RESEARCH ADMINISTRATION NEWSLETTER

http://www.brown.edu/research/research-administration-newsletters

NOVEMBER 2017

The monthly newsletter provides timely information on agency updates; sponsor and University policy and procedural information; and guidance in all aspects of sponsored project administration for Researchers and Research Administrators. Content for the newsletter is contributed from the offices under the Vice President for Research:

- Office of Research Administration Information Systems (RAIS)
- Office of Research Development
- Office of Research Integrity (ORI)
- Office of Sponsored Projects (OSP)

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Research Administration Updates

Office of Sponsored Projects

➢ Award Acceptance – What is your Grant & Contract Administrator Negotiating?

U. S. Department of Defense sponsored grants and contracts are a small percentage (9%) of Brown University's overall research portfolio; however, this source of funding is expected to increase in future years. In federal contracts, the Government's standard terms are known as "FAR" clauses for **F**ederal **A**cquisition **R**egulations, and the U.S. Department of **D**efense has its own section of the FAR, known as **D**FARS. One of the most notorious clauses is DFARS 252.204-7000, entitled **"Disclosure of Information",** and its full text can be read here. The clause prevents University researchers from releasing any information arising from or pertaining to the contracted research activity. It is a prohibition on the publication of research findings which is contrary to Brown's research policies.

Fortunately, there is a remedy available within the clause to allow institutions of higher education to proceed with the research in accordance with customary academic and scholarly practices. It requires negotiation by OSP with the sponsoring agency's Contract Officer so that the following language is written into the contract:

"The information results from or arises during the performance of a project that involves no covered defense information (as defined in the clause at DFARS 252.204-7012) and has been scoped and negotiated by the contracting activity with the contractor and research performer and determined in writing by the contracting officer to be fundamental research."

The magic words are **'fundamental research'** which designates that results of the research project are not subject to any type of publication restriction and that "Covered Defense Information" (which requires special secure handling) is not involved. With this remedy in place, Brown can proceed to sign and accept the contract. Note that the fundamental research determination is also required when Brown is a subcontractor. Should you have questions regarding the contract negotiation and acceptance process, contact your OSP Grant & Contract Administrator.

➢ Robert Wood Johnson Foundation has updated its travel policy

The Foundation is excited to announce a new Travel Policy for Grantees and Service Providers. Some of the changes include:

- A single travel policy for both grantees and service providers
- An increase in the per day/per meal limits to $100/$75
- An increase in clarity around items that are allowable/reimbursable, including the combination of personal travel and/or other business travel with Foundation-support business trips.

Please visit https://www.rwjf.org/en/how-we-work/grants-explorer/grantee-resources/legal-and-policy-information/travel.html for more information. Or contact your OSP Grant/Contract Accountant.

Office of Research Integrity

➢ Health Insurance Portability and Accountability Act (HIPAA) and Research at Brown

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its regulations, including the Privacy Rule and the Security Rule, as well as the Health Information Technology for Economic and Clinical Health (HITECH) Act, govern the way certain health information is collected, maintained, used, and disclosed. The Privacy Rule establishes a set of safeguards around certain types of health information known as Protected Health Information (PHI) and sets forth a national minimum level of protection for PHI. It also describes ways in which a Covered Entity can use or disclose PHI for research purposes.

Brown University is not a Covered Entity under HIPAA for research purposes. Brown researchers may wish to receive PHI from a Covered Entity and therefore must understand the appropriate methods for receiving such data and the obligations to ensure that data are released to you in a manner that complies with HIPAA and that the data are appropriate protected at Brown once received.

Disclosure of PHI to Brown for Research Purposes

There are circumstances in which health information maintained by a covered entity is *not* protected by the Privacy Rule. PHI excludes health information that is de-identified. Health information that is de-identified can be used and disclosed by a covered entity without Authorization or any other permission specified in the Privacy Rule. Under the Privacy Rule, covered entities may determine that health information is not individually identifiable in either of two ways as described below.

The Privacy Rule permits covered entities to use and disclose PHI without Authorization for certain types of research activities. For example, PHI can be used or disclosed for research if the covered entity obtains documentation that its Institutional Review Board (IRB) or Privacy Board has waived the requirement for Authorization or allowed an alteration to Authorization. The Privacy Rule also allows a covered entity to enter into a Data Use Agreement for sharing a limited data set. Further, there are provisions for how PHI can be used or disclosed for activities preparatory to research and for research on decedents' information.

Business Associate Agreements (BAAs)

It is rare that any Brown researcher is truly acting in the capacity of a Business Associate in the conduct of his/her research at Brown; researchers **are no**t business associates solely by virtue of their own research activities. You may find that covered entities insist that entering into a Business Associate Agreement (BAA) is the only way to provide PHI to Brown. If you encounter this, please contact the Director of the Office of Research Integrity to discuss how best to facilitate the transfer of PHI for the purpose of research in a way that satisfies the covered entity's concerns. Remember, a Business Associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A Business Associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule. As such, why sign a BAA when it's not required and when it's not the appropriate mechanism for sharing data?

➢ Guidelines for Medication Management in Human Subject Research

The Human Research Protection Program (HRPP) recently implemented "Guidance for Investigators: The Management of Human Research Studies Involving Drugs and Medication." This guidance is relevant to all human subjects research that includes the use of prescription medications within a study design, and addresses compliance with Rhode Island Board of Pharmacy requirements and Brown University procedures. In addition to the guidance document, the HRPP has developed the "Prescription Drug/Medication Management Addendum" for submission with new protocols that include provision of prescription medications to study participants; this addendum should also be included with amendments to active protocols that request to add such activities to the current protocol.

➤ Animal Research Protection Program (ARPP) Updates

The ARPP remains committed to reducing regulatory burden. The latest developments aimed at this goal include the implementation of two new changes:

1. Animal researchers submitting protocol that do not involve United States Department of Agriculture (USDA)-regulated species or Department of Defense funding are no longer required to designate USDA pain categories! See the updated Guidelines for Assigning Animals to Pain and Distress Categories for more information; and

2. The Institutional Animal Care and Use Committee (IACUC) recently implemented the use of the Veterinary Verification and Consultation (VVC) review process to reduce review turnaround time for certain protocol amendment requests. Average turnaround time for VVC approvals is currently 3 business days!

The IACUC also adopted new Record-keeping Guidelines for USDA-regulated Species to provide best practices and clarify regulatory requirements for record-keeping for USDA-covered species.

➤ Military Sponsors and Fundamental Research

Researchers submitting proposals to military sponsors, such as the Department of Defense (DoD), must pay particular attention to protecting the Fundamental Research Exclusion (FRE). Much of the research funded by military agencies, especially research that is defined as "basic (6.1)" or "early applied (6.2)", is generally considered *Fundamental Research* and comes with no publication or participation restrictions.

Over the past year, we have noticed a number of military funders that are less clear about the *Fundamental Research* designation, with some explicitly restricting publication or participation of certain nationals, and some indicating that the research may be or may become controlled or even classified.

While all military funded research agreements are reviewed by OSP and the ORI Export Control Compliance Team, Researchers are encouraged to work with their OSP Grant & Contract Administrator to determine how best to insert the following language (or a version thereof) into the transmittal letter, coversheet and/or document:

"Should this proposal be selected for funding Brown University, as a non-profit research and education institution, will perform fundamental research as defined by the National Security Decision Directive (NSDD) 189. Accordingly, Brown University expects to receive award terms and conditions appropriate for the fundamental nature of the work being performed including unrestricted dissemination of research results."

Please note that developmental items produced under Department of Defense (DoD) funding including specially designed parts, components, accessories, and attachments may be subject to the International Traffic in Arms Regulations (ITAR) (regardless of Fundamental Research) unless these items are identified in the relevant DoD award agreement as being developed for both civil and military applications.

Researchers who are creating or modifying equipment or materials under a DoD agreement (grants, cooperative agreements, contracts) and believe that the items have both civil and military applications (i.e. "dual use"), should explicitly state this in the agreement and/or statement of work. We recommend the following language:

"It is understood that any developmental items and specially designed parts, components, accessories and attachments generated under this Defense Department agreement are being developed for both civil and military applications."

If the funding agreement does not include this or similar language, any such hardware or materials created or modified under the agreement will need to be handled as "developmental" items subject to ITAR unless Brown receives a Commodity Jurisdiction from the Department of State determining it is not.

If the item truly doesn't have civil application, do not try to make the case that it does. In such cases, contact the Export Control Compliance Team to assess if the item and your research may be subject to control under the ITAR. Importantly, ITAR-controlled, Non-FRE projects cannot be conducted at Brown.

Research Development

➢ OVPR Internal Funding Opportunities

Grant Resubmission Awards
- Deadline: **Rolling** (via UFunds)
- Provide up to $15,000 for investigators to improve an already highly-rated proposal for re-submission.
- Any Brown faculty member whose research is administered through Brown is eligible. Emeritus, adjunct, and visiting faculty, as well as post docs, are not eligible to lead projects, but may be included on the research team.

Complete guidelines on these and other opportunities are available on the Internal Funding Opportunities page of the OVPR website**.** Questions? Please contact Margaret Manning at Research_Opps@brown.edu or 863-5145.
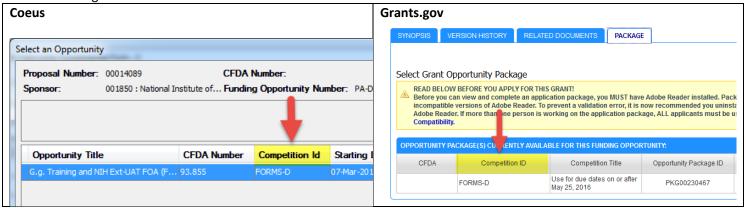
Research Administration Information Systems

➢ Grants.gov Forms-D and Forms-E: Matching Form Packages and Individual Forms

Mixing forms from Grants.gov form package sets Forms-D and Forms-E will may cause your submission to fail. A prime example of this is uploading a Forms-E Subaward Budget form into a Forms-D opportunity package. Be sure to use the correct Grants.gov form set based on the **submission date** of the funding opportunity that you are applying for. *Any submissions prior to 1/25/18 are still using Forms-D*.

Determining the Which Forms Package your Opportunity is Using
- To identify which Form Set your funding opportunity is using, navigate to the "Competition ID" field either in Coeus or Grants.gov. That field will show either "Forms-D" or "Forms-E".

RAIS is currently testing Forms-E to prepare it for use in Coeus. Forms-E will be available in Coeus in time to prepare submissions for dates after 1/25/18, when Forms-E are officially in use. We will keep you updated once Forms-E becomes available in Coeus.

➢ Grants.gov Workspace

As of **12/31/17** Workspace application packages will replace the legacy PDF packages at Grants.gov. Workspace will only be used in instances where a proposal cannot be submitted via Coeus System-to System (S2S) or via the sponsor's direct submission website (e.g., NIH ASSIST, NSF Fastlane, etc.). **Coeus S2S is still the preferred method of submission when applicable.**

For the scenarios that a submission will need to be prepared and submitted in Grants.gov Workspace, RAIS is working to get users set up in the system. **A major difference between the Grants.gov legacy PDF package and Workspace is that Workspace requires you have an account in Grants.gov to create or access a funding opportunity Workspace.**

Registering for a Grants.gov Workspace Account:
If you regularly work on proposal creation in your department, now is the time to register for a Grants.gov account so that you are prepared to create a Workspace proposal, if needed. If you do not normally work on proposals, there is no need to register for a Grants.gov account at this time.

When registering for a Workspace account from the Grants.gov site, RAIS will be notified and will process your account as follows:
- Those who currently hold the proposal Aggregator role in Coeus will be assigned a **Workspace Manager** role. This role allows you to Create a Workspace and have full access to manage that workspace.
- If you are *not* a Coeus Aggregator, you will be granted a Workspace account without a role. This will still enable you to perform work on a Workspace proposal if a Workspace Manger adds you as a '**participant**' to a Workspace.

IMPORTANT: If you are registering for a Grants.gov account at Brown, be sure that you choose Organization Applicant as you 'continue' through your registration. In order to create proposals for Brown University, you must sign up under an Organizational account, using Brown's DUNS number (001785542) and your employee position information and email at Brown.
Note: Principal Investigators are not currently required to have a Grants.gov account in order for a Research Administrator to route a Workspace application package with their name on it. (Coeus currently handles the Certification of a proposal by the PI for Brown Authorized Official approval.) PI's still wanting an account at this time can sign up at Grants.gov under the Organization Applicant registration.

Full training on roles and Workspace is available at the Workspace section of the Grants.gov website and also on their Workspace tutorial video playlist on YouTube and at this full Workspace Webinar video.

➢ Coeus Help Tip: Proposal Hierarchy Guide

The process for creating proposal hierarchies in Coeus can be a little confusing, especially for those that do not work on them often.   Whether you are working on a parent or child on a hierarchy proposal, there is a step-by-step guide available to help!

The Proposal Hierarchy Guide can assist to avoid common mistakes in creating and working in a parent/child hierarchy proposal. This guide contains 3 Appendices at the end that address many of the questions RAIS receives from end-users:
- **Appendix A – Entering the Data and Syncing the Proposals –** this is a table of each tab in Coeus Premium and whether it should be completed in the Parent or Child or both.
- **Appendix B – Proposal Hierarchy Roles – Who can View / Modify the Parent Proposal –** this is a table of each tab in Coeus Premium and what can be modified or viewed based by Role (Parent Aggregator / Child Collaborator).
- **Appendix C – Note about Coeus Lite and Proposal Hierarchy –** Proposal Hierarchies can only be created and maintained in Coeus Premium. Child proposals can be created in Coeus Lite, but once linked to a hierarchy; the proposals can only be modified in Premium.

The Proposal Hierarchy Guide and many other helpful Coeus Guides can be found on the Coeus Proposal Development page at the RAIS section of the OSP website.

Sponsor /Agency Updates

NIH UPDATE	➢ **Substance Abuse and Mental Health Services transition to eRA** Substance Abuse and Mental Health Services Administration (SAMHSA) has transitioned to NIH's eRA (Electronic Research Administration) grants system. There are changes to the Post Award Amendment submission process. The types of Post Award Amendment applications that will be submitted through NIH eRA Commons include: • Budget Revisions • Formal Carryover Requests • Change in Key Personnel and/or Level of Effort • Change in Organizational Information • Change in Scope • Merger, Successor-In-Interest, Transfer or Name Change • No-Cost Extension A link describing the process can be found at https://era.nih.gov/era_training/samhsa_videos.cfm#submission
NSF UPDATE	➢ **NSF Proposal & Award Policies & Procedures Guide (PAPPG)** NSF 18-1 A revised version of the NSF Proposal & Award Policies & Procedures Guide (PAPPG), has been issued. The new PAPPG will be effective for **proposals submitted, or due, on or after January 29, 2018**. Significant changes include: • Addition of a new eligibility subcategory on international branch campuses of U.S. Institutions of Higher Education; • Revision of eligibility standards for foreign organizations; • Implementation of the standard Collaborators and Other Affiliations (COA) template that has been in pilot phase since April; • Increase in the Budget Justification page limitation from three pages to five pages; • Restructuring of coverage on grantee notifications to and requests for approval from NSF, including referral to the Prior Approval Matrix available on the NSF website; and • Numerous clarifications and other changes throughout the document. While this version of the PAPPG becomes effective on January 29, 2018, in the interim, the guidelines contained in the current PAPPG (NSF 17-1) continue to apply. NSF will ensure that the current version of the PAPPG remains on the NSF website, with a notation to proposers that specifies when the new PAPPG (including a link to the new Guide) will become effective. A webinar to brief the community on the new PAPPG will be held on **December 8 at 2 PM EST**. Registration is now available at: https://nsfgrantsconferences.com/pappg-update-webinar/ If you have any questions regarding these changes, please contact the Policy Office at (703) 292-8243 or by e-mail policy@nsf.gov.

Training & Conferences

OSP & RAIS Fall Training

The Office of Sponsored Projects offers a variety of research administration training opportunities in order to provide staff with the knowledge base to support faculty and researchers in the management of their research.

Fall Training Schedule		
Track	Class	Date
Pre Award	Cost Sharing	12/04/2017
Coeus	Coeus Premium Advanced Budgeting	12/05/2017
Post Award	Effort Certification	12/13/2017

To register for classes, please navigate to the Brown Learning Point Page and log in. The training classes can be found by clicking on the "Sponsored Research Related Training" from your homepage.

Visit the Sponsored Projects Training and Outreach Webpage or the Coeus Training Classes page to learn more about the classes.

UPCOMING CONFERENCES & PROGRAMS

NCURA Region I – Research Administration Discussion Group
  ➢ **Federal Update & Holiday Networking Event:** December 14 | Cambridge, MA

For more details, see NCRUA Region I Discussion Group

NCURA National Meetings posted for 2018
  ➢ **Financial Research Administration (FRA)**
    Conference: March 5-6, 2018 |Orlando, FL
    Workshop Day: March 7, 2018

  ➢ **Pre-Award Research Administration (PRA)**
    Conference: March 8 – 9, 2018| Orlando, FL
    Workshop Day: March 7, 2018

  ➢ **Annual Meeting**
    August 5-8, 2018 **|** Washington, DC

For more details, see http://www.ncura.edu/Education/MeetingsConferences.aspx

*Questions or comments about the Newsletter should be directed to
the Office of Research Administration Information Systems – RAIS@brown.edu*