

JOHNS HOPKINS UNIVERSITY SCHOOL OF NURSING

CENTER FOR NURSING RESEARCH AND SPONSORED PROJECTS

PROPOSAL PREPARATION AND POST-AWARD GUIDELINES

School of Nursing

JOHNS HOPKINS
UNIVERSITY



Johns Hopkins University School of Nursing
Center for Nursing Research and Sponsored Projects
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Center for Nursing Research and Sponsored Projects Mission Statement

The mission of the Center for Nursing Research and Sponsored Projects (CNR) is to facilitate the advancement of knowledge to promote health and improve health services. The CNR supports and facilitates the development and implementation of research projects or programs and other sponsored projects with particular emphasis on research excellence and external funding opportunities. Additionally, the CNR facilitates the research and external funding activities of doctoral students and post-doctoral fellows.

Services and Resources

- Consultation
 - Funding opportunities
 - Research design and methods
 - Biostatistics
 - Data safety monitor plans and boards
 - Human and animal subjects protection
 - HIPAA
 - Conflict of interest and conflict of commitment
 - Faculty development in research
 - Research team building
 - Electronic submission processes
- Internal Review of Proposals prior to submission
- Administrative Coordinator Training
 - Grant application forms / process
 - Manuscript preparation
 - Preparation of tables
 - Literature reviews
 - Reference Manager
 - NIH eSubmission
- Budget Preparation and Administration
- Continuing Education for Principal Investigators
 - NIH Grantsmanship Seminar
 - Post-Award research conduct
- Assistance with Grant Submission
 - Provide templates/assistance with Biosketches
 - Provide assistance with tables and figures
 - Copying
 - Provide sample Letters of support
 - Form templates available
 - Courier arrangements (for paper submission)
 - Proofreading
 - Reference Manger, PubMed Help
 - Coeus assistance (separating and uploading files, etc)
 - Converting/Combining documents in .pdf form

Standard Grant Applications and Information

To assist in the proposal preparation process, information, instructions and application forms for standard Department of Health and Human Services(DHHS) grant submissions may be found at the Center for Nursing Research and Sponsored Projects website (<http://www.son.jhmi.edu/research/resources/applications.aspx>) under “Applications.”

Additional information and application forms may also be obtained from the following sites:
[Centers for Disease Control & Prevention Grants and Cooperative Agreements](#)
[National Institute of Justice Funding Opportunities](#)

The CNR is providing the following templates required for most DHHS applications:
[Johns Hopkins University Resources and Environment Boilerplate information](#)

Additional Links:

[JHU Research Administration](#)

[JHM Institutional Review Board eIRB](#)

[JHUSON Conflict of Interest Policy \(secured site\)](#)

[NIH Administrative Requirements](#)

Proposal Preparation Guidelines for Sponsored Projects

These guidelines apply to all faculty, doctoral students and post-doctoral fellows preparing proposals.

Sponsored Projects include research and non-research proposals and subcontracts to foundations, corporate and government sponsors. Non-research proposals may include institutional training grants, individual training grants, educational training grants, clinical program activity and evaluation proposals, and dissertation awards. **All proposals require the “Intent to Submit a Proposal” form discussed below.**

Overview - Proposal Preparation General Timeline

Item	Date	Example
Due Date to Sponsor	DD Day	June 16th
Final and complete grant due to CNR	10 days before DD Day -Electronic	June 6th
	5 days before DD Day - Paper	June 11th
Biosketches and all Key personnel information due to CNR	25-30 days before DD Day	May 16th
Call or e-mail Business Office to schedule your budget meeting	30 days before DD Day-NO Subcontract	May 16th
	45 days before DD Day-YES Subcontract	May 1st
SRC Review	Takes place the month before DD Day (SRC is the second Tuesday of the Month.)	May 13th
Draft due for SRC Review	The draft is due one week before SRC.	May 6th
Intent to Submit completed	2 months before DD Day. We understand there are times you find out late about a grant. Even if you are just contemplating putting it a proposal-PLEASE put in your ITS. If you change your mind-THAT’S OK- Just e-mail the CNR Sr. Admin Coordinator and we will withdraw the ITS.	April 16th

Intent to Submit a Proposal

(Due 2 months prior to sponsor due date)

The principal investigator (PI) must complete the “Intent to Submit a Proposal” form online. On this form they must provide the following:

- Request for Applications (RFA), Program Announcements (PA), or Funding Opportunity Announcement (FOA) from the sponsoring agency or an Internet link (if applicable)
- Proposal application forms and instructions or an Internet link (if applicable).

When the PI submits the electronic “Intent to Submit a Proposal” form, the CNR, Department Administrative Managers, Department Chairs and the Business office are notified.

Changes to the Intent to Submit a Proposal

The PI should notify the CNR Senior Administrative Coordinator as soon as possible with any changes on the Intent to Submit form, e.g., sponsor due date, proposal title, program announcement change, funding mechanism, cancellation of submission, etc.

Budget Preparation

(30 days prior to sponsor due date; 45 days if a subcontract is involved)

Office of Finance & Administration

The assigned Financial Manager (FM) from the Office of Finance & Administration will assist the PI in preparing the budget for the proposal. It is the PI’s responsibility to contact their FM to schedule their initial meeting to discuss the following:

- Budget information needed for proposal
- Assigned responsibilities
- Timeline for completion

If subcontracts with other institutions are involved (Appendix C & D), it is the responsibility of the PI and the FM to prepare all subcontract material. Please refer to Appendix C for specific instructions.

The FM prepares a preliminary budget based on information gathered from the PI at the proposal preparation meeting. **The PI is responsible for completing the budget justification.** See the CNR portal for examples. The PI and the FM are responsible for reviewing and changing the budget and budget justification. The FM is responsible for inputting budget data onto the required sponsor forms prior to submission. The PI is responsible for collecting all subcontract materials and providing them to the business office.

Reminder: the PI is ultimately responsible for reviewing the entire proposal, including budget.

Computer Network Services

Often, new research projects require computers and/or other technological equipment. If computers are expected to be used for the proposed project, Computer Network Services requires that the PI include technological requirements in the initial detailed budget of the grant proposal. A representative from Computer Network Services will help in pricing computers and other related equipment.

The PI is required to contact Computer Network Services to initiate the process of determining technological requirements for the project. (See appendix B)

Scientific Proposal Review

(1 month prior to sponsor due date)

A review of the proposal and abstract is mandatory for all proposals seeking external funding and it is recommended that this occur at least 1 month prior to sponsor due date.

Scientific Review Committee

Standing Scientific Review Committee (SRC) meetings are scheduled through the CNR and the dates are available by contacting the CNR Senior Administrative Coordinator. During regular proposal due dates when submissions are numerous or during times when proposal due dates do not correspond with standing SRC meetings, the CNR Senior Administrative Coordinator will arrange additional scientific review meetings as needed. SON faculty currently make up a standing SON (SRC). A primary and secondary reviewer is assigned to each proposal. Both reviewers are responsible for a detailed and constructive review of the proposal.

The PI or Administrative Coordinator is responsible for providing a draft copy of the proposal and abstract to the CNR Senior Administrative Coordinator 1 week prior to the Scientific Review date. If the application is a revised application, the inclusion of the comments from the previous review and the introduction to the revised application should be included in the documents submitted for SON SRC review. PhD students submitting an NRSA should also include the training plan. The CNR Senior Administrative Coordinator is responsible for confirming the SRC meeting schedule and for distributing draft copies of the proposal and abstract to each SRC member.

Changes to the proposal recommended by the SRC following the review meeting should be considered by the PI and the revised proposal. If recommendations are considerable and substantive, the revised proposal should be submitted to the primary reviewer to review the changes and make a recommendation to the Director of the Center for Nursing Research as to whether the application should proceed. **PhD students submitting an NRSA should follow the same procedure; however, the revised proposal should be submitted to the student's advisor.**

In addition, the CNR Director or Associate Dean for Research must sign-off on the abstract during the proposal signature process (see Process on the following page). Thus, the PI is required to include the final abstract with the signed face page and other documents needed for signature to the Business Office on the appropriate date for timely submission of the application.

External Reviewer

In addition to the scientific review by the SRC, the PI of a major research grant proposal is encouraged to use an external expert reviewer. An external reviewer is defined as any expert reviewer outside of the JHUSON Scientific Review Committee. This includes JHUSON faculty who are not currently on the Committee, other JHU faculty, and experts outside the University.

The PI is responsible for contacting the external reviewer to request their participation and notifying the CNR Senior Administrative Coordinator. Upon receipt of the draft proposal and abstract, the CNR Senior Administrative Coordinator will provide a copy to the external reviewer(s)–3-4 weeks prior to the sponsor due date. The external reviewer should send review comments to the CNR Senior Administrative Coordinator by the Scientific Review date. Other arrangements can be made in consultation with the CNR Director.

Upon receipt of the reviewer's comments, the CNR Senior Administrative Coordinator will provide a copy of the external reviewer comments to the PI, and arrange for compensation for the external review.

Compensation will only be given to expert reviewers outside of Johns Hopkins University who review the proposal independently. External reviewers are invited to join the SRC meeting.

Electronic Submission: Review and Signature Process

(Required: 10 working days prior to sponsor due date)

Once all proposal components have been uploaded into COEUS the CNR will review the file to make sure all required fields are complete. Once this is complete the FM will give the eIS form and abstract to the Director of the CNR for approval. The eIS form is then given to the PI for signature, and finally given to the Associate Dean for Finance and Administration for signature.

This 10 working day period will allow adequate time for review by the FM, the CNR, and the Associate Dean for Finance and Administration. In rare circumstances, an exception to the 10-working-day requirement can be made contingent on approval by the Associate Dean for Research or the Director of the CNR.

Paper Submission: Review and Signature Process

(Required: 5 working days prior to sponsor due date)

The CNR will prepare a PI-approved proposal package for review, including but not limited to Abstract, Budget, Budget Justification, and compliance review, and official signature at least 5 working days prior to the sponsor due date. This package should include:

- Electronic Information Sheet signed by PI
- Face Page signed by PI
- Abstract
- Budget and Budget Justification
- Subcontract Information (if applicable)
- Checklist
- Budget spreadsheet

This 5 working day period will allow adequate time for review by Research Administration, the CNR, and the Associate Dean for Finance and Administration. In rare circumstances, an exception to the 5-working-day requirement can be made contingent on approval by the Associate Dean for Research or the Director of the CNR.

Submission of Proposal to Sponsor

For Electronic Submissions, once all signatures have been obtained by the Research Administration the available Signing Official (SO) will submit the proposal to the sponsoring agency. Once notice is received that the sponsoring agency has received a proposal, Research Administration will download a copy to save as the “proposal of record.”

For paper submissions, request for courier service can be handled through the CNR or with the PI’s Administrative Coordinator.

Please note: Specific funding agencies will only accept applications from a courier service (i.e. Federal Express, same-day courier services). NIH applications, for example, will only accept courier or postal service delivered applications. NIH will not accept applications delivered by anyone from the applicant’s institution.

In addition to the copies of the proposal required by the sponsor and the copy retained by the PI, additional hardcopies should be sent to Research Administration (1 copy) and the Senior Administrative Coordinator of the CNR for Nursing Research and Sponsored Projects (1 copy); this copy will be the “proposal of record”.

Notification of Agency Comments

Upon receipt of the review panel score and reviewer comments, the PI is asked to submit a copy to the CNR Senior Administrative Coordinator. In the case of NIH proposals, this information is called the “Summary Score” and “Summary Statement.” This is not required.

Summary

RESPONSIBLE PARTY	COMPLETE
PI	<ul style="list-style-type: none"> Appendix A – Proposal Budget Checklist; bring to proposal meeting with FM Appendix B– Computer Network Services Checklist Appendix C & D– work with FM to prepare material for subcontract (if applicable). Appendix E – eIS compliance questions Responsible for tracking completion of all proposal preparation requirements. Submit a draft copy of the proposal and abstract for review by the SRC or external reviewer(s). Responsible for revisions to proposal and abstract suggested by SRC or external reviewer(s). Submit revised proposal and abstract to the CNR for re-review. Submit final signed budget packet to FM (see section on Signature Process). Submit final proposal to sponsor. Deliver a hardcopy of the submitted proposal to the FM and the CNR Senior Administrative Coordinator. Identify that proposal is accurate and adheres to guidelines.
Financial Manager	<ul style="list-style-type: none"> Appendix A (with PI) – Proposal Budget Checklist Appendix C & D – Prepare Subcontract material with PI (if applicable). Appendix E – Complete eIS using completed eIS compliance questions Review and approve all SON proposals for accuracy and adherence to guidelines. Manage grant signature process.
CNR	<ul style="list-style-type: none"> Arrange for a draft of the proposal and abstract to be submitted and reviewed by the SRC or external reviewer(s). Provide PI with review comments from SRC or external reviewer(s). Arrange for compensation for the external review (non-JHU reviewer) Answer questions related to Institutional Review Board and HIPAA compliance procedures. Assist the PI and the Department Administrative Coordinator in preparing the application for submission to the sponsor. Verify Compliance training for PI and all proposal key personnel. Arrange Courier Service for Proposal
Computer Network Services	<ul style="list-style-type: none"> Appendix B – Complete with PI submit to FM (if applicable)
Department Administrative Manager and Administrative Coordinator	<ul style="list-style-type: none"> Become familiar with the sponsor application instructions and RFA (if applicable). (The PI is responsible for tracking completion of all proposal preparation requirements.) Prepare or gather the biographical sketches and other support information for the research team designated by the PI. Obtain Letters of Support from a list of individuals provided by the PI. Other duties as agreed upon. Manage Post-Award Budget (Including but not limited to Account reconciliation)

Institutional Review Board Review and Approval

The Johns Hopkins Medicine Institutional Review Boards (JHMIRBs), which include the Western Institutional Review Board (WIRB), are charged to review, to approve the initiation of, and to conduct periodic review at required intervals of research involving human subjects conducted by Hopkins faculty and staff at the Institutions covered by the Multiple Project Assurance (MPA M1011). Faculty and staff at the Institutions must submit any research project that includes human subjects for review, regardless of funding source (or lack of funding) and regardless of location at which the study will be conducted. The primary purpose of JHMIRB review is to assure the protection of the rights and welfare of the human subjects.

Investigators who wish to apply to the JHMIRBs for consideration of their human subjects research study must complete and submit an application. As of May 1, 2004, the JHM IRB application process is electronic. The website for eIRB is <http://e-irb.jhmi.edu/>. It is the responsibility of the PI or designee to review the eIRB website and JHMIRB website (<http://irb.jhmi.edu/>) for IRB application guidelines and procedures.

The JHMIRB information includes when to submit for IRB approval. This information specifically pertains to the “Just in Time” procedures from the NIH which state that IRB approval should be obtained after a proposal has received a fundable score. The JHMIRB follows the “Just in Time” procedures for all federal agencies except in cases where the federal agency requires IRB approval with the application submission.

To determine which IRB should receive the initial review application, refer to the following determinants:

Prepare the IRB review application for submission to the internal JHMIRB office if:

- The study is a new federally-funded study and has received a fundable score ([Just-In-Time Procedures](#)), unless otherwise instructed.
- The study is a gene therapy study (commercially or federally funded).
- Protocol under review by the JHU Conflict of Interest Committee.
- The study is a foundation-supported study.
- The study is a PI-initiated or non-funded study.
- Prepare the IRB review application for submission to the JHU/WIRB office if the study is commercially-funded. Please note: JHU/WIRB charges a fee for this service.

Both types of IRB applications are available on the eIRB system.

In addition, the JHMIRB website provides information on HIPAA regulations and the process for compliance. HIPAA refers to the Health Insurance Portability and Accountability Act, a federal law enacted in 1996. Part of the law deals with the privacy and confidentiality of health care information. The Department of Health and Human Services (DHHS) has issued final regulations addressing privacy and electronic transactions, and proposed regulations addressing the security of this information. The privacy regulations became effective on April 14, 2003. The electronic transactions regulations became effective October 16, 2002, but covered entities were permitted to file for a one year extension, making the effective date October 16, 2003. All affected Hopkins' entities filed for this extension, and therefore the affected date for Hopkins is October 16, 2003.

Please read the JHMIRB website information carefully before preparing an IRB application.

NOTE: ALL PI'S ARE REQUIRED TO SUBMIT A COPY OF THEIR INITIAL IRB APPROVAL LETTER AND SUBSEQUENT RENEWALS TO THEIR RESEARCH ADMINISTRATION FINANCIAL MANAGER.

IRB Compliance Monitoring

The CNR Senior Administrative Coordinator has appendix materials for review by the PI for IRB compliance monitoring. These forms are also available on the SON Intranet. PI's are encouraged to use these appendix materials to assure they are in compliance for IRB reviews.

Animal Care and Use Committee (<http://www.jhu.edu/animalcare/>)

The care and use of animal subjects is regulated by the Animal Welfare Act, through the U.S. Department of Agriculture. Johns Hopkins University (JHU) has one assurance with the federal government (the Office of Laboratory Animal Welfare [OLAW]) and, therefore, JHU has one institutional animal care and use committee (IACUC). Faculty from the School of Nursing, School of Public Health, the School of Medicine, and the Homewood campus serve on this committee.

All animal users MUST be registered with the Animal Exposure Surveillance Program (AESP) in Occupational Health Services, located at 98 N. Broadway, Room 421 (Church Home Professional Office Building). The hours of operation are Monday through Friday, 7:30 a.m. through 4:00 pm. The registration process takes less than 30 minutes. The AESP can be reached at 410-955-6211. An approved protocol MUST be obtained before animals can be purchased.

In addition, all individuals working with laboratory animals must successfully complete the online internet training module available at the website listed above.

The Institutional Animal Care and Use Committee can be contacted at (443)287-3738 for questions involving submissions of protocols. <http://www.jhu.edu/animalcare/committee.html>

Foundation/Corporation Proposals

Please note: These and all proposals must follow the CNR guidelines. This includes submission of an Intent to Submit a Proposal form and budget preparation. Additionally, if the proposal is a research project, there must be an SRC review.

- Sponsored Projects/Accounts are defined by Research Administration as funds received from outside sources which are dedicated as to purpose and/or use and require the University to provide technical or financial reporting. Restrictions may be applied to the nature or scope of work to be performed or to the types or levels of expenditures to be made.
- Gifts are defined by Research Administration as monies that a donor or other outside agency has provided to the University or to a department, school, unit, as opposed to an endowment. The monies may be expended as needed or in accordance with the conditions of the gift, and many are restricted to use.

The Johns Hopkins Institutions seek to avoid duplicate solicitation of corporations, corporate foundations, private foundations, and family foundations by different entities within Johns Hopkins University. To this end, the JHU Central Development office requires that clearance be given via the SON Development Office to PIs submitting to the funding agencies that fall under the above categories. Therefore, faculty, staff and students must notify the SON Development Office before contacting or if contacted by any corporation, corporate foundation, private foundation, family foundation, etc., regarding funding opportunities.

The SON Development Office is contactable at (410) 955-4284 and is situated on the 5th floor in room 529. The Associate Dean for Development & Alumni Relations is Fiona Newton, email: fnewton1@son.jhmi.edu. The Director of Corporate & Foundation Relations is Lisa O'Shea, email: loshea@son.jhmi.edu.

The Development Office will work closely with the PI to help ensure a high quality proposal is prepared and submitted that fully meets the grant-making criteria, or sponsorship interests, of the company or foundation. The Development Office expects to provide the following support to PIs for all approaches to companies, corporate foundations, and other charitable foundations:

- background research to assess the organization's capacity and propensity to support your initiative / program
- advice and guidance regarding the viability and likelihood of success in making an application
- attendance with you at exploratory meetings with company and foundation staff
- provision of standard information to the proposal writer, e.g. background of the SON, history of support from other foundations and companies, Johns Hopkins University IRS Form 990, IRS letter of incorporation for JHU, JHU annual accounts (if required)
- for large funding requests, assistance with writing the proposal (ideally, please give at least 4-6 weeks notice prior to proposal deadline if you need Development help with writing)
- Will work in collaboration with the Business Office Financial Manager regarding budget items, including whether F&A costs can be included, and how to structure the budget to demonstrate the impact the proposed funding will have
- coordination of official thank you letters from the Dean of the SON and the President of JHU
- reminders about, and assistance in coordinating, end of year feedback reports to the donor or sponsor regarding the impact of their funding (details must be provided by the PI)

Note, the Development Office must be included in the final approval process for any proposals sent to companies and foundations.

In most cases, clearance to submit a proposal to a foundation or corporation can be given very quickly. If there is a conflict such as a proposal having already been submitted to a potential funding agency by another Hopkins entity, the Development Office can arrange for the School of Nursing to be in line for the next approach. This policy protects everyone and is administered uniformly throughout all of the units and departments of the University and Health System.

Proposals Involving Student Participation/Academic Programs

If a proposal contains any initiatives that involve student recruitment, student scholarships or stipends (non-doctoral), or special student programs, the School of Nursing Associate Dean for Student Affairs must review the proposal during the proposal review phase (3-4 weeks prior to sponsor due date). Proposals involving development of new academic programs or academic courses should be seen by the Senior Associate Dean for Academic Affairs and the Director of the involved program as well.

Post-Award Guidelines for Sponsored Projects

Just-in-Time Procedures

Just in time is a term that refers to submitting information to NIH when an award is likely. Be sure to submit this information as soon as possible, since it is required before NIH can issue the award.

Information we request in the just in time notice:

- Human subjects assurance.
- Certification of IRB approval of proposal.

- Certification of human subjects education.
- Animal welfare assurance.
- Certification of Institutional Animal Care and Use Committee (IACUC) approval.
- Other support information.

Please note: A budget number will not be assigned until IRB approval has been granted. Remember to send a copy of the IRB approval letter and all other applicable “Just-in-Time” material to Research Administration.

Notice of Grant Award

If a notice of grant award (NGA) is received, it means that the application information has been sent in, received, and accepted, and the awarding agency is going to award the grant. The NGA will state the amount of funding for current and future years, start and end dates, and the terms and conditions of the award. The NGA also contains important contact information for the program officer/agency contact and grants management specialist.

For most federally funded grants, there will be a NGA for every budget period of the award. Be sure to read each notice of grant award carefully; as the awarding agency may place restrictions on project activities until certain requirements (e.g., IRB approval) are completed.

Actions When Notice of Grant Award is Received

All award notifications must be processed through the Financial Manager (FM). When a Principal Investigator (PI) receives an award notice, it must be immediately presented to the FM for processing. A budget number will be set up. Unless specified in the award notice, no spending can occur prior to the grant start date.

Directions are available at the JHMIRB website: <http://irb.jhmi.edu/> for assistance with JHMIRB applications and help in writing a consent form. Additionally, consultation is available at the CNR. Contact the CNR Senior Administrative Coordinator for assistance.

If applicable, the Financial Manager will negotiate agreements/contracts where subcontracts are involved.

Principal Investigator’s Obligation as Grantee

Read the Terms and Conditions of the award before beginning the project. Be sure to comply with the specific terms and conditions of each award as stated in the contract or grant documents and with all administrative requirements, as set forth in various sponsoring agency and campus policy statements. These conditions and requirements will concern issues such as publication, intellectual property, equipment screening, proprietary data, consultants, human subjects, animal subjects, recombinant DNA, or regulated substances.

Understand and comply with the reporting requirements of the contract or grant which may include periodic progress reports, reports of project accomplishments, reports of interventions, reports of publications generated, reports of major items of equipment acquired, and financial reports. A final progress report and financial status report upon conclusion of the project may also be required. All project records must be kept accessible after the project is finished.

If applicable, periodically visit the NIH website listed on the Notice of Grant Award to read NIH notices for policy changes that may affect the project.

The principal investigator (PI) is responsible and accountable for the proper conduct of the research project. The PI has considerable freedom to conduct the project, such as hiring and training the staff. However, some actions require prior approval from NIH as they constitute a change in the scope of the project. These are listed at the [NIH Administrative Requirements](#) website and include such actions as a change in the principal investigator, a change in the specific aims of the project, etc. If in doubt about whether a contemplated change requires prior approval, contact the program officer for clarification.

Reporting Requirements

It is the PI's responsibility to complete all progress reports by the agency's required due date. The due date of progress reports to NIH is set by the agency. Check for "pending progress reports" at their website: http://era.nih.gov/userreports/pr_due.cfm. Hopkins Institutional Profile File (IPF) number is 4134401. The reports are generally due two to four months before the year end date, depending on the agency. The NIH notice of grant award will provide some guidance of what format to use, i.e. A) "SNAP" (Streamed lined Non-competing Award Process) or B) Specific Instructions, at <http://grants.nih.gov/grants/funding/2590/2590.htm>

Other award notices from foundations and/or other agencies should include complete reporting guidelines and forms.

Account Management

The PI's Department Administrative Manager or Administrative Coordinator is trained to process all purchases and invoices for faculty members. They will file documentation and match the receipts monthly to the financial statements obtained through HopkinsOne Business Warehouse. The PI should initial the statement, verifying the accuracy of the report and matching documents. All discrepancies must be discussed with the Financial Manager. The review of financial statements is a good opportunity to review categories of over- or under-spending.

The assigned Financial Manager will generate budgets in HopkinsOne for all awards. The Department Administrative Manager will meet with the PI, the FM, the Project Coordinator, and the Administrative Coordinator quarterly (at a minimum) to review the status of the budgets. The discussion will include the following:

- Managing payroll forms to ensure appropriate charges are timely applied for all internal and external supported effort.
- Reviewing actual and encumbered expenses for the current grant year.
- Monitoring subcontractor expenses (PI should sign-off on invoices).
- Preparing expense projections.
- Monitoring billing and collections for grant.
- Pre-planning for continuations and/or no cost extensions.
- Pre-planning for account close out within 3 months of grant ending.
- Processing all required close out entries and submit final financial status report.
- Approving Financial Status report prior to submission to sponsor.
- Discussing any anticipated proposal submissions for the future.

Effort Reporting

The PI should review the "Other Support" documents for accuracy (internal and external) in comparison to effort reporting before certifying. If errors are observed, please contact your FM before certifying.

Hiring and Training the Research Team

One of the first objectives of a newly funded project is to hire and train the research team members who are not already part of the project. Although the PI may feel some urgency to accomplish this task, it takes time and effort to create new positions through the Johns Hopkins University Office of Human Resources, advertise, interview applicants, and carefully select appropriate research staff. Also, the University is required to follow certain federal guidelines and comply with affirmative action and EEOC standards. Grant staff are employees of the School of Nursing and all grant positions must be advertised within the University following standard procedures. The HR Coordinator in the School of Nursing Business Office is in charge of personnel issues and is available to consult with PIs during the hiring process.

The first step in the process is the development of an appropriate job description for all positions to be filled. Ms. Biglari has the forms for this and can advise investigators about appropriate descriptions and salary ranges. Job descriptions are submitted to the Business Office and are forwarded to the University Office of Human Resources where a staff member is assigned to the job and the advertisements are prepared. This staff member will review applications and forward to the PI those meeting the position requirements. If a qualified person is identified prior to beginning the process, refer that person to the staff member at the office of HR where they will be directed to complete an application. Remember that all positions must be posted by the university. **DO NOT ADVERTISE POSITIONS WITHOUT GOING THROUGH THE BUSINESS OFFICE AND DO NOT ACCEPT APPLICATIONS DIRECTLY FROM INDIVIDUALS.**

When the decision to hire an applicant is made, notify the office of HR to make the job offer. When selecting a candidate, please be sure that the minimum job requirements stated on the job description are met. International students must have an appropriate work visa to become university employees. The Institute for Johns Hopkins Nursing offers a certificate program to train research coordinators, research nurses, and other study personnel. Contact the Institute for additional information.

All new employees are on probation for the first 90 days of university employment. The PI is responsible for evaluating the employee at the end of the 90 days on a form that will be sent to the PI from the Business Office. The PI should use this opportunity to re-evaluate the decision regarding this individual's suitability and performance in relation to the job skills needed for the position. If there are problems with a new employee, do not wait to counsel them, discuss the issues, or record the circumstances. Consult the CNR or the Assoc. Dean for Finance and Administration for assistance. Thereafter, reviews are completed annually.

Timesheets for hourly employees must be completed and signed by the PI every week.

Consultant Work

No work shall be completed by consultants until they have been set up as vendors in the HopkinsOne system and issued a vendor number. Forms must be completed by the PI and the consultant. This process can take up to 3 weeks. Please allow time for processing. Forms can be found at <http://ssc.jhmi.edu/accountspayable/forms.html>.

Research Training Compliance

The Government, the funding agency, and the University require that all research staff complete certain research training. It is the PI's responsibility to assure that all members of the research team are in compliance with the training requirements. The SON Research Administration, Senior Administrative Coordinator to the Assoc. Dean for Research will monitor that all are in compliance and send quarterly requests for updates on new team members and proof of compliance. Not being in compliance could potentially prevent a project from being funded or suspension of funding to an existing project. The website where these trainings are located is: <https://secure.lwservers.net/>.

The Research Compliance Training Courses required are:

- General Privacy Issues- must be completed by all research team members.
- Human Subjects Research- must be completed by everyone on a research project involving human subjects.
- Animal Care and Use- must be completed by everyone on a research project involving animal subjects.
- Course on Research Ethics- to be completed by all PIs and Fellows.
- Effort Reporting - must be completed by all research team members other than students.
- Conflict of Interest – must be completed by all faculty members
- Privacy Issues Relating to Research/ HIPAA & Research - must be completed by all research team members.
 - *Please note that the HIPAA & Research course was implemented in September 2007 and replaces the HIPAA Privacy Issue Relating to Research course (IRR). If you have taken the IRR course, you are not required to take the new HIPPA and Research course. If you need to take this training it is available online at <http://www.jhminteractive.com/INT/>*

Monitoring Progress of the Study

The principal investigator is responsible and accountable for the proper conduct of the research project, including monitoring the progress of the study. A monitoring plan should be developed for the project as part of the Manual of Operations. The PI should meet regularly (e.g., at least monthly; weekly is recommended) with the research team to monitor all aspects of the project including subject accrual, adverse events, data management, and compliance with regulatory requirements such as IRB approval, HIPAA regulations, and regular reports.

If the study is a Phase III clinical trial, a Data and Safety Monitoring Board (DSMB) is required and one may be advisable for some Phase II clinical trials. A DSMB meets at predetermined intervals as needed during the course of the trial to monitor adverse events and other safety issues as well as data quality and study outcomes.

Appendix B: Computer Network Services Checklist

(Completed by Computer Network Services personnel)
(Submitted to Financial Manager)

Declared budgetary limit on the system _____

Recommended Base system:

Dell OptiPlex Pentium 4

512 MB (1 DIMM)

3 yrs parts & onsite labor

Monitor: _____

Boot hard drive: _____

Floppy drive: _____

CD-ROM: _____

Operating System: Windows 2000 Professional SP

Need other software? _____

Writeable CD drive? _____

Printer needed? _____

Web Site requested? _____

Estimated Hours required: _____

Special Project assistance (ex: teleform)? _____

Estimated Hours required: _____

Teleform Needs: _____

Database Needs: _____

Appendix C: Procedures for Subcontracts

Section 1: JHU Subcontracts work to an outside institution (JHU is the Principal Institution):

If a portion of the workscope other than the services of a consultant is to be provided by an institution outside of J.H.U., the costs should be budgeted under “subcontracts” and a formal subcontract will be required if the grant or contract is awarded. The collaboration is ordinarily such that the P.I. on the subcontract will assist in designing the project, participate in the project on an ongoing basis, and expect to be named as a co-author on publications.

Part I (Responsibility of PI and Financial Manager):

The following items are needed from the subcontractor at the time of proposal submission:

1. A letter of intent from the subcontractor indicating their willingness to collaborate on the project (signed by both the other institution's P.I. and Institutional Official, as well as the JHU Institutional Official), including the following required wording if the proposal is to an NIH/PHS agency: "The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."
2. A budget specifying both direct and facilities and administrative (Finance & Administration) costs.
3. An Abstract or description of the Workscope.
4. Other Support.
5. Biographical Sketch.
6. Resources and Environment.
7. Relevant Human Subject IRB approval and Vertebrate Animal IACUC protocol approval.
8. Checklist (showing calculation of the Finance & Administration).

The total costs (direct and indirect) should be entered in your direct cost budget under the category "Consortium/Contractual Costs," e.g., "Subcontract, University of XYZ: \$25,000." The first \$25,000 of each subcontract, per project period, is included in the indirect cost base.

Part II (Responsibility of Financial Manager):

Administrative Process once grant is awarded:

1. Financial Manager uses a “Subcontract Checklist” as a guide.
2. The FM issues formal subcontract request to cooperating institutions, negotiates any budget, terms and conditions revisions if necessary, and issues the purchase order.
3. When the subcontractor has returned the fully executed copies of the subcontract a copy will be kept in the Research Administration files.

Section 2: Outside institution subcontracts work to JHU (Outside institution is the Principal Institution):

Other institutions may request a subcontract proposal for purposes of collaboration on their research grants or contracts. Such proposals must be processed through the Financial Manager.

Part I (Responsibility of the PI and Financial Manager):

Include an application Face Page pertinent to JHU as the subcontracting institution, a budget specifying both direct and Finance & Administration costs (expressed as a dollar amount, not just as a percentage), a description of the Workscope, Other Support, Biographical Sketch, Resources and Environment, and a Checklist. For NIH and other PHS agencies, the Principal Investigator will need to express his willingness to collaborate on the project by also including a covering letter (signed by both the other institution's P.I. and Institutional Official, as well as the JHU Institutional Official) with the following required wording:

"The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."

Part II (Responsibility of the Financial Manager):

Administrative Process once grant is awarded:

1. Faculty member notifies the Financial Manager of award and provides prime contact information.
2. Prime sends the Financial Manager award package, which includes a copy of original Notice of Award.
3. The Financial Manager receives the formal subcontract from the prime institution, negotiates terms and revisions.

Appendix E: Sample Electronic Information Sheet (eIS)

(Completed by Principal Investigator and submitted to the Finance & Administration

eIS ID: K _____ Compliance Section

Help and where to find more information is provided at the end of this document.

Will the project involve or require any of the following?

Check one:	
Yes___No___	1. To the best of your knowledge, do any participating personnel, or their spouse or dependents, have any financial interest in the sponsor or other entities having a financial interest in any intellectual property, product or service which is a subject of the proposed research? If Yes, a disclosure statement is required.
Yes___No___	2. Use of human subjects via contact and/or survey, use of human tissue, serum, or other fluids? If Yes: Protocol (#1) _____ Status: Not submitted___ Submitted___ Approved___ IRB: _____ Application/Protocol# _____ Senior PI _____ Approval Date (mm/dd/yy) ___/___/___ <OR> Exemption# _____
Yes___No___	3. Does this project involve disclosure of protected health information to sponsor or third parties?
Yes___No___	4. Use of live vertebrate animals? If Yes: Protocol (#1) _____ Status: Not submitted___ Submitted___ Approved___ Application/Protocol# _____ Senior PI _____ Approval Date (mm/dd/yy) ___/___/___
Yes___No___	5. Use of Infectious Agents or bio-hazardous materials? If Yes: Approved___ Pending___ Approval # _____ Approval Date(mm/dd/yy) ___/___/___
Yes___No___	6. Use of radioactive materials? If Yes: Approved___ Pending___ Approval # _____ Approval Date(mm/dd/yy) ___/___/___
Yes___No___	7. Use of hazardous and highly-toxic chemicals (e.g., carcinogens, mutagens, chemicals NIOSH IDLH level)? If Yes: Approved___ Pending___ Approval # _____ Approval Date(mm/dd/yy) ___/___/___
Yes___No___	8. Use of recombinant DNA? If Yes: Approved___ Pending___

	Approval # _____ Approval Date(mm/dd/yy) ___/___/___
Yes___No___	9. Need for alterations, renovations, additional electrical or steam service? If Yes, Please Describe: Location: _____ Facility cost estimate acquired? Yes___ No___ Cost in budget? Yes___ No___ Explanation: _____
Yes___No___	10. Equipment cost over \$5,000 for the proposed project?
Yes___No___	11. Are any administrative costs included in the budget? If Yes, a justification must be included.
Yes___No___	12. Do you anticipate that program income will be generated under this project? If Yes, please identify income: _____
Yes___No___	13. Subawards or subcontracted efforts to other organization? If Yes, supporting documentation is required.
Yes___No___	14. In this project, will you be utilizing information provided under a Confidentiality Agreement? If Yes, please provide the name of company or institution: _____
Yes___No___	15. In this project, will you be utilizing materials provided under a Material Transfer Agreement? If Yes, please provide the name of company or institution. _____
Yes___No___	16. Do you anticipate that this project will involve an existing JHU invention (yours or another investigator's) or other intellectual property? If Yes, please identify JHU reference number: _____ Use disclosed to the Division of Licensing and Technology Development? Yes___No___
Yes___No___	17. Additional space in any project location? Institutional approval acquired? Approved___ Pending___ Description: _____
Yes___No___	18. Will you require a federal license to export information or technology (either to a non-US location or to a non-US citizen, regardless of location)?
Yes___No___	19. Will you need a license because you or a member of your research team may be traveling to or sponsoring an activity (e.g. a conference or meeting) in a country on the US Embargoed Nations list?

Additional Information

1. Conflicts of interest
See http://www.jhsph.edu/schoolpolicies/ppm_faculty_4_conflicts_of_interest.shtml
To download conflicts of interest form, click [here](#)
2. Human subjects
See <http://irb.jhmi.edu/>
3. HIPAA (Health Insurance Portability Accountability Act)
See <http://www.jhsph.edu/hipaa>
4. Animal use
See <http://www.jhu.edu/animalcare/>
5. JHU Health, Safety & Environmental
Environmental Health Officer (EHO) of the Health, Safety and Environment, 2024 East Monument Street, Ext. 5-5918
<http://www.hopkinsmedicine.org/hse/>
Radioactive materials The Radiation Control Unit (RCU) administers the radiation control program at The Johns Hopkins Medical
6. Institutions, procures radioactive materials, and provides for radioactive waste disposal. Forms for projects that involve radiation exposure to human subjects are available at <http://irb.jhmi.edu/Forms/index.html>
The manual may be obtained at <http://www.hopkinsmedicine.org/hse/manuals.htm>
7. Hazardous and highly-toxic chemicals
Researchers who use toxic chemical agents or materials in quantities and procedures which may lead to environmental perturbation or which may have acute or chronic toxicity to workers by inhalation, skin absorption or ingestion exposure should notify the Environmental Health Officer (EHO) of the Health, Safety and Environment, 2024 East Monument Street, Ext. 5-5918. Forms for registration of Hazardous and Toxic Chemicals and the criteria for chemicals meeting HSE requirements for registration are available at <http://www.hopkinsmedicine.org/hse/>
8. Recombinant DNA
The Institutional Biosafety Committee, reviews research registrations involving recombinant DNA. The form and a copy of the latest NIH Guidelines for Research Involving Recombinant DNA Molecules may be obtained from the Biosafety Officer, Ext. 5-5918 or downloaded from the HSE Web Site <http://www.hopkinsmedicine.org/hse>
9. Renovations Include cost estimate for renovations prepared by Facility Management Office.
10. Equipment cost An article of tangible, nonexpendable, personal property that has a useful life of more than 1 year and an acquisition cost of >\$5,000 or more per unit.
11. Administrative cost
The direct charging of these costs may be appropriate where the nature of the work performed under a particular project requires an extensive amount of administrative or clerical support that is significantly greater than the routine level of such services provided by academic departments
12. Program income
Program income is the gross income earned by a recipient that is directly generated by a supported activity or is earned as a result of an award. <http://www.controller.jhu.edu/progrinc.pdf>
13. Subawards
The following items are needed from the subcontractor at the time of proposal submission:
A letter of intent from the subcontractor indicating their willingness to collaborate on the project (signed by both the other organization's P.I. and Institutional Official, as well as the JHU Institutional Official), including the following required wording if the proposal is to an NIH/PHS agency: "The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the NIH consortium grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy."
 - A budget specifying both direct and indirect costs.
 - An Abstract or description of the workscope.
 - Other Support.
 - Biographical Sketch.
 - Resources and Environment.
 - Relevant Human Subject IRB approval and Vertebrate Animal IACUC protocol approval.
 - Checklist.
 - Subcontract Information Sheet document <http://.....>
14. Confidentiality Agreement
Confidentiality agreements that relate to ongoing research at Johns Hopkins or potential research at Johns Hopkins should be sent to the

Office of Research Administration.

Confidentiality agreements that relate to technology licensing should be sent to the Office of Licensing and Technology Development.

NDA/Conf Agreement: http://www.ltd.jhu.edu/business_partners/nda.html

15. Material Transfer Agreement

Following link allows you to create an MTA, sign the agreement electronically, and then obtain the electronic signature of your institution's authorized representative (if needed). Hopkins MTAs are to be used only for transfers of materials to investigators at academic or non-profit institutions for internal, non-commercial research purposes. <http://webapps.jhu.edu/mtaonline/>

16. JHU Invention To report new intellectual property, a Report of Invention (ROI) must be completed which includes assignment of ownership interest to the University.

Mail your report of invention to:

Director,

Johns Hopkins University

Licensing Technology and Development

100 North Charles Street, 5th Floor

17. Additional Space

Approval must be obtained prior to submitting a proposal.

Appendix F: Faculty and Staff Directory

Center for Nursing Research

Personnel & Contact Info	Title
Jerilyn Allen, ScD 525 N. Wolfe St., Rm 304 Baltimore, MD 21205-2110 P: 410-614-4882 F: 410-614-1446 E: jallen@son.jhmi.edu	Associate Dean for Research
Gayle Page, RN, DNSc, FAAN 525 N. Wolfe St., Rm 301 Baltimore, MD 21205-2110 P: 410-955-7484 F: 410-614-1446 E: gpage@son.jhmi.edu	Director
Maggie Denny 525 N. Wolfe St., Rm 306 Baltimore, MD 21205-2110 P: 410-955-7484 F: 410-614-1446 E: mdenny1@son.jhmi.edu	Senior Administrative Coordinator for the Center of Nursing Research and the CNR Director
Rose Previte 525 N. Wolfe St., Rm 306 Baltimore, MD 21205-2110 P: 443-287-2902 F: 410-614-1446 E: renglun1@son.jhmi.edu	Senior Administrative Coordinator for the Assoc. Dean for Research

SON Office of Finance & Administration

Personnel & Contact Info	Title
Claire Bogdanski Finance & Administration 525 N. Wolfe St., Rm 338 Baltimore, MD 21205-2110 P: 410-955-7535 F: 410-614-7088 E: cbogdan1@son.jhmi.edu	Associate Dean, Finance & Administration

Ruth Hurd Finance & Administration 525 N. Wolfe St., Rm 339 Baltimore, MD 21205-2110 P: 410-614-1447 F: 410-955-9177 E: rhurd1@son.jhmi.edu	Financial Manager Research Administration
Sharon Ennis Finance & Administration 525 N. Wolfe Street, Rm 333 Baltimore, MD 21205-2110 P: 443-287-0173 F: 410-955-9177 E: sennis1@son.jhmi.edu	Financial Manager Research Administration

SON Office of Development

Personnel & Contact Info	Title
Fiona Newton Office of Development 525 N. Wolfe St., Rm 529 Baltimore, MD 21205-2110 P: 410-614-0878 F: 410-614-9704 E: fnewton1@son.jhmi.edu	Associate Dean, Development & Alumni Relation
Lisa Russell O'Shea Office of Development 525 N. Wolfe St., Rm 530 Baltimore, MD 21205-2110 P: 410-614-6363 F: 410-614-9704 E: loshea@son.jhmi.edu	Sr. Associate Director of Development