreement. Background IP is developed prior to or independent of any research performed pursuant to the Agreement which may be necessary to perform project work. The PI/JHU retains sole ownership of Background IP.

**Foreground IP** is the intellectual property created by the PI under the award. Some sponsors insist on owning what is developed under an award; others allow the PI’s institution to own (usually with a license back to the sponsor). Some sponsors require joint ownership.

Do not verbally agree to intellectual property terms that seem restrictive. Discuss with Director of Sponsored Projects first.

Faculty members should be aware that JHU owns all rights, title and interest in and to intellectual property developed as a result of support either directly from or channeled through JHU. By accepting employment with JHU, faculty members agree to assign to JHU, all of their rights, title and interest to Intellectual Property developed as a result of JHU support.

When JHU can license an invention, the net revenues to JHU are distributed:
- 35% to inventors personally
- 15% to inventors for research share
- 15% to inventor’s department
- 30/25% to JHSON
- 5/10% to JHU

**SON Ownership and Use of Educational Materials**
SON has a policy on the use and ownership of educational materials:
1. Faculty own their traditional works of scholarship
2. JHU owns educational materials created by faculty/staff for SON courses
3. Faculty has rights to use educational materials they create for JHU courses to:
   a. Create traditional works of scholarship
   b. Teach elsewhere if leave SON or as otherwise permitted by SON.

**V. AWARD MANAGEMENT/POST-AWARD**

**A. Subagreements**

The Subagreement process can begin once an award is active in JHU’s accounting system. The SPG is responsible for entering a request to draft a Subagreement into the JHURA Subagreement Checklist System.

Sponsored project awards made to JHU are generally conducted within the physical boundaries of JHU by University faculty and staff. Occasionally, however, a significant
portion of the required work may need to be provided outside the University by a third party, called a Subrecipient.

The Subrecipient is made responsible for a discrete portion of the project award, providing the leadership and direction of a responsible investigator and the resources necessary to conduct that portion of the work. Costs associated with this work may include: personnel costs, supplies, equipment, travel, and overhead.

JHURA has a Subawards team for drafting, negotiating, tracking, and managing subagreements. The team works in conjunction with JHU faculty, department administrators, financial analysts, the Office of Finance, the Controller’s Office, IT, and the General Counsel’s office to ensure that, in the most efficient way possible, the proper subagreement is executed for each unique situation.

If a subrecipient is new to JHU, it will need to fill out and submit a Financial Questionnaire. In addition, for every new sub (JHU has worked with or not), the PI must fill out a sub determination form which will be uploaded by your Sr. GCA into the sub checklist system.

- As of December 2016, unless a fixed price Subaward was approved in the initial proposal, it will need prior agency approval. In addition, even if approved, it cannot exceed $150,000.

**Subaward vs. Vendor/Consultant:** Below you will find the differences between a subrecipient and a vendor/contractor. Determining sub vs. vendor is critical as it impacts on F & A recovery and budget planning. The PI will need to fill out a Sub Determination form prior to the creation of a new Subaward.

**Subrecipient:**

- Substantive, programmatic work or an important or significant portion of the research program or project is being undertaken by the collaborating party.
- The research program or project is within the research objectives of the entity.
- The entity participates in a creative way in designing and/or conducting the research.
- The entity retains some element of programmatic control and discretion over how the work is carried out.
- The entity commits to a good faith effort to complete the design or conduct of the research.
- The entity makes independent decisions regarding how to implement the requested activities.
- A PI has been identified at the entity and functions as a “Co-Investigator.”
- There is the expectation that the entity will retain ownership rights in potentially patentable or copyrightable technology or in products that it produces in the course of fulfilling its scope of work.
- Publications may be created or co-authored at the entity.
Contractor/Vendor:
- The entity is providing specified services in support of the research program.
- The entity has not significantly participated in the design of the research itself, but is implementing the research plan of the University’s investigator.
- The entity is not directly responsible to the sponsor for the research or for determining research results.
- The entity markets its services to a range of customers, including those in non-academic fields.
- Little or no independent decision-making is involved in the design and conduct of the research work being completed.
- The entity commits to deliverable goods or services, which if not satisfactorily completed will result in nonpayment or requirement to redo deliverables.
- The entity does not expect to have its employees or executives credited as co-authors on papers that emerge from the research.
- The expectation is that the work will not result in patentable or copyrightable technology or products that would be owned by the entity.
- In the case of an individual vendor or consulting services, the person has no employment relationship with the University, either academic or administrative in nature.

Subrecipient Monitoring
JHU is required to flow down all necessary provisions of the prime award and to closely monitor the progress and financial activity of the subrecipient. Policies and procedures specific to this requirement have been established by the Controller’s Office.

All subawards are given a risk assessment of high or low by JHURA. Domestic institutions and nonprofits are generally low whereas foreign sites or corporate recipients are generally high. Subrecipients classified as “high risk” require closer programmatic and financial monitoring.

B. Discretionary Funds as Distinguished from Sponsored Funds
Discretionary fund accounts represent a budget allocation of unrestricted funds made by the SON and are established to accomplish some JHU purpose. The SON may impose additional restrictions on the use of funds in a particular discretionary fund account.

C. Post-Award Changes
After an award has been made, changes affecting the scope of work, budget, award period, or other administrative details are sometimes necessary. Regulations regarding post-award changes vary among agencies. Changes in some items may require prior approval, such as
changes in budget of over 25%, change in PI, scope of work, or adding a foreign collaborator. Your Sr. GCA will work with JHURA to obtain Sponsor approval.

D. Audits

All sponsors reserve the right to conduct an audit of the expenditures incurred on a research project. Sponsors may determine that certain expenditures should be disallowed if regulations are not followed. If a sponsor contacts you regarding an audit, immediately contact your Sr. GCA. JHSON will consult with the JHU Sponsored Research Compliance office.

E. Reporting Requirements

Most grant and contract agreements require interim and/or final reports, such as equipment, invention, financial, and/or technical reports. Most of these reports are required to be submitted on an annual basis; however, some sponsors may require more frequent reporting. For the majority of sponsored awards, final financial reports are required at the close of the award. For most federal awards, it is usually due within 120 days of the expiration of the final project funding period; progress reports are usually due within 120 days of agreement close. For non-federal awards, the reporting will be set forth in the award agreement.

It is important that all reporting responsibilities be fulfilled, as failure to do so may jeopardize future funding to the entire University.

F. Working with Budget Analysts

The Finance and Administration office includes 5 Sr. GCAs and 3 Budget Analysts. A bit of clarification on roles. If a PI needs to hire a vendor from a sponsored account, you should reach out to your Sr. GCA who will review the account budget and award to ensure the charge is allowable to that grant. If so, your Sr. GCA will work with the assigned Budget Analyst to coordinate payment with the JHU Purchasing group. If a PI needs to create a vendor relationship off a NON SPONSORED account, the PI needs to work directly with the Budget Analysts. There are real differences in how payment vehicles are decided with Purchasing depending on: Is the vendor an individual or a company, how much will the payment be and over how long a period of time, is a PO needed or just an on line payment.

Budget Analysts:

- Judi Damask: jdamask1@jhu.edu
- Ronnie Medina: rmedina5@jhu.edu
- Steven Burchenson: sburche2@jhu.edu
G. Account Reconciliation

The PI is ultimately responsible for assuring that all approved expenses in support of a project are properly charged to the project. Prompt and accurate charging to the correct account will preclude costly department labor and paperwork later to effect cost-transfers to rectify errors and avoid audit findings.

MONTHLY, the Business/Finance office:

- Compares actual expenses with the budget
- Ensures that expenses hitting the account are accurate and allowable
- If mischarges have made to an account, creates eForms to correct erroneous salary charges and journal vouchers for non-salary expenses.
- If Subagreements are part of the award, reviews subrecipient expenses to ensure they are correct and are paid timely

Faculty receive expenditure reports for each of their accounts on a monthly basis that must be reviewed. If you notice any errors in your account statement, contact your Sr. GCA in order for the error to be corrected.

Actual expenses must be compared to the budget to ensure:

1. Total funds on the grant have not been exceeded
2. Total funds are used appropriately
3. Total funds for any cost category have not been exceeded if restricted in the award itself.

QUARTERLY

The Sr. GCA and PI will meet to do the quarterly account reconciliations. Such meetings should take place face-to-face, but if difficult, can take place by phone.

At these meetings the Sr. GCA and the PI will review the prior 3 months on each account. It is vital that the PI ensure he/she has have reviewed the accounts prior to this quarterly meeting.

If charging errors are identified, cost transfers will be initiated by the Sr. GCA. Cost transfers are used to correct: erroneous charges and unreasonable, unallowable charges.

The Sr. GCA will set up the quarterly meetings. The Sr. GCA will retain documentation of all meetings and list action items to be addressed.

Both the PI and Sr. GCA must sign off on a form documenting these quarterly meetings.

H. Effort Reporting
The **Effort Reporting System (ERS)** is the web-based interface that JHU uses to certify effort. All personnel who are required to certify effort must use the ERS to do so. Training can be done through [myLearning](#) or on the ERS web page.

**All faculty who are eligible to submit proposals, must take the effort reporting training.**

For Faculty (and Sr. Staff), effort certification is twice yearly. The reporting periods are: July 1- Dec. 31 and Jan. 1 to June 30th.

When the effort reports are shared with JHSON, the Sr. GCAs will go into the ERS system and pre-review the PI’s effort sheets and, if correct, the system will forward forms to the PI to review and certify.

As PI, if you notice errors on your effort form, you should not certify; call your Sr. GCA for them to correct first. If faculty are teaching or hold an administrative position at JHSON, 10-15% of effort should be reserved for that work.

I. **Invoicing Sponsors**

In most cases, Accounts Receivable and Shared Services are responsible for invoicing sponsors or otherwise collecting revenue. Sr. GCAs will ensure that sponsors are Up-to-date in their payments. Sr. GCAs are responsible for reviewing open invoices and following up with sponsors. Should a PI receive a check directly, please bring it to you Sr. GCA immediately.

J. **Travel Expenses**

Eligible travelers should book travel with World Travel, Inc. (WTI) agents directly or via Concur. Concur is the online booking tool that links with WTI systems for comprehensive coverage of your travel needs. You must complete a traveler profile before booking. See: [www.travel.jhu.edu](http://www.travel.jhu.edu). Concur will automatically register your trip in the JHU system. Concur handles both domestic and international travel, including car rentals, trains, and lodging. If you use Concur, you are responsible for paying using personal credit card or corporate cared. You will be reimbursed upon submission of receipts. If traveler chooses to have airfare, hotel, rail or care rental paid for directly by JHU, they must use the **Central Bill Travel Card** accessible on the JHU Finance website.

**DOMESTIC TRAVEL** – travel within the 50 states and Washington D.C.

- Costs are handled upon employee submission of receipts. Actual receipts must be submitted for hotel and meals; per diems are not allowable for domestic travel. The only exception is when the RFA itself requires per diems for domestic travel. Per Diem rates would then be found on the US General Services Administration website.

**FOREIGN TRAVEL** – may be overseas travel from the U.S., or if working abroad, travel would be between countries

- Travel expenses are reimbursed based either on actual expenses or per diem.
• **Per Diem rates** are available by city, state and country are fixed maximum amounts. There are per diem rates for meals and incidental expenses. Actual receipts for hotels are required. The US Department of State sets forth these amounts. No receipts for meals are required when per diem is used. If per diem is used, it must be used for the entire trip. (Cannot mix payment methods in one trip). Breakdown of daily M&IE per diem can be found on the US Dept. of State website broken down by breakfast, lunch and dinner. If lunch is provided while attending a conference, then the lunch per diem amount should be subtracted from the daily M&IE rate for that day. Actual lodging receipts are required and Meals and Incidentals Expense (M&IE) is to be used for meals. Note that when using per diem for foreign travel, the traveler gets only 75% per diem for the first and last days of travel.

• **Business Class:** Travelers may only fly business class if they will be in transit for at least 14 hours. This transit time includes layovers, but not overnight stops. **Generally, only coach travel is acceptable.** If you want to travel business class, you can either pay the difference between coach and business or you can seek permission from Associate Dean for Finance. There is a form on the JHU Finance website, “Business Class Air Travel Justification and Approval” that needs to be completed by traveler.

**Fly America Act:** For travelers under a **FEDERAL GRANT:** By an act of Congress, all travelers for the federal government must use US carriers whenever possible. It may be more expensive to fly US carriers, but the extra cost must be incurred if a Federal award is paying for the ticket. If you do use a non-US carrier, you must fill out a “Fly America Act Waiver Checklist,” found on the JHU finance website under Accounts Payable, Forms. **Fly America Act Waiver Checklist.pdf.** For non-federal grant travelers: You still must fill out the Fly America Act form but would only need to check the first box stating this isn’t being charged to a federal grant.

**Meals and Lodging:** While on travel, meals and lodging are reimbursable as long as the cost is reasonable. If you are being reimbursed, please maintain itemized receipt for meals and obtain a hotel folio for lodging. The method of payment must be shown on all hotel and airfare receipts.

**Sample of Non-Reimbuble Travel Expenses:** health club fees, health insurance, hotels or air fare purchased with “points”, laundry or valet services, mini bar alcoholic refreshments, spouse or family member travel or meals, personal telephone calls, clothing or toiletry items, donations and souvenirs or personal gifts.

**VI. COMPLIANCE**

A remarkably large and sometimes confusing set of laws, regulations, and internal policies apply to the research, technical services, and educational activities that faculty and other JHU employees pursue. The SON Business Office along with other JHU offices endeavor to identify instances in which those laws, regulations, and policies require some kind of action on our part to ensure compliance. Below, you will find information which will enable you
to partner with us to anticipate and address compliance issues connected with your research or other work at JHU.

What compliance training must I complete as a faculty member?

For a complete list of compliance requirements, please see the JHSON website.

On the myLearning website, you will be asked a few questions to determine your required courses, and then will be instructed to log in to register for these courses.

Faculty should familiarize themselves with the following JHU Policies:

1. Animal Care and Use
2. Disclosure and Professional Commitment/Conflict of Commitment & Conflict of Interest
3. Copyright Compliance
4. Human Research Participants
5. Information Technology
6. Intellectual Property
7. Personally Identifiable Information
8. Preventing Fraud, Waste & Abuse
9. Purchasing
10. Research Compliance
11. Research Misconduct
12. Responsible Conduct of Research

As campus needs change, these policies and procedures may be updated periodically.

The following policies affect research most directly:

Conflict of Interest and Commitment: JHU maintains principles of integrity in research and the well-being of patients. Authentic and apparent financial conflicts of interest and/or commitments, need to be identified. PIs must recertify their conflict of interest training every four years.

E-Disclose: JHU eDisclose is a website that supports submission, tracking, review and management of disclosures of outside activities and interests. Jessica Ames, in OSI, is the SON contact for these disclosures. Please refer to the website to determine: When to disclose, what information is required for the disclosure and what happens after the disclosure.

In the School of Nursing, all faculty with full-time and part-time appointments must complete an Annual Certification.

Human Subjects (IRB)

A “human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention or interaction with the individual, or
(2) identifiable private information.

Note: This can include secondary data analysis, as well as research involving direct contact with human participants.
If your research potentially includes the involvement of human subjects, your project must be reviewed by the Institutional Review Board (IRB). The JHSON uses the School of Medicine’s IRB. The main purpose of the IRB is to protect the rights and welfare of research subjects who participate in research studies. The IRB, where relevant, also determines what information should be provided to the potential research participant in the consent document.

**IRB Compliance Training Tool includes:**
- Basic Human Subjects Research (CITI)
- HIPAA for Research
- Conflict of Interest and Commitment

You register for the required courses on the Hopkins *myLearning website*: [myLearning@johnshopkins](mailto:myLearning@johnshopkins). *(Go to [myJHU Portal](https://www.jhu.edu) on the myJHU Portal)*

Recertification training is required every 3 years. For more information on Recertification...

PIs are also required to complete 2 REWards workshops within 1 year of the initial IRB application submission. REWards is only offered 5x/year.

An IRB application must be submitted before the research activity begins. Often, if IRB has not approved the project, sponsors will accept proposal if noted that IRB approval is pending.

If your project contains multiple, collaborative DOMESTIC sites, NIH rules require that the sites must choose one central IRB for review and certification. In the proposal stage, study teams must include their plan for single IRB review, identification of IRB, confirmation from all sites that they will comply with the NIH policy on **Single IRB**. If the grant is awarded, the NIH approval for single IRB use will appear as a term and condition in the Notice of Award. NIH has released a new PHS Human Subject and Clinical Trial Information Form (Forms “E”) that includes information about Single IRB. See: [http://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm](http://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm).

**Definition of Federal Clinical Trials.** Answers must be yes to all of the following questions:
1. Does the study involve human subjects?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health related biomedical or behavioral outcome?

**Good Clinical Practice Training**

The NIH has issued a policy requiring all NIH-funded investigators and their research staff involved in the conduct of clinical trials, as defined by the NIH, to complete Good Clinical Practice ("GCP") training. Effective January 1, 2017, it applies to both new applications, and
ongoing programs. The NIH definition of a clinical trial is “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.” This definition also encompasses trials that do not involve drugs or devices. Investigators should review the NIH definition for more detail. Although GCP training is typically associated with FDA-regulated drug or device studies, the training requirement also applies to NIH-funded studies that are only studying behavioral interventions. In addition, all members of the research team who may be engaged in the research must complete the training.

To comply with the NIH GCP training requirement, faculty and their research staff who may be subject to this NIH requirement should complete the CITI GCP training module, which is available through myLearning.

Research Misconduct

JHU considers any fabrication, falsification, plagiarism, or forgery in proposing, performing, reviewing, or reporting results in any sponsored project to be research misconduct. In addition, the University defines research misconduct as failing to comply with federal and state laws, refusing to follow rules or regulations, disregarding policies or relevant procedures, or ignoring any academic or Professional standards.

VII. ADDITIONAL JHU OFFICES WE INTERACT WITH

A. The IRB:

The IRB ensures the protection of the rights, privacy, and welfare of all human participants in research studies conducted by JHU and its associated faculty, staff, and students.

- Reviews studies to assess safety, privacy and confidentiality concerns as they relate to the study.

Major Functions:

- Identifies, discusses, and resolves ethical issues that relate to safeguarding the rights and welfare of human subjects;
• Reviews all research and all related activities carried on by faculty, students, and employees that involve human subjects;

B. Johns Hopkins Technology Ventures (JHTV)

JHTV is the University’s intellectual property center. Please let Sponsored Projects Director know if you need assistance with connecting to JHTV.

• Serves Johns Hopkins researchers and inventors as the licensing, patent, and technology commercialization office
• Acts as an active liaison to parties interested in leveraging JHU research or materials for academic or corporate endeavors. https://ventures.jhu.edu.

Major Functions:

• Encourages the disclosure of new ideas and discoveries. Contact Sponsored Projects Director with all questions regarding whether a Disclosure Statement is warranted.
• Protects and manages the University’s intellectual and tangible property
• Licenses the University’s technologies
• Facilitates collaborations among researchers, companies, and entrepreneurs interested in developing University innovations and returning appropriate revenue to University laboratories
• Encourages product development; and
• Seeks and nurtures contacts with national and international companies and entrepreneurs that are capable of developing and commercializing University innovations for the public good.

C. The Office of the Controller

The Office of the Controller is organized into the following categories: Accounts Payable, Accounts Receivable, Fixed Assets, HR/Payroll, Inter-Entity, Sponsored Projects, Supply Chain, and Travel. Http://finance.jhu.edu

• Produces the audited financial statements of the University
• Serves as a principal liaison with external agencies on all financial matters.
• Ensures compliance with University, Trustee, State, and Federal requirements for funds received, spent, and reported

Major Functions:
- Administers post-award sponsored research, including invoicing and submitting financial reports
- Manages payroll and taxes, and
- Negotiates the University’s indirect cost rate and fringe benefits.

D. **The Office of General Counsel**

The Office of the General Counsel provides legal counsel and representation to The Johns Hopkins University and all of its schools, divisions, affiliates, and related entities on a broad range of legal matters affecting the University.

**Major Functions:**

- Provides the highest quality legal services in a responsible, helpful, and timely manner;
- Protects and promotes the mission and values of the University, including compliance with its obligations, and protection and promotion of its interests;
- Minimizes legal risks and costs; and
- Addresses and resolves legal disputes.

E. **The Office of Export Controls**

The Office the Export Controls develops, monitors, and documents a program that is focused upon preventing the transfer of certain restricted items and information to certain foreign countries or to their citizens.

**Major Functions:**

- Identifies activities throughout the Johns Hopkins Enterprise that are controlled by U.S. export control regulations;
- Communicates with Federal agencies or other regulatory bodies to ensure institutional compliance with export control regulations; and
- Counsels and trains JHU personnel to identify export control issues and to address the issues in cooperation with the ECO.

F. **Sponsored Projects Shared Services (SPSS)**

- Sets up and maintains each award’s master data elements
- Monitors awards for compliance with applicable institutional policies
- Completes financial reporting to external sponsors and close out awards within the SAP system according to Sponsor requirements
• Serves as a resource to SON in all aspects of post-award financial administration.

G. Institute for Clinical and Translational Research (ICTR)

There is NO COST to use the ICTR. ICTR addresses obstacles in translating basic science discoveries into research in humans, translating clinical discoveries into the community and communicating experience from clinical practice back to researchers. The ICTR houses three Translational Research Communities for investigators across multiple disciplines that focus on drugs, biologics, vaccines and devices; biomarkers and diagnostic tests; and behavioral, social and systems interventions. These communities of researchers help prioritize clinical problems in need of new treatments, apply new technologies and methodologies, support junior investigators, work with translational partners outside of Johns Hopkins, fund pilot projects, provide regulatory assistance and promote efficient research.

Another ICTR program, The Research Studio, provides both a place and a process for investigators and their teams to obtain multidisciplinary guidance to solve clinical and translational research problems. Additionally, the ICTR provides research teams across the university and affiliated research institutes with a range of services within five coordinated Cores: Translational Laboratories, Human Subjects Research, Quantitative Methodologies, Clinical Research Informatics, Research Participants and Community Partnerships. Through a robust portfolio of training, education and career development programs, the ICTR also provides rigorous, comprehensive training to medical students, graduate students, fellows, junior faculty, practicing physicians and the wider research team, thus promoting the most effective, efficient, collaborative translational research enterprise.

H. The Office of the Provost

The Provost’s Office works closely with the university’s academic and administrative leaders to advance its missions and ensure the future of Johns Hopkins as a world leader in research and education. Johns Hopkins University’s mission is to educate its students and cultivate their capacity for life-long learning, to foster independent and original research, and to bring the benefits of discovery to the world.

The Office of the Provost advances the mission of Johns Hopkins’s diverse community by:

• Identifying and facilitating initiatives that transcend divisional boundaries.
• Coordinating and strengthening university policies and procedures.
• Supporting research, education and the student experience.
The University Research Integrity Policy applies to all University faculty, trainees, students and staff engaged in the proposing, performing, reviewing or reporting of research, regardless of funding source. Please take time to familiarize yourself with this policy.
**VIII. Conclusion**

**PLEASE DO NOT HESITATE TO CONTACT US** if you have additional questions or need guidance on the contents of this manual in terms of how it applies to you and your specific project.

Our goal is to provide excellent pre- and post-award service to the SON community.

**WE ARE HERE TO GUIDE, ADVISE AND ASSIST!**

Dbrodlie@jhu.edu
IX. Glossary

- **Audit** – A formal examination of an organizations’ or individual’s accounts or financial situation. An audit may also include examination of compliance with applicable terms, laws and regulations.
- **Award** – Funds that have been obligated by a funding agency for a particular project.
- **Background Intellectual Property** – All intellectual property owned by University and rights therein in existence as of the date of execution of a sponsored research agreement and which may be needed to practice the new technology to be developed.
- **Broad Agency Announcement** – An announcement of a federal agency’s general research interests that invites proposals and specifies the general terms and conditions under which an award may be made.
- **Close Out** – The act of completing all internal procedures and sponsor requirements to terminate or complete a research project.
- **Contract** – A mechanism for procurement of a product or service with specific obligations for both sponsor and recipient. Typically, a research topic and the methods for conducting the research are specified in detail by the sponsor, although some sponsors award contracts in response to unsolicited proposals.
- **Cooperative Agreement** – An award similar to a grant, but in which the sponsor’s staff may be actively involved in proposal preparation, and anticipates having substantial involvement in research activities once the award has been made.
- **Copyrights** – Protected works of authorship, such as writings, music, software, and works of art that have been tangibly expressed. The Library of Congress registers copyrights, which last for the life of the author plus 70 years.
- **Cost Reimbursement** – A contract/grant for which the sponsor reimburses the University for the Full Costs incurred in the conduct of the work up to an agreed-upon amount.
- **Cost Sharing** – A general term, used as a noun or adjective, that can describe virtually any type of arrangement where more than one party supports research, equipment acquisition, demonstration projects, programs, or institutions.
- **Derivative Work** – Under copyright law, a work based upon one or more preexisting works, such as translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgment, condensation or any other form in which a work may be recast, transformed, or adapted. A work consisting of editorial revisions, annotations, elaborations or other modifications, which, as a whole, represent an original work of authorship, is a “derivative work.”
- **Direct Costs** – Clearly identifiable costs related to a specific project. General categories of direct costs include, but are not limited to, salaries and wages, fringe benefits, supplies, contractual services, travel and communication, equipment, and computer use.
- **Facilities and Administrative Costs** – Costs that are incurred for common or joint objectives and, therefore, cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity. F&A costs are synonymous with Indirect Costs and are usually expressed as a percentage of the direct costs.
- **Fixed Price** – A contract/grant for which one party pays the other party a predetermined price, regardless of actual costs, for services rendered.
- **Foreground Intellectual Property** – All intellectual property owned by the University and rights therein
resulting from a sponsored research agreement.

- **Gifts** – Awards given with few or no conditions specified. Gifts may be provided to establish an endowment or to provide direct support for existing programs. Frequently, gifts are used to support developing programs for which other funding is not available.

- **Grant** – A type of financial assistance awarded to an organization for the conduct of research or other program as specified in an approved proposal. A grant, as opposed to a cooperative agreement, is used whenever the awarding office anticipates no substantial programmatic involvement with the recipient during the performance of the activities.

- **Grants.gov** – The federal government’s primary source to find and apply for Federal government grants.

- **Incremental Funding** – A method of funding contracts that provides specific spending limits below the total estimated costs. These limits may be exceeded only at the contractor’s own risk. Each increment is, in essence, a funding action.

- **Indirect Cost Rate** – The rate expressed as a percentage of a base amount established by negotiation with the cognizant federal agency on the basis of the institution’s projected costs for the year, and distributed as prescribed in the Uniform Guidance. Indirect costs are applied to salary and wages (S&W) or the modified total direct cost (MTDC) base. The indirect cost rate is charged on a set of direct costs known as an indirect cost base.

- **Indirect Costs** – Costs related to expenses incurred in conducting or supporting research or other externally funded activities but not directly attributable to a specific project. General categories of indirect costs include general administration (accounting, payroll, purchasing, etc.), sponsored project administration, plant operation and maintenance, library expenses, departmental administration expenses, depreciation or use allowance for building and equipment, and student administration and services.

- **In Kind Contributions** – Assistance in a form other than money. Equipment, materials, or services of recognized value that are offered in lieu of cash. Contributions must be documented in entirety to be used on an award.

- **Intellectual Property – Creations of the mind** – creative works or ideas embodied in a form that can be shared or can enable others to recreate, emulate, or manufacture them. Can be any writing or discovery that is a new and useful process, machine, and composition of matter, life form, article of manufacture, software, trademark, trade secret, copyrighted work, or tangible research property. There are four ways to protect intellectual property: patents, trademarks, copyrights, and trade secrets.

- **Invention** – Any art or process (way of doing or making things), machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, that is or may be patentable under the patent laws of the United States.

- **Key Personnel** – The personnel considered to be of primary importance who contribute to the scientific development or execution of a project. The term usually applies to the senior members of the project staff.

- **License** – A permit to do that which would otherwise be unlawful. Licenses are contracts that deal with the rights, permissions, and restrictions related to the use of information assets and intellectual property, and with contractual and other obligations associated with the exchange in which these rights, permissions, or restrictions are transferred.

- **Material Transfer Agreement** – A contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes.
- **Modification** – An award document that modifies any aspect of an existing award. Examples include carryover approvals, adding or deleting special terms and conditions, changes in funding levels (including NSF’s research experience for undergraduates, NIH’s minority supplement, DOD’s ASSERT programs), administrative changes initiated by the agency, extensions that include changes in terms, change of PI, etc.

- **Modified Total Direct Costs** – The basic indirect costs are calculated on a subset of direct costs, normally excluding among other costs, equipment, patient care, space rental, alterations and renovations, and subaward costs in excess of the first $25,000.

- **No Cost Extension** – An extension of the period of performance beyond the expiration date, at no additional cost, to allow the principal investigator to finish a project.

- **Notice of Grant Award** – The legally binding document that serves as a notification to the recipient and others that a grant or cooperative agreement has been made, contains or references all terms of the award, and documents the obligation of funds.

- **Patent** – A property right granted by the U.S. Government to an inventor to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States for a limited time in exchange for public disclosure of the invention when the patent is granted.

- **Period of Performance** – The total time for which support of a project has been programmatically approved. A project period may consist of one or more budget periods.

- **Prime Award** – A governing agreement between the recipient and the awarding agency.

- **Principal Investigator** – The individual responsible for the conduct of research or other activity described in a proposal for an award.

- **Program Announcement** – Describes existence of a research opportunity. It may describe new or expanded interest in a particular extramural program, or be a reminder of a continuing interest in an extramural program.

- **Proposal** – An application for funding that contains all information necessary to describe project plans, staff capabilities, and funds requested. Formal proposals are officially approved and submitted by the organization in the name of a principal investigator.

- **Request for Proposal** – Announcements that specify a topic of research, methods to be used, product to be delivered, and appropriate applicants sought. Proposals submitted in response to RFPs generally result in the award of a contract. Notices of federal RFPs are published in the Commerce Business Daily.

- **Revision** – A modified and resubmitted request for funding for a project that was previously not funded either because it was denied by the sponsor or withdrawn by the PI.

- **Scope of Work** – The description of the work to be performed and completed on a project.

- **Small Business Innovative Research** – Agency administered programs supported by ear-marked federal funds, making grants to small business entities.

- **Sole Source** – A situation in the marketplace where there is clearly and legitimately a single source of supply that meets the necessary requirements. A sole source justification implies that any attempt to obtain bids would result in only one option.

- **Sponsor** – The organization that funds a research project.

- **Subcontract, Subgrant or Subagreement** – A document written under the authority of and consistent with the terms and conditions of an award (a grant, contract or cooperative agreement) that transfers a portion of the research or substantive effort of the prime award to another institution or organization.
▪ **Subcontractor, Subrecipient** – The recipient of a subaward awarded to a foreign or domestic organization (either a non-profit, educational institution, state or local government, or private industry) for the performance of a portion of the work statement covered by a prime agreement that is funded either directly or indirectly with sponsored funds. It does not include agreements with individuals for consulting services or purchase orders for equipment, materials or other services. A subrecipient receives an award of assistance from a pass-through entity and conducts its own scope of work. Also referred to as subawardee, subgrantee or lower-tier institution.

▪ **Subject Invention** – Any invention conceived or first reduced to practice in the University’s performance of work under a federal grant or contract.

▪ **Task Order** – A legally binding document authorizing work and appropriating funds as a supplement to a master agreement/IDIQ.

▪ **Teaming Agreement** – An agreement between two or more parties to participate in a research project or teaching activity.

▪ **Trade Secret** – The Uniform Trade Secrets Act defines trade secrets as information, including a formula, pattern, compilation, program, device, method, technique, or process, which derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure, and is the subject of efforts that are reasonable under the circumstance to maintain its secrecy.

▪ **Uniform Guidance** – Regulations codified in 2 CFR Part 200, et seq., published by the federal Office of Management and Budget (OMB) that establish the principles for determining the administrative requirements, cost principles, and audit requirements applicable to grants, contracts, and other government agreements.

▪ **Work Made For Hire** – Under copyright law, a work prepared by an employee within the scope of his or her employment; or a work specially ordered or commissioned for use as a contribution to a collective work, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire. JHU typically does not engage in work made for hire agreements, as they are in direct conflict with the University’s publication policy.

### XI. Acronyms

- **BAA** – Broad Agency Announcement
- **CA** – Contract Associate
- **CDA** – Confidentiality Agreement (aka NDA)
- **CFR** – Code of Federal Regulations
- **CR** – Cost Reimbursement
- **CRADA** – Cooperative Research and Development Agreement
- **CTA** – Clinical Trial Agreement
- **DUA** – Data Use Agreement
- **DUNS** – Data Universal Numbering System
- **EIN** – Employer Identification Number (aka TIN)
- **F&A** – Facilities and Administrative Costs (aka IDC)
▪ **FP** – Fixed Price
▪ **GA** – Grants Associate
▪ **Sr. GCA** – Senior Grants and Contracts Analyst
▪ **IACUC** – Institutional Animal Care and Use Committee
▪ **IDC** – Indirect Costs (aka F&A)
▪ **IHE** – Institute of Higher Education
▪ **I/O** – Internal Order
▪ **IP** – Institution Proposal record (in COEUS) or Intellectual Property
▪ **IRB** – Institutional Review Board
▪ **MOU** – Memorandum of Understanding
▪ **MTA** – Material Transfer Agreement
▪ **MTDC** – Modified Total Direct Costs
▪ **NCE** – No-Cost Extension
▪ **NDA** – Nondisclosure Agreement (aka CDA)
▪ **NGA** – Notice of Grant Award
▪ **NOA** – Notice of Award
▪ **OMB** – Office of Management and Budget
▪ **OSI** – Office of Science and Innovation
▪ **PD** – Proposal Development record (in COEUS) or Project Director
▪ **PI** – Principal Investigator
▪ **POP** – Period of Performance
▪ **PTE** – Pass through Entity
▪ **RFP** – Request for Proposal
▪ **RFQ** – Request for Quote
▪ **SBIR** – Small Business Innovative Research
▪ **SOW** – Scope/Statement of Work
▪ **SPG** – Sponsored Projects Group-Sr. GCAs
▪ **SPSS** – Sponsored Projects-Shared Services
▪ **S2S** – System to system
▪ **TDC** – Total Direct Costs
▪ **TO** – Task Order
▪ **UG** – Uniform Guidance