

School of Public Health & Health Services

THE GEORGE WASHINGTON UNIVERSITY

GW SPHHS RESEARCH OPERATIONS GUIDELINES:

Grant and Contract Proposals and Awards

Issued by: Dean's Office, Associate Dean of Research

Date: 4/15/13 v.1

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GW SPHHS RESEARCH OPERATIONS GUIDELINES:

Grant and Contract Proposals and Awards

There are several steps that must be followed to identify a potential funding opportunity, to process and submit a proposal to a sponsor (pre-award), and to manage a grant once funded (post-award). Multiple individuals within the various departments, the School, and the University have responsibilities for each step in the process. The following guidance is intended to lead investigators through the key processes of proposal and grants management.

I. Levels of Responsibility

A. Principal Investigator

A Principal Investigator (PI) per GW Faculty Handbook (2004, Section 5.2) "... **must be a regular or research professor (rather than in limited-service status) or have an appointment as a research scientist or higher.**" Faculty members are encouraged to seek clarification from department chairs if they are uncertain as to their faculty status. As soon as a PI makes a decision to apply for a sponsored project, s/he should inform the Department Chair and the Administrative Manager (or other administrative staff per Department policy) so that appropriate resources and support are allocated. PIs who intend to submit large, complex grant proposals (e.g., for Centers, Program Projects, or other multi institutional initiatives) should also notify the Associate Dean of Research as early as possible. When a student is indicated as PI (such as for a dissertation grant) s/he must also have a GW faculty member noted as the internal PI of record.

In terms of pre-award responsibilities, the PI prepares the technical narrative and drafts the budget to support the proposed activity. The PI also identifies the need for subcontracts, collaborators, and additional space or funding requirements. In certain circumstances, the PI should discuss needs (e.g., space) with the Associate Dean of Research in advance of preparing the proposal. The PI must approve all proposal forms and required regulatory forms as prepared by the assigned grants administrative staff, and confirm that the proposal conforms to a sponsor's technical and administrative requirements as prepared by the administrative staff. As a part of post-award management, the PI is responsible for the overall management of the scientific, technical, financial, compliance, and administrative aspects of the sponsored research program in accordance with relevant federal and/or sponsor regulations, University Policy and the Faculty Handbook. This includes preparing technical reports, monitoring sub-awardee performance, and maintaining communication with the Office of the Vice President of Research (OVPR) and the School of Public Health and Health Services (SPHHS) administrative staff on all fiscal and personnel matters.

B. SPHHS and Department Sponsored Project Staff (Local Administration)

Staff in the Dean's Office and across departments comprise 'Local Administration'. Local administration includes positions such as department managers, finance administrators, and other staff that function in various roles in pre- and post-award management processes. In the pre-award phase, duties range from having primary responsibility of task completion, giving approvals for certain tasks or processes, or providing support or consultation for tasks or processes. Specific responsibilities may include preparing budgets; completing and compiling sponsor- or GW-required forms; and submitting the proposals, among other administrative tasks. During post-award phases, responsibilities may include monitoring sub-awardee financial performance, acquiring and providing background documentation to support requests for purchase order creation, processing Procurement Credit Cards (PCards), processing encumbrances and clearing transactions. **All faculty have designated points of contact for grants management.** Refer to list of "**Points of Contact**".

C. Office of the Vice President for Research Staff

The SPHHS has specific points of contact in OVPR. Refer to "**Points of Contact**" on the SPHHS Research Resource Portal for the most current list. Their duties range from having primary responsibility of task completion, giving approvals for certain tasks or processes, or providing support or consultation for tasks or

processes. Specific responsibilities during pre-award phases include tasks such as reviewing and approving proposals; prequalifying sub recipients; submitting proposals; and negotiating/accepting the terms and conditions of the award. Post-award responsibilities include tasks such as establishing sub-award agreements, preparing financial reports, and closing out awards. Refer to the [OVPR website](#) for additional information.

D. Grants and Contracts Accounting Services (GCAS)

GCAS has the primary responsibility of the financial management of sponsored project funds. [GCAS](#) is primarily involved in the post-award phase and works closely with OVPR. Responsibilities include establishing and administering financial policies and procedures, including negotiating the University's facilities and administrative costs (indirect costs) and fringe benefit rates with the federal government; preparing and filing financial reports; issuing sponsor invoices; reviewing new awards and award modifications; and ensuring that proper payment is received from research grants.

II. Pre-award Processes

A. Locating Funding

SPHHS investigators may explore potential funding sources using a variety of resources (e.g., <http://www.grants.gov> and <http://www.scangrants.com>). The SPHHS's Research Office also provides extensive resources on its ongoing, interactive [Research Accelerator Blog](#) hosted by the Associate Dean of Research. *Moreover, we encourage all faculty to register with GW's PIVOT service.* The Office of the Vice President for Research provides this subscription-based service with more than 25,000 funding opportunity records. PIVOT develops a draft of the professional profile for all GW faculty. You simply log in and claim your profile at <http://pivot.cos.com>. Claiming your profile will unlock additional services, such as tailored searches, lists of potential collaborations here at GW and elsewhere, and it will also maintain up-to-date publication listings. If you need help with PIVOT, please contact Laura Walker in OVPR (alwalker@gwu.edu). OVPR provides additional resources for locating [funding](#).

B. Determining Proposal Types

The SPHHS supports and encourages a diverse portfolio of proposals, including:

- **Solicited Proposals** are submitted in response to a particular program announcement or request for proposal. The sponsor seeks proposals in a certain area with specific deadlines, guidelines and requirements for proposal preparation and submission. These proposals are usually, but not exclusively, associated with federal agencies and the US DHHS.
- **Unsolicited Proposals** are initiated by a faculty member without a specific request from the sponsor. However, they are usually aligned with broad sponsor missions or focus areas. The proposals are often associated with private organizations and foundations. Most of these sponsors have general requirements for submission of unsolicited proposals.
- **Invited Proposals** are specifically directed to faculty by the sponsor, and are often related to prior work or relationships with between the PI and the sponsor. They usually focus on the PI's unique capabilities. These solicitations typically include foundations or other private organizations. Read more below on "[Award-proposal combinations](#)."

GW provides distinct guidance on the *difference* between [gifts and grants](#). In addition, GW provides guidance on various types of [funding mechanisms](#).

C. Pre-routing Essentials

1. Engaging grants management staff

It is very important for a PI to contact the designated departmental grants administration staff as early as possible. Early engagement of staff increases the likelihood that your proposal routing and submission will go

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smoothly. The SPHHS Research Office maintains a list of [SPHHS Sponsored Projects Staff Points of Contact](#). **Note: This list is subject to change so be sure to verify contacts with your department administrator and also confirm any other pre-routing requirements established by your department.**

2. Full scientific review of proposals and copy editing

The SPHHS offers provisions for comprehensive scientific reviews of proposals. If a PI wants a proposal to receive in-depth internal or external **scientific review**, please contact the Associate Dean of Research at the time of the decision to pursue the application. The Dean's Office requires a minimum of four weeks to obtain external scientific reviews; internal scientific reviews require a minimum of two weeks. Completed research plans/narratives must be provided if a PI requests scientific review. The Associate Dean of Research will work closely with the PI to determine appropriate reviewers. OVPR may also provide scientific reviews through the Research Enhancement Unit—the same lead-time applies to these internal reviews. Arrangements also can be made for **copy edit review** of proposals. Contact the Associate Dean of Research at least three weeks prior to the proposal due date to discuss options.

3. Locating biostatistics support and other resources

The SPHHS has an invaluable resource in the **Biostatistics and Epidemiology Consulting Service (BECS)** which is embedded in the GWU Department of Epidemiology and Biostatistics. BECS provides biostatistical, epidemiological, and study design support for health-related research projects. Currently, pre-award services are available free of charge to our investigators, but it is important that you plan ahead and contact the BECS director, Dr. Sam Simmens (simmens@gwu.edu) promptly upon decision to prepare a proposal. Also, the SPHHS provides investigators numerous templates and resources through the **Research Resources Portal** (under development) including sample proposals, form templates, and facilities and resources sections, among other grant writing resources.

D. Routing Proposals

GW requires faculty, staff, and student PIs to route all proposals for external funding through the following internal levels for review and approval prior to submission:

- PI and all co-investigators
- Division and Department for each PI and co-Investigator
- School for each PI and co-Investigator
- OVPR

This requirement applies to all new, continuation, renewal, revised, and supplemental grants for research, training, fellowships or other proposals for all types of external research funding sources, including governmental, nonprofit, commercial, or private foundations. Investigators are encouraged to review additional guidance on [OVPR's website](#). GW's routing process involves **review and approval of all proposals** at the level of the **departments, the Schools, and OVPR**. Currently, routing is facilitated by the OVPR Proposal Routing Form). The SPHHS requires that PIs adhere to routing procedures and timelines shown in Figure 1. No proposal, regardless of the type, can be negotiated with a sponsor or awarded without going through the routing process.

The **role of the Dean's Office** in routing (specifically the Associate Dean of Research) includes the following:

- Confirming the individual's eligibility to be a Principal Investigator
- Determining the proposed project alignment with the SPHHS-wide strategic plan/mission
- Assessing the proposed commitment of effort, space, equipment, and other resources committed
- Approving any funds committed as cost sharing
- Ensuring the proposal conforms to SPHHS policies and sponsor guidelines
- Confirming budget accuracy—including salary, fringe benefits and F&A

Key elements of the routing process:

1. Timeline (the 5-day rule)

Proposals should be submitted to SPHHS Dean's Office through the SPHHS's OVPR Sponsored Project Team (Manager, Tracy Clark and Mary Gardner, Sponsored Project Administrator) in ***complete and final form no later than 5 business days*** prior to the agency deadline. Approvals must be granted by the Associate Dean of Research and a representative of the Sponsored Project Team before it is further routed through OVPR for final approval. **It is important to underscore that when proposals reach the level of approval by the SPHHS's Sponsored Project's Team and the Associate Dean of Research applications must be fully completed**. Please note that the Associate Dean of Research reviews submissions in unison with the sponsored project team and within the 5-day window. Also, a near final draft of proposal narratives may be submitted for review. OVPR will strictly reinforce the directive which is detailed in the faculty handbook. *Complex projects, such as program project or center grants, require a longer review period. Pls should contact the Associate Dean of Research to assure that the appropriate timeline and adequate resources are arranged for these types of applications.* **Plan accordingly to be sure that department administrators also have enough time to meet the 5-day rule.** These requirements facilitate positive workflow and efficiency that foster not only the quality of the PI's proposal but the SPHHS's overall research culture, productivity, and credibility. The required timeline for internal routing ensures that proposals receive adequate compliance review and head off potential problems negatively affecting the application. See additional guidance at <http://research.gwu.edu/five-day-submission-deadline>. Refer to Figure 1. Also, see the ***SPHHS Routing Process*** document, linked from the Appendix.

Proposals, in paper or electronic form, should be submitted to OVPR Sponsored Projects in **final form**^[1] 5 full^[2] business days to the appropriate Sponsored Projects Administrator in OVPR prior to the funding agency deadline. **“Final Form” Routing Packet contains:**

- A signed and completed GW Routing Form
- FINAL Sponsor's form pages
- FINAL GW internal budget form
- FINAL Budget justification (if applicable)
- DRAFT proposal narrative (Including detailed Scope of Work)
- FINAL Collaborators' Letters of Intent
- FINAL statement of work
- FINAL budget
- If PHS Funded^[3]: documentation of all Financial Conflict of Interest documentation and trainings completed^[4]
- If applicable: Requests for Indirect Cost Waivers, Minimum Effort Waivers, and Publication Waivers

NOTE: Minor modifications to the final *proposal narrative* may be accepted by OVPR Sponsored Projects no later than two (2) full business days prior to the funding agency deadline.

If the proposal is not submitted by the five day deadline, consequences may include: (a) return to the PI, (b) submission with minimal or no OVPR review, (c) withholding from submission if the proposal does not conform to sponsor guidelines and regulations and/or GWU policy, (d) post-submission scrutiny which may result in withdrawal from competition by GWU, (e) if awarded, a delayed start date because of additional time needed to review terms and conditions.

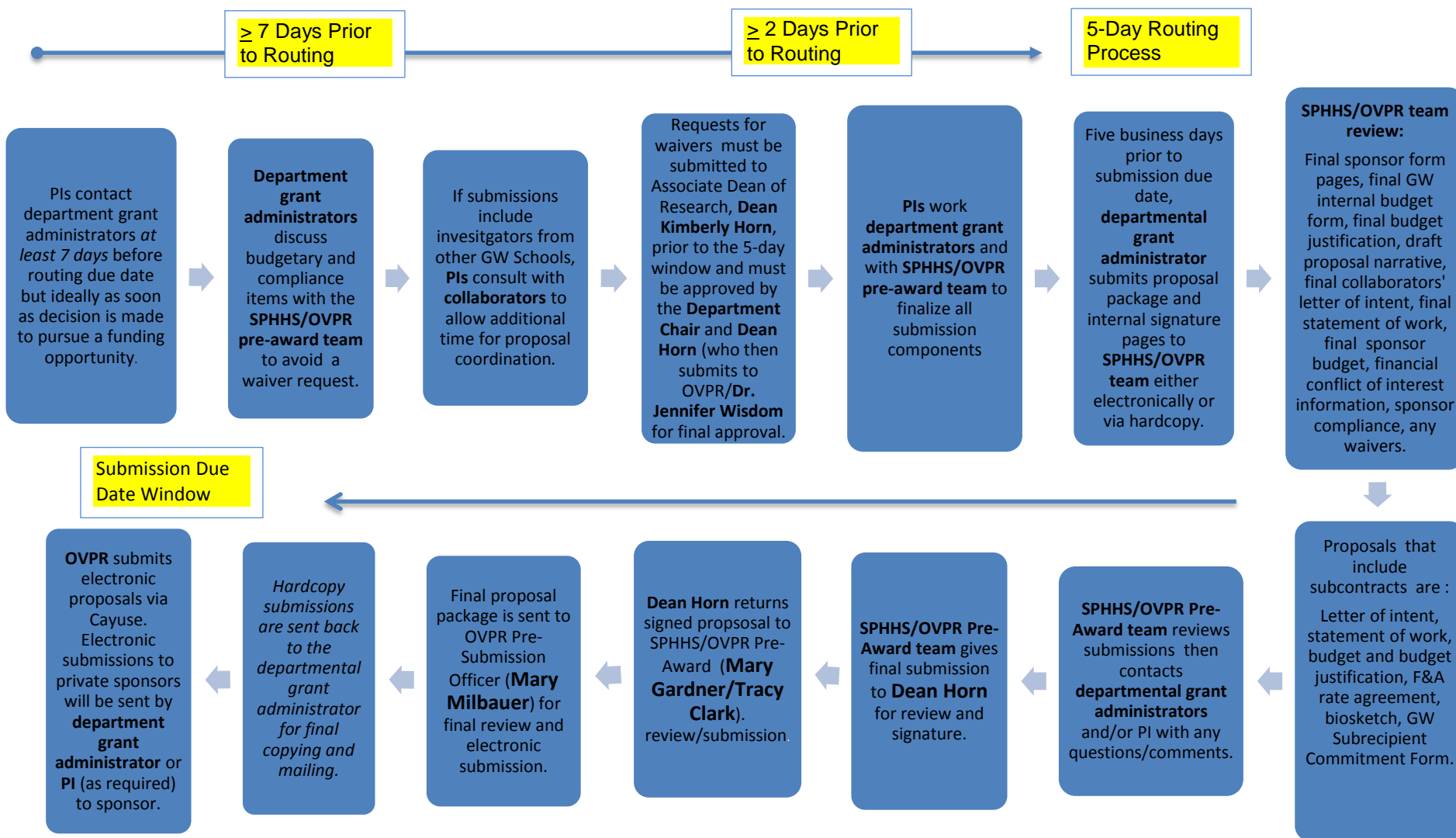
[1] SPHHS and OVPR allow PIs to make minor changes to the routed body of proposal up to the time of submission, but any last minute changes to internal or external budgets must be re-routed with assurance that PI and other affected parties have approved the changes. [2] See Faculty Handbook: Section 5-2 "Administrative Support Structure for Research". [3] And other agencies/entities that have adopted PHS FCOI regulations. [4] For "Investigators" as defined by 42 CFR Part 50 and 42 CFR Part 94.

2. Exceptions

Under *rare* circumstances, PIs may request submission of proposals outside of the 5-day window. ***This scenario, for instance, is more likely to occur under the circumstance of “award-proposal combinations” than on federal grant applications with well-established rolling deadlines.*** The PI must

request and receive approval in writing *via email* from the Department Chair, the Associate Dean of Research, and the Associate Vice President of Research before the 5-day window. Permission for late routing will be considered but may not be approved; approval is contingent upon a variety of factors and should be considered by PIs as a *high-risk request*. If approved, late proposals may also receive a limited review, which could negatively affect proposal compliance and, in turn, result in rejection by the sponsor. ***When rapid-response opportunities arise, it is very important to communicate promptly with the Associate Dean of Research.***

FIGURE 1: SPHHS ROUTING PROCESS FOR PROPOSAL SUBMISSIONS



3. Required forms and templates

OVPR provides a variety of required [forms](#) for proposal submission. Also, the SPHHS provides investigators numerous templates and resources through the [Research Resources Portal](#) (under development) including sample proposals, form templates, and facilities and resources sections, among other grant writing resources.

4. Cost Share

The SPHHS adheres to OVPR's requirement that all cost sharing approvals on extramural grant applications must be obtained in writing from the PI's Chair and Associate Dean of Research as well as the OVPR. It is expected that these approvals are obtained as early in the development of a proposal as possible; estimated cost share commitments are acceptable and may pertain to costs such as salary, rent, IDC, and fringe benefit rates. Upon making these requests, it is important for the PI to indicate whether the cost share is mandatory or voluntary. See additional [OVPR guidance](#) or [University guidance](#).

5. Negotiating Indirect Costs with sponsors

There are situations where a sponsor does not accept GW's federally negotiated IDC rates. In this case, when a sponsor does not have a published policy on what they allow to be charged as indirect costs, then the negotiation of the IDC is handled through OVPR by individuals who are authorized to negotiate on behalf of GW. To begin this process, the PI must submit a request to waive the IDC to the SPHHS Associate Dean of Research. If approved at the level of the SPHHS, the request must subsequently be approved by the Associate Vice President of Research, then officially negotiated. *It is important to underscore that every effort should be made to achieve budgeting goals without voluntarily foregoing university IDC.* Information is available in regards to [SPHHS F&A transitioning plans and F&A rates](#).

6. Signatures

Original signatures on required internal and external forms are preferred and should be obtained whenever possible. Signatures must be obtained prior to routing the proposal to OVPR. In rare circumstances where a PI is not available to sign documents, signature authority may be delegated in writing or via email to an individual for signing or approving on his/her behalf. This may occur using time stamps, e-signatures, or email. *It is important to underscore that PIs, Department Chairs, or other faculty or staff employees of GW are not authorized to and should never sign a sponsored program proposal, contract or grant on behalf of the University—only OVPR designees have this legal authority.* GW provides additional guidance on "[Who can sign on behalf of GW](#)".

Officials Authorized to Negotiate (as of 2/1/2013):

- [Dr. Leo Chalupa](#), Vice President for Research (202) 994-7315
- [Dr. Anne Hirshfield](#), Associate Vice President for Research (202) 994-7402
- [Jackie Bendall](#), Director, Sponsored Projects Administration (202) 994-7991
- [Terri Taylor](#), Assistant Director (202) 994-6255
- [Charles Maples](#), Assistant Director (202) 994-3909
- [Sylvia Ezekilova](#), Assistant Director (202) 994-5496

Officials Authorized to Commit the University (as of 2/1/2013):

- [Dr. Leo Chalupa](#), Vice President for Research
- [Dr. Anne Hirshfield](#), Associate Vice President for Research
- [Jackie Bendall](#), Director, Sponsored Projects Administration
- [Terri Taylor](#), Assistant Director
- [Sylvia Ezekilova](#), Assistant Director

7. Paper routing versus electronic routing

The SPHHS uses both paper and electronic routing processes in accordance with OVPR requirements.

[Cayuse 424](#) is a web-based application used to create, review, approve, and submit grant proposals. Cayuse currently supports 95% of all federal agency proposals, including AFSOR, AHRQ, CDC, CDMRP, DARPA, HRSA, NIH, NSF, DOE, DOD, DOS, USAID, and USDA. The SPHHS is currently using CAYUSE for some non-federal proposals. Instructions are available on how to use [Cayuse](#) at GW. **Who submits the final documents?** For proposals that are submitted electronically, the PI must *approve* the final, uploaded

documents before official submission to Grants.gov. In certain circumstances, the PI may delegate the final review task to a colleague; however, the ultimate responsibility for the content of the proposal cannot be delegated. Cayuse interfaces with Grants.gov for final submission of all required documents. At this time, all other proposals are routed in paper form and submitted per the requirements of the sponsor. It is the responsibility of the PI to approve all final documents for submission. *Please note that any last minute changes to the internal or sponsor's budget must be re-routed with documentation that the PI has approved the changes.* Once approved by the PI, electronic proposals are submitted officially by OVPR; paper proposals to private sponsors are mailed by the designated department administrator and a copy of the proposal should be provided to the SPHHS OVPR Sponsored Project Team (Tracy Clark/Mary Gardner). In certain instances, private sponsors may require electronic submission of proposals. These are submitted by the department administrator.

8. Award-proposal combination

In the absence of an official RFA/PA, the PI must provide the SPHHS and OVPR with timely written documentation (email, letter, or memo) addressed to the PI (or designee) from the sponsor explaining (a) parameters of the request, (b) deadline, (c) funding amount, and (d) any other specific requests. This document will serve as a proxy for the RFA/PA. *Investigators are cautioned against working ahead of the contract or proposal award. However, if circumstances necessitate advanced work, the steps for **Administrative Establishments** outlined above should be followed.*

9. Sub-awards

The SPHHS frequently generates proposals involving collaborations with sub-recipients. Establishing these agreements can be complicated and time consuming and are a common reason that proposal routing is delayed if not initiated in a timely manner. **Provide your grants administrators with information about sub-awardees as far in advance of the proposal deadline as possible.** OVPR provides a [checklist](#) for sub-awardee processing. Sub-awardees must adhere to GW's [Subrecipient Compliance Policy](#).

Also note that if the prime award represents PHS funding, the sub-recipient will be required to certify their institution has a policy compliant with the current PHS regulations related to Conflicts of Interest, [42 CFR Part 50 Subpart F](#). If sub-recipient does not have a PHS-compliant policy, the sub-recipient investigators will be subject to the [GWU Conflicts of Interest policy](#) and required to provide [disclosure forms and certifications](#):

- Budget
- Budget justification
- Sub-awardee specific scope of work
- Letter of intent
- [Subrecipient Commitment Form](#)
- Other documents as required by the sponsor

Note: When setting the receipt deadline for these documents from the sub-awardee, allow enough time to incorporate the documents into the GW routing packet.

10. Grants versus gifts

GW defines a Sponsored Project as specific research, training, service, or similar activity for which funding is provided by an external sponsor under an agreement with the University. Both grants and gifts can be considered a sponsored research project. Importantly, status as a gift does not preclude routing through the SPHHS and OVPR. Click here for additional guidance [on grants vs. gifts](#).

11. Inter-departmental/SPHHS collaborations, IDC, and other issues

Whether or not a sponsored project is determined to be On- or Off-campus is based on where the majority of the effort (not dollars), inclusive of all personnel but excluding sub recipients and independent contractors, is performed. This also includes *Cost Sharing*. When a proposal involves investigators or personnel from multiple units or departments, we use the IDC from the department constituting the majority of work being performed.

For example, if SPHHS (using a 26.5% IDC rate) proposes a project with SMHS (using a 58.5% IDC rate) and the majority of the work will be done in the SPHHS, then the 26.5% rate would be applied to the overall project. Preponderance of work is based on location of the percentage of effort for the proposed personnel. The amount of IDC distributed to the respective Schools or units follows the dollars associated with the percentage of effort for the personnel listed in the budget. Upon award, OVPR will setup cost centers for various schools and departments in order to allocate IDC accordingly. IDC allocations differ per award and are based upon personnel, time and effort, and location of work performed. **Please refer to the [SPHHS F&A transitioning plans and F&A rates guidance](#) for details.**

12. Competitions with limited proposal submissions

Per OVPR requirements, when funding agencies or sponsors limit the number of grant applications that the institution may submit, interested investigators should notify the SPHHS Associate Dean of Research and send an email to askOVPR@gwu.edu immediately. OVPR will initiate an internal competition to determine the proposal(s) that may move forward and ensure that GW sends only the allowable number of proposals.

Participating in an [internal competition](#) is required in order for GW OVPR to move your application forward; work closely with Dean Horn on these submissions.

13. Administrative establishments

When a sponsor has confirmed/guaranteed in writing that funding will be granted but the contract negotiation process and agreement require additional time, the PI may ask the Department Chair to request the project's PTA account be established in advance. In the event that the award is never received, the financial culpability falls to the Department. The PI should ask the Department Chair to submit an email to OVPR requesting an administrative establishment and reference the following information:

- Project PI
- Project Title
- Project Sponsor
- Project Start and End Date
- Project Number (if award is a continuation of an existing project)
- Statement that – “If for any reason, the contract is not executed as anticipated the Department will assume responsibility for all costs incurred during the administrative establishment time period. The Oracle Alias (*name specifically*) will assume those charges.”

E. Determining Conflicts of Interest

The complex relationships among universities, government, and industry require attention to standards of procedure and conduct in research. While the Faculty Code states, “faculty shall have a primary responsibility of devoting their time, thought, and energy to service of the University, of no less importance is a faculty member’s responsibility to further her or his own professional development and the goals of her or his professional discipline. Conflicts of interest may occur when there is a divergence between a faculty member’s private interests and professional service to the University.” Under the University’s “One-day-a-week” rule, a full-time faculty member (except for research and medical faculty) may spend the equivalent of up to one day a week on outside consulting and other professional activities, as long as it does not interfere with University obligations.

Conflict of interest in research involves circumstances under which a researcher has any *significant financial interest* that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research. This could *include* personal compensation from industry, equity interest or a management role in a company, or royalties generated from intellectual property rights from any source. You may view GW’s [current policy](#) here.

The federal government also has [new supplemental requirements](#) (compliance date August 24, 2012). GW provides required training offered through CITI. In summary, the recent policy changes require that institutions adhere to the following:

- Must disclose all financial interests related to university duties (teaching, research, practice, etc.)
- Must have a procedure to determine if interests are related to an investigator’s research

- Reduction in what constitutes financial conflict of interest (from \$10,000/year to \$5,000/year)
- Must disclose income from private non-profits
- Must disclose reimbursed/sponsored travel except travel sponsored by universities, government agencies, or academic medical centers
- Mandatory training on financial conflict of interest
- Institutions must make fiscal conflict of interest information public
- Institutions must monitor compliance with management plans
- Prescriptive action for non-compliance
- Institutions must report financial conflicts of interest to PHS

Frequently asked questions related to Conflicts of Interest:

What is the difference between the annual Financial Conflict of Interest (FCOI) form filed by GW faculty and staff and the new PHS requirement? The new PHS requirement relates to the disclosure of Significant Financial Interest (SFI), regardless of whether or not an investigator perceives it to be related to the proposal at hand. It is reported on the new Supplemental Disclosure Form (SDF). The SDFs must be filed in addition to the annual FCOI process, not in lieu of.

Who is required to report SFI on the new supplemental disclosure forms (SDFs) and how are the forms filed? Per federal policy, as of August 24, 2012 investigators submitting a proposal (for a grant or contract) under the PHS umbrella must file the supplemental form. The OVPR website provides information on [forms](#) along with other general information about the new federal SDFs and disclosure requirements. *Upon completion of the form, investigators must simultaneously submit the forms via email to OVPR, rescomp@gwu.edu *and* to the SPHHS Dean's Office, sphhsCOI@gwu.edu.* Please note that the latter email address is an addition to the OVPR procedure adopted by the SPHHS to increase control over these forms at the School level. No grant or contract under the PHS umbrella can be submitted without these forms on file in OVPR. Moreover, no PHS award can be set up without these forms in place at GW, even if the application was submitted prior to August 24, 2012. Forms also need to be submitted to the two email addresses upon *renewal* of existing PHS awards funded prior to August 24, 2012. *Investigators are not required to email nor should they be asked by others to email or copy these forms to any other individuals.* See Table 1 below for a summary of the required disclosures. Note that most disclosures are unlikely to be considered financial conflicts of interest.

Who qualifies as an investigator? According to PHS, the definition of an investigator is as follows: *"...the project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research...and may include consultants and collaborators."* This definition may be independent of an investigator's employment at GW. Final determination about investigator status will be made on a proposal-by-proposal basis following routine proposal review by the SPHHS Research Office. Generally, consultants on most of the SPHHS proposals are not considered "investigators", but the SPHHS Associate Dean of Research will review all consultants and collaborator roles for final determination. Sub-awardees will also be reviewed as potential investigators. Investigators (either as consultants or sub-awardees) from other institutions who provide official documentation that their institutions have a Financial Conflict of Interest/Disclosure process in place will not need to submit a disclosure form to GW. However, if external investigators' agencies or institutions do not have this process in place, they must file the forms with GW according to SPHHS and GW procedures. PIs will be consulted if there are any concerns about an investigator's status. The disclosure issues of IDIQ collaborators will be addressed on a case-by-case basis.

Are students included on research proposals required to file SDFs? Students are unlikely to serve as investigators on PHS research. An exception may apply to doctoral students submitting as a PI on a federal application to support their dissertation research. Final determination will be made by SPHHS Associate Dean of Research upon routine proposal review.

Who has to complete the required training? All investigators who have or may plan to apply for funding from PHS must complete the training, which is provided via CITI. Investigators should complete the [training](#) as

soon as possible. No award can be issued without completed training. In accordance with the current federal policy, training must be renewed every four years. Upon completion of training, investigators will receive an email from CITI certifying that training is complete. Please maintain the email confirmation in your files.

Table 1: Disclosure Requirements: How the Revised Federal Regulations Affect Disclosure Reporting

Category	Now	On and after August 24, 2012
Consulting for industry	Consulting fees must always be disclosed; disclosure of travel expenses has not been required.	If you participate in Public Health Service ¹ funded research, all travel expenses ² associated with outside activities paid for you or reimbursed to you by industry must now also be disclosed. Travel expenses include transportation, hotel accommodations, and meals.
Consulting for non-profit organizations	Not required.	All payments for consulting for non-profit entities, AND travel expenses ² associated with outside activities paid for you or reimbursed to you by a non-profit must now also be disclosed.
Teaching, lecturing or giving a seminar	Required when you are paid for speaking at an event sponsored by industry or other for-profit entity.	All payments/honoraria AND travel expenses ² for speaking at for-profit AND non-profit sponsored programs paid for you or reimbursed to you must now be disclosed. *This does NOT include income or travel expenses received from U.S. state, federal or local government agencies (e.g., NIH, IOM, CDC, state health departments), teaching hospitals, medical centers, or institutes of higher education and their related research institutes. Examples of non-profit entities that DO require disclosure are the American Heart Association and the Gates Foundation. Foreign government activities DO require disclosure.
Service on boards of directors, scientific advisory boards, advisory committees, study sections or review panel	Required when you are paid for such service by an industry or for-profit entity.	All payments for serving on such boards or panels AND travel expenses ² for meetings paid for you or reimbursed to you by for-profit AND non-profit entities must now be disclosed. Exclusions and inclusions to this requirement are the same as those listed above (*).
Interests of spouse and dependent children in for-profit entities	Required if the specific entity provides funds or materials for your research or markets products based on your research. Mutual funds are not included.	Required if these interests could be related to your institutional responsibilities (e.g., research, teaching, clinical practice).
Income received from publishing, editing or authoring	Not required.	Disclosure now required for any income paid directly to you for these activities.
Service as founder, officer or manager of a company, as well as ownership of equity in that company	Required for for-profit company.	Required for for-profit AND non-profit entities.

Notes about Table 1: This is a comparison of the key changes based on the new federal regulations, and is not an all-inclusive list of required disclosures. Note that these requirements apply only to associations you have with organizations outside of GW that are not processed through the university or sponsored projects (i.e., OVPR). This table was adapted from a document prepared by the Johns Hopkins Bloomberg School of Public Health, August 17, 2012. ¹**Public Health Service (PHS) Funded Research:** This includes research funded by the Public Health Service and its agencies, which include: National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Toxic Substances and Disease Registry (ATSDR). ²**Travel Expense Reporting:** Travel reporting requirements apply only if you participate in PHS funded research, but reporting is required even if the travel is unrelated to your PHS funded research activities. Travel reimbursements made to GW accounts, travel payments made by GW, or travel charged to a GW account do NOT need to be reported.

How often must investigators update disclosure forms? Investigators are responsible for updating SDFs promptly whenever circumstances change. *If your circumstances change, you MUST submit an updated disclosure to rescomp@gwu.edu and to sphhsCOI@gwu.edu.* Proposals will be submitted as long as all GW investigators have filed a SDF. NOTE: The annual faculty and staff disclosure form is NOT the same as the PHS SDF. When an award is made, *OVPR will send all GW investigators an email asking them to confirm that their earlier disclosure is still accurate & complete. Awards cannot be set up until all affirmations or new up-to-date supplemental disclosure forms are on file and have been reviewed by the Dean's designee to determine that there is no conflict of interest.* Disclosures should be reported prior to undertaking the activity and within 30 days of initiation. Disclosures must also be updated within 30 days of acquiring or discovering new or changed financial interests.

Are the completed forms confidential? The SDFs are currently submitted via email. Eventually, the SPHHS intends to initiate a protected electronic submission process for our faculty. In the interim, the SPHHS Dean's

Office and OVPR confirms that the email addresses are accessible to a very few personnel (only enough to ensure coverage). The only SPHHS staff with access to the email address is the Finance Director or representative (in his absence)—emails will be deleted after six months. OVPR appoints a designee under the supervision of Associate Vice President. Department chairs will not have access to the forms, but will be notified if a conflict emerges. The SPHHS departmental administrative staff will ask investigators to verify that SDFs have been filed by initialing the proposal routing form. Following receipt of the SDFs in OVPR, a designated individual uploads the forms to a secure GW Docs folder. Upon receiving the SDFs in SPHHS, the Dean's Office then files the forms on a secure share drive only accessible the Dean, Senior Associate Dean, Associate Dean of Research, and the Finance Director. *The SDFs will not be reviewed until there is an award.* If the SPHHS leadership determines a conflict of interest, a management plan will be enacted (as is the School's current procedure). The Dean or designee will develop a management plan and the plan will be reviewed with the investigator and Chair.

What happens if an investigator's form is not filed prior to proposal submission? It is important to underscore that investigators are responsible for sending the supplemental disclosure forms to the appropriate email addresses noted in #2 above. *If a researcher is included in a proposal and has not filed the necessary disclosure, the proposal will not be signed by the SPHHS Dean's Office, nor will it be submitted to the sponsor by OVPR. Also, awards cannot be set up until up-to-date forms are on file.*

III. Post-award Management

Generally, PIs are minimally involved in post-award management, other than actions related to the scientific implementation. However, there are several post-award procedures that warrant PI communication with Department Administrators, SPHHS Associate Dean of Research, and/or OVPR. These include:

- Change in effort among key personnel;
- Change of Project Director or PI;
- Equipment transfers or changes in facilities;
- Grant and contract transfers;
- Monitoring project expenses;
- Requesting that invoices be generated;
- Requesting no-cost extensions;
- Certifying time and effort;
- Providing progress reports and deliverables;
- Requesting project close out.

OVPR provides guidance on **post-award transactions**, including a variety of forms that may be useful. It is suggested that, upon funding, investigators **request a Kick-off Meeting** with their department administrator and an OVPR post-award administrator plus any other key stakeholders to confirm project goals and the timeline for implementation. This may be especially important for projects that have tight turnaround for project deliverables, new employment hires, new lab or supply purchases, equipment purchases, and service agreements.

A. Initiating Sub-awards

To initiate the sub-award process, the designated departmental grants administration staff must work with the PI to assemble materials such as the sub-awardee's statement of work (SOW), detailed budget, budget justification, PI identification, Sub-recipient Commitment Form and organizational contact information. This sub-award documentation must be submitted to OVPR. Should it be necessary to change any portion of a sub-award, the PI in conjunction with designated departmental grants administration staff, should contact OVPR to amend the sub-award. Common reasons for amending a sub-award include providing additional funding or extending the period of performance. Changes such as scope of work modifications, reassignment of sub-award recipient's PI or transfers of the sub-award from one recipient to another, may require the prior approval of the prime sponsor.

1. Financial monitoring of sub-awards

In accordance with the sub-award, invoices should be provided on a regular basis. The PI, in conjunction with designated departmental grants administration staff, should review the invoices to ensure the payment is consistent with the effort performed and the award budget. The PI should provide approval prior to payment of the sub-award invoices.

2. Monitoring

All PIs are encouraged to engage in sub-award monitoring including the following:

- Determine if sub-award recipient's progress is commensurate with the costs claimed (invoiced);
- Determine if the costs claimed (invoiced) are within the amount of the sub-award;
- Determine that the invoice dates are within the sub-award period of performance;
- Determine if the invoices contain any unallowable costs;
- If there are cost share commitments, determine that the sub-award recipient fulfilled its commitments.

B. Recruiting and Hiring Research Staff

Once funded, PIs often have the responsibility of hiring project staff. As a first step, all PIs should become familiar with GW's online [Supervisors Guide](#). The Supervisors Guide is an open document, continually changing, so refer to it with each new hire. **The SPHHS has a Human Resource Office with staff dedicated to research hires.** The PI's department must initiate recruitment by completing the Recruitment Action Request Form (RAR). In addition to the RAR, the following should also be included in the recruitment package:

- Proposed job description;
- Memorandum detailing what has changed within the department and the business need for the new position and duties (how it affects or compares to other department positions, functions, etc.);
- Current organizational chart and proposed organizational chart (applies when reclassifying a vacant position, reclassifying a current employee, introducing a brand new position into the department, and proposing a reorganization of a department);
- Resignation letter from the incumbent if applicable.

The processes for recruitment of staff is the same as research staff, with the only exception being that budgetary approval will come from an OVPR administrator. If the position is being funded by multiple funding sources (i.e., the position is being funded by operating money and grant money), the position will have to obtain OVPR approval in addition to approval from the department's Financial Director. If there are any concerns with the identified funding source, the assigned OVPR administrator/Financial Director will reconcile directly with the department, prior to releasing to the HRCP for final review. Once all approvals have been obtained, the SPHHS Human Resources Office will initiate action and submit to the University Recruitment Office for review and posting. Once the position has been posted, the Human Resources Office will provide the departmental initiator with the qualified resumes. **The hiring agent or PI may review all resumes or allow the Human Resources Office to pre-screen the potential candidate.** It is very important to work closely with Human Resources Office throughout the recruitment and hiring process. The following additional guidance for the SPHHS may be useful:

- There is no administrative difference in the hiring process when hiring PT vs. FT employees;
- All PT and FT Research titled and funded positions are Exempt and a grade 0 (e.g., Research Asst., Research Admin, Research Scientist etc.);
- University titled positions funded by research are graded and can be exempt or non-exempt (e.g., Administrative Assistant, Communication Assistant)—SPHHS Human Resources Office will review all requests and make the final decisions on titles and classifications based on the description provided by the Hiring Manager/PI.

C. Hiring Post-doctoral Fellows—This policy is currently under development at GW.

D. Procurement

PIs have minimal involvement with GCAS and procurement issues. However, one aspect that investigators must keep in mind is that the purchases of goods/services greater than \$3,000 must be (a) formally put through a bidding process or (b) receive advanced approval for a sole source selection. It is essential to work with department administrators on this process. PIs should not purchase goods on their own, without approval.

E. Post-Award Communications

As a SPHHS investigator, your research and other professional activities can help advance the public's understanding of public health issues. The SPHHS Office of Communications will assist in promoting award announcements and subsequent research findings. Such media coverage establishes certain investigators as the go-to expert on a public health topic, heightens the visibility of the School, and promotes public knowledge.

Investigators should contact the SPHHS Office of Communications once a study, report or commentary is completed and weeks prior to it being made public. Once a study has been published online or released to the public, it is more difficult to interest media in a story because they consider it "old news." Also, investigators should keep in mind that it can take time to produce an accurate and compelling press release—one that you have the time to review. The Office of Communications will also draft studies and reports in the SPHHS Faculty/Staff newsletter or a Content Alert Bulletin for various stakeholders or policy makers. Investigators should inform the Office of Communications if presenting a talk at a scientific conference or special meeting—such presentations may merit a news release or some other promotional activity. The Dean's Office encourages investigators to **contact the SPHHS Office of Communications when a reporter calls or requests information from an investigator**. They will assist in setting up the interview and conducting necessary follow-up with a reporter or news outlet.

IV. Human Subjects Research and the Institutional Review Board

If you are planning to conduct research involving human subjects you must obtain Institutional Review Board (IRB) review and approval before collecting or analyzing any data. Visit the Office of [Human Research website](#) to learn about the IRB process and requirements for submitting your protocol for review and approval. Click on the Forms page to view:

- Decision charts to determine which type of review is appropriate for your study.
- Consent from guidance documents (under Full Review and Expedited Review)
- IRB submission forms appropriate for each type of review
- HIPAA forms

The IRB is composed of more than 40 members representing University faculty, staff, students, Medical Faculty Associate (MFA) and George Washington University Hospital employees and the local community. The IRB is comprised of two independent review committees and a third, executive committee, comprised of chairs and vice-chairs of the other two panels. Each committee meets monthly to review human subjects research and related issues. Please note that GWU is now utilizing Western IRB (WIRB) to review all sponsored clinical trials research. Contact the Office of Human Research (OHR) at Ross Hall, Suite 613, ohrib@gwumc.edu, or 202-994-2715.

CITI Training (Human Subjects)—The Collaborative Institutional Training Initiative (CITI) is a subscription service providing research ethics education to all members of the research community. All Principal Investigators and members of the research team are required to have completed CITI training prior to requesting IRB review of a research proposal and prior to conducting any research involving human subjects. This training requirement also applies to student researchers and their faculty advisors. It is also important to maintain current [CITI training](#) until your study is closed through the Office of Human Research.

APPENDIX

[SPHHS Sponsored Projects Staff Points of Contact \(online link\)](#)

[Gifts and Grants \(online link\)](#)

[Grants Vs. Contracts Vs. Gifts Definitions \(online link\)](#)

[The SPHHS Routing Process \(online link\)](#)

[SPHHS F&A Transition Plan \(online link\)](#)