

RESEARCH ADMINISTRATION NEWSLETTER

DECEMBER 2016

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



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)

For more details, please see Matrix of Recent Legislative Actions Taken to Reduce

Research Regulatory Burden published by COGR 12/19/16.

- Office of Research Development
- Office of Research Integrity (ORI)
- Office of Sponsored Projects (OSP)

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Office of Research Integrity

➢ ORI welcomes new Research Compliance Specialist, Holly Clifford!

ORI is pleased to announce that Holly Clifford, MHS, has joined our team. Holly will be a key member of the Human Research Protection Program (HRPP), answering incoming queries and triaging protocols for review, and will also provide administrative support to the Institutional Biosafety Committee (IBC). For the last decade, Holly was a Research Scientist at Boehringer Ingelheim Pharmaceuticals, Inc., where she worked on *in vivo* and *in vitro* studies of cardio metabolic diseases and also served on the company's Institutional Animal Care and Use Committee (IACUC). We're thrilled to welcome someone with Holly's background to our group!

Human Research Protection Program (HRPP) updates

Did you know that your NIH-funded social/behavioral research study may be a clinical trial?

It's important to recognize that clinical trials are neither specific to, nor limited to, FDA regulated research involving biologics, drugs or devices. The NIH defines a <u>clinical trial</u> as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on <u>health-related biomedical or behavioral outcomes</u>." This definition is fairly straightforward; however, it has created enough confusion that the NIH provides a <u>decision tree</u> and FAQs to provide assistance with application of the definition.

Why do we care?

NIH policy requires clinical trials to be monitored, and applicants and offerors seeking NIH support are expected to describe their plans for data and safety monitoring in their applications and proposals. Final data and safety monitoring plans must be approved by the NIH prior to award. In addition, throughout the life of the award, NIH staff monitors the clinical trial's progress to ensure that milestones are met and that any safety concerns are addressed. Finally, there are <u>additional training requirements</u> that apply to NIH clinical trials by which investigators and their research teams must abide.

In addition to the decision tree and FAQs, below are some examples of research studies that meet the NIH definition of a clinical trial:

Example 1: A study plans to randomly assign individuals to an experimental intervention to promote weight loss or to a control intervention. After a year, participants' behaviors will be assessed to measure their adherence to exercise regimens. Is this study a clinical trial? **YES**!

- The study involves human subjects.
- Subjects are prospectively assigned to an intervention.
- The study identifies a health-related behavioral outcome (adherence to exercise regimens).

Example 2: A large-scale study is designed to evaluate the effectiveness of community-based interventions in influencing smoking behavior. Thirty-four communities across the U.S. are randomly assigned to receive the experimental intervention or to receive one of two control interventions. Each community has a population between 100,000 and 500,000 individuals. The experimental intervention includes public awareness campaigns and educational pamphlets. Is this study a clinical trial? **YES!**

- The study involves human subjects within communities (clusters).
- The study involves interventions to which subjects (in clusters) are prospectively assigned.
- The study identifies a health-related behavioral outcome (smoking behavior).

For more information regarding NIH Clinical Trial research, please contact, <u>Christiana Provencal</u>, QA/QI Administrator at 401-863-5729.

> 2017 Edition of the International Compilation of Human Research Standards

On December 7, 2016, the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (HHS) announced the availability of the annually updated edition of the International Compilation of Human Research Standards. The updated standards are available online at http://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html as well as on the https://www.hbs.gov/ohrp/international/compilation-human-research-standards/index.html as well as on the https://www.hbs.gov/ohr

Investigators conducting, or planning to conduct international research are responsible for knowing the local laws and regulations

regarding human research. This compilation is an extremely useful resource for accessing that information. The Compilation features listings of over 1,000 laws, regulations, and guidelines on human subject protections in 126 countries, as well as standards issued by a number of international and regional organizations.

The updated edition includes hundreds of updates from the previous year. Six new countries are included in the 2017 edition: Benin, Bermuda, Democratic Republic of the Congo, Dominican Republic, Guyana, and Senegal.

The listings are organized into eight categories:

- 1. General Research
- 2. Drugs and Devices
- 3. Clinical Trial Registries
- 4. Research Injury
- 5. Privacy/Data Protection
- 6. Human Biological Materials
- 7. Genetic Research
- 8. Embryos, Stem Cells, and Cloning

Many of the listings include a hyperlink that allows the user to directly access the law, regulation, or guideline of interest.

> Roll-out of New Exempt Research Policy and Application

We are pleased to announce the roll-out of a **new policy and procedures regarding the review of exempt research at Brown**. Beginning during the first week of 2017, the following significant changes will take effect to our former policies and practices:

- 1) New exempt category for non-federally funded research. Brown is taking advantage of the flexibility in our Federal wide Assurance (FWA) with the Department of Health and Human Services (DHHS) to implement a category of exemption for non-federally funded, low risk research. This Brown Exempt Category #7 will apply to low risk, non-invasive procedures that don't fall under the current Exempt categories found in the Common Rule 45 CFR 46.
- 2) Exempt application form. Investigators who will be conducting research that meets the criteria for exemption will no longer be required to write a complete protocol. Instead, they will fill out a brief application form to describe study procedures and provide the information needed for HRPP staff to determine that the project meets the criteria for exemption.
- 3) No expiration date for research that qualifies for exemption. Research that is determined to be exempt from the regulations at CFR 46, will no longer be considered to have an expiration date, as long as the project is conducted unchanged. Any changes to the proposed research must still be passed by HRPP to determine whether the project will still meet the criteria for exemption. HRPP staff will contact investigators periodically to check in on the status of exempt research, and we ask that investigators notify the office when an exempt project is complete.

Further details about the policy and the application form can be found on the <u>HRPP Forms</u> web pages during the first week of January, 2017!

> Responsible Conduct of Research (RCR) Online Training Completion Records

Brown University offers the Collaborative Institutional Training Initiatives (CITI) online program for students and trainees to use to satisfy certain Responsible Conduct of Research (RCR) training requirements. Please note that the CITI training alone does *not* satisfy the National Institute of Health (NIH) RCR requirements, but may be used to satisfy current National Science Foundation (NSF) RCR requirements. The Office of Research Integrity (ORI) receives electronic completion notifications from CITI for all trainees who complete RCR training modules and selected "Brown University" as their home institution. If you need RCR training completion records or completion verification for students or faculty in your department, please contact Jules Blyth in ORI: juliane blyth@brown.edu.

Responsible Conduct of Research (RCR) BEARCORE Spring 2017

Registration for the BEARCORE 2017 RCR course is now open. BEARCORE fulfills NIH and NSF RCR requirements and will be held weekly on Mondays, starting March 20, 2017 through April 24, 2017 (11 am - 1 pm). For more information about the course and how to register, please go to ORI's website: https://www.brown.edu/research-integrity/ori-staff-directory/bearcore or contact Jules Blyth (401-863-3295 of juliane blyth@brown.edu).

➤ Conflict of Interest: When does an Investigator come under Brown's Financial Conflict of Interest (FCOI) policy and what does that mean?

Many researchers at Brown frequently collaborate on research grants with colleagues at other institutions. In some instances, these colleagues may come under Brown's FCOI policy and are then required to submit Financial Interest Disclosure forms to Brown as well as complete Brown's FCOI training. This requirement is set by federal regulations.

The Public Health Services (PHS) FCOI regulations, which mandate FCOI training for *Investigators*, require that institutions train their *Investigators* not only on the PHS FCOI regulations, but also on institutional policies and procedures. Since institutional policies and procedures vary, Brown cannot accept training taken at another institution in lieu of Brown's FCOI training.

The following steps help determine when a collaborator comes under Brown's FCOI policy:

1. Is the collaborator designated as an *Investigator*?

The PHS FCOI regulations <u>only</u> apply to *Investigators* on PHS funded research, and the term *Investigator* has a very specific definition under the PHS FCOI regulations.

Investigator means "project director or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS". This may include, for example, postdoctoral fellows, collaborators or consultants. At Brown, the **Investigator** designation is made during proposal creation in Coeus. PIs are required to fill out the "NIH Additional Investigator" questionnaire. Anyone listed in this questionnaire has been designated by the PI as fitting the above definition of **Investigator** and will, therefore, be subject to the PHS FCOI regulations.

Questions #2 and #3 below apply if a collaborator is designated as an **Investigator**.

2. Is there a subcontract to the collaborator's home institution?

If there is a formal subcontract to the collaborator's home institution, Brown will verify that the home institution has an FCOI policy that is compliant with the requirements of the PHS FCOI regulations (42 C.F.R. part 50 subpart F). If the home institution has an FCOI policy that is compliant with 42 C.F.R. part 50 subpart F, the subcontract issued to the collaborator's home institution will have a flow-down clause for federal FCOI requirements. The home institution will become responsible for the collaborator's FCOI review and training.

If the collaborator's home institution does not have an FCOI policy that is compliant with 42 C.F.R. part 50 subpart F, then there are two options:

- Option A: the institution certifies that it will implement a compliant FCOI policy. Brown will issue a subcontract with a flow-down clause for FCOI requirements.
- Option B: the institution elects to "come under Brown's FCOI policy". What does this mean? If an institution elects option B, all *Investigators* at that institution working on Brown's research project will come under Brown's FCOI policy for the duration of that research. Brown will collect Financial Interest Disclosure forms from all Investigators and require completion of its online FCOI training.
- 3. <u>Is the collaborator working on the research without a formal subcontract to the collaborator's home institution?</u> If there is no formal subcontract to the collaborator's home institution, the collaborator will come under Brown's FCOI policy. Brown will collect a Financial Interest Disclosure form and require completion of Brown's online FCOI training.

Please contact <u>Jules Blyth</u> or <u>Rebecca Haworth</u> with any questions about this requirement.

Research Development

OVPR's Health Disparities Collaborative Seed Funding Proposals Due January 3rd

The 1st Annual Research Networking Event, focusing on health disparities, took place on October 25th. The purpose of the event was to create new and exciting collaborations across institutions and also launched a new \$50,000 seed funding opportunity!

Eligibility: Any participant of the Health Disparities Networking Event that took place on October 25th. However, a Brown faculty member whose research is administered through Brown MUST be part of the team. Emeritus, adjunct, and visiting faculty, as well as post docs, are not eligible to lead projects, but may be included on the research team.

Submission Process: Proposals should be submitted electronically to Edel Minogue in the Office of the Vice President for Research at Research Opps@brown.edu by **5pm on Tuesday, January 3rd**.

Please contact Edel Minogue at (401)863-5465 or Research Opps@brown.edu with any questions.

Research Awards Deadline Extended

OVPR is pleased to extend until **January 9, 2017** the deadline for nominations to the inaugural **Research Achievement Awards** program. This program is intended to recognize outstanding research achievements of Brown faculty. Five awards will be given annually that each carries a research stipend of \$5,000. OVPR invites nominations on **UFunds** from deans, department chairs, center directors, colleagues and also invites self-nominations. Please see **website** for details and contact **Margaret Manning@brown.edu** with any questions.

Grant Resubmission Awards

Deadline: Rolling

Provide up to \$15,000 for investigators to improve an already highly-rated proposal for re-submission.

Research Development and Grant Writing Newsletter

The <u>December</u> issue is now available online; this newsletter offers strategies on how to compete successfully for research funding and highlights new funding opportunities.

Sponsor / Agency Updates

NIH / AHRQ UPDATE

> Ruth L. Kirschstein National Research Service Awards (NRSA) Postdoctoral Stipends, Training Related Expenses, Institutional Allowance, and Tuition/Fees Effective for Fiscal Year 2017

NOT-OD-17-003

NIH recently announced stipend level changes to the **Postdoctoral Career Level** only.

- All FY 2017 awards previously issued using FY 2016 stipend levels will be revised to adjust stipends to the FY 2017 level.
- Appointments to institutional training grants that have already been awarded in FY 2017 must be amended to
 reflect the FY 2017 stipend levels once the training grant award has been adjusted by the NIH. Amended
 appointments must be submitted through xTrain in the eRA Commons.

Postdoctoral Stipend levels for FY 2017

Career Level	Years of Experience	Actual Stipend for FY 2016	Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	\$43,692	\$47,484	\$3,957
	1	\$45,444	\$47,844	\$3,987
	2	\$47,268	\$48,216	\$4,018
	3	\$49,152	\$50,316	\$4,193
	4	\$51,120	\$52,140	\$4,345
	5	\$53,160	\$54,228	\$4,519
	6	\$55,296	\$56,400	\$4,700
	7 or More	\$57,504	\$58,560	\$4,880

For institutional training grants (T32, T90, TL1) and individual fellowships (F32), the stipend level for the entire first year of support is determined by the number of full years of relevant postdoctoral experience when the appointment is made or the award is issued. Relevant experience may include research experience (including industrial), teaching, internship, residency, clinical duties, or other time spent in a health-related field beyond that of the qualifying doctoral degree. Once the appropriate stipend level has been determined, a trainee or fellow must be paid at that level for the entire grant year. The stipend for each additional year of Kirschstein-NRSA support is the next level in the stipend structure and does not change mid-year.

Training Related Expenses, Institutional Allowance, and Tuition/Fees remain the same. For full details, see the <u>NIH Notice</u>.

> Revised SF424 (R&R) Application Guides and Supplemental Instructions Available

NIH has updated their application guide and supplemental instructions.

Based on applicant feedback, minor changes have been made to the layout and style of the instructions, located on the <u>How to Apply – Application Guide</u> webpage. They have also incorporated several clarifications to our current Forms-D instructions.



Within the instructions, new instructions are marked with this symbol.

Changes to the application guide are included in the <u>Significant Changes</u> section of the application instructions. They include:

Form Instruction Changes

R&R Senior/Key Person Profile (Expanded) Form

- Clarified Implemented Bio sketch instructions for research, institutional research training, institutional career development, research education, fellowship, and dissertation awards, as well as diversity supplements.
- Clarified that figures, tables, or graphics are not allowed in the Bio sketch. Previous instructions noted this only under Section A. Personal Statement. This is not a policy change, but a clarification of instructions.

R&R Budget

- Instructions added for "K. Total Costs and Fee" field included in preparation for future form use.
- The letter label ("K" or "L") for the "Budget Justification" section will vary depending on the version of the form included in the application package.

PHS 398 Career Development Award Supplemental Form

Includes the new appendix policy that goes into effect for applications due on or after January 25, 2017. This
policy redefines the allowable appendix materials. See the Guide Notice on Allowable Appendix Materials for
more information.

PHS 398 Cover Page Supplement

- Instructions have changed so that program income and human embryonic stem cell information are no longer collected at the Overall Component in multi-project applications.
- A system-generated summary of all program income and human embryonic stem cell information that is provided in Other Components will be included in the summaries section of the assembled application image.

PHS 398 Research Plan

Includes the new appendix policy that goes into effect for applications due on or after January 25, 2017. This
policy redefines the allowable appendix materials. See the Guide Notice on Allowable Appendix Materials for
more information.

PHS 398 Research Training Program Plan

Includes the new appendix policy that goes into effect for applications due on or after January 25, 2017. This
policy redefines the allowable appendix materials. See the Guide Notice on Allowable Appendix Materials for
more information.

PHS Fellowship Supplemental Form

Includes the new appendix policy that goes into effect for applications due on or after January 25, 2017. This
policy redefines the allowable appendix materials. See the Guide Notice on Allowable Appendix Materials for
more information.

➤ New to NIH Grant Process? NIH Announces 2017 NIH Regional Seminars

NIH is offering two annual NIH Regional Seminars on Program Funding and Grants Administration in 2017 for those that wish to learn the latest grant Processes and policy information directly from NIH.

The NIH Regional Seminar offers a comprehensive program for the NIH extramural community about the NIH grants process and related policies, including such topics as Fundamentals of the NIH, compliance, peer review, grant writing for success, pre-award and post-award issues for administrators and investigators, animal and human subject research, and how to interact electronically with NIH. In addition to a wide variety of sessions for research administrators, a New Investigators' track provides step-by-step guidance on mapping your career and understanding the funding process.

Registration for both seminars will open in January:

New Orleans, Louisiana:

- Wednesday, May 3, 2017: Optional Pre-Seminar Workshops
- Thursday-Friday, May 4-5, 2017: 2-Day Seminar

Baltimore, Maryland:

- Wednesday, October 25, 2017: Optional Pre-Seminar Workshops
- Thursday-Friday, October 26-27, 2017: 2-Day Seminar

For more details and registration, see NIH Regional Seminars website.

New Features for xTRACT

Several new features have been recently added to xTRACT; the <u>Extramural Trainee Reporting And Career Tracking</u> system that is accessed via eRA Commons. It allows applicants, grantees and assistants to create research training tables for progress reports and institutional training grant applications.

The new features include:

- Ability to copy data from a recently prepared Research Performance Progress Report (RPPR) Research Training Dataset (RTD) into a Renewal RTD
- Improved Performance of Preview/Finalize RTD
- Adjustment to the auto-population of Faculty Research Support, from NIH and Other Agency Sources
- Applicants and Entrants Section

➤ NIH Date Extension – Strategies for NIH Data Management, Sharing, and Citation.

NIH has extended the response date for comments on "Strategies for NIH Data Management, Sharing, and Citation". The new response date is **January 19th**, **2017**. Please see the Guide notice http://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-025.html for more details.

NIH Effective Date for the New Single IRB Policy Extended

NIH has extended the effective date for the new Single IRB policy until September 25, 2017. Please see the NIH guide notice for more information, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-027.html.

NSF UPDATE

> Revision to the Major Research Equipment and Facilities Construction Threshold

The Major Research Equipment and Facilities Construction threshold has been changed to \$70M. This adjustment responds to emergent scientific research opportunities and addresses the gap that previously existed between smaller instrumentation and major facility projects. The scientific community should incorporate this change in their long range portfolio planning and prioritization efforts.

This change will be reflected in the 2017 revision of NSF's Large Facilities Manual which will be published in December 2016. See Notice 138.

NSF Grants.gov Application Guide

A revised version of the <u>NSF Grants.gov Application Guide</u> has been issued. The new <u>NSF Grants.gov Application</u> <u>Guide</u> will be effective for proposals submitted, or due, on or after January 30, 2017.

The NSF Grants.gov Application Guide has been updated to align with changes to. All References to the Grant Proposal Guide (GPG) and Award & Administration Guide (AAG) have been replaced with references to the Proposal & Award Policies & Procedures Guide (PAPPG). Editorial changes have also been made to either clarify or enhance the intended meaning of a sentence or section or to ensure consistency with data contained in NSF systems or other NSF policy documents.

Revisions have been made to the following documents:

- Grant General Conditions (GC-1);
- Cooperative Agreement Financial & Administrative Terms and Conditions (CA-FATC);
- Cooperative Agreement Supplemental Financial & Administrative Terms and Conditions for Managers of Large Facilities;
- Cooperative Agreement Supplemental Financial & Administrative Terms and Conditions for Managers of Federally Funded Research and Development Centers (FFRDCS);
- International Research Terms and Conditions;
- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Phase I Grant General Conditions;
- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Phase II Grant General Conditions; and
- Administration of NSF Conference or Group Travel Grant Special Conditions (FL 26).

If you have any questions regarding these changes, please contact the Policy Office on (703) 292-8243 or by e-mail to policy@nsf.gov. For technical questions relating to Grants.gov, please contact Grants.gov directly at 1-800-518-4726 or support@grants.gov.

Update: NSF Frequently Asked Questions (FAQs) on Proposal Preparation and Award Administration

NSF has issued a revised set of <u>Frequently Asked Questions (FAQs) on Proposal Preparation and Award Administration</u>. These FAQs accompany the NSF <u>Proposal & Award Policies & Procedures Guide</u> (PAPPG), <u>(NSF 17-1)</u>, and are effective for proposals submitted or due, and awards made on or after, January 30, 2017.

If you have any questions regarding these FAQs, please contact the Policy Office in the Division of Institution & Award Support at 703.292.8243 or by e-mail to policy@nsf.gov.

PCORI

Patient-Centered Outcomes Research Institute (PCORI) – Updated Instructions for Writing Draft Final Research Report

PCORI has updated its instructions for writing the required Draft Final Research Report for all PCORI-funded research awards. This report will undergo an external peer review process, which is required by PCORI's authorizing legislation, and is considered a "Draft" Final Research Report until PCORI accepts it as "final" following peer review.

The main goal of PCORI's peer review process is to ensure that the Final Research Report is a full, unbiased account of the research, its limitations, and its interpretation in light of those limitations. The Draft Final Research Report represents a complete account of the research study, funded by PCORI.

The updated instructions include:

- Required content of the Draft Final Research Report
- Methods Program awardee specific section
- PCORI Methodology Standards
- Required Ancillary Information Conflicts of Interest Disclosure Form

Once the report is submitted, it will be peer reviewed to assess its scientific integrity, adherence to the PCORI Methodology Standards, and relevance and usefulness to patients, clinicians, and other stakeholders. Following the external peer review process, PCORI will post the Final Research Reports online, so that they are a permanent record of the scientific standards that PCORI and its awardees have committed to maintain.

Below are links to the following resources:

- · Draft Final Research Report instructions
- · Step-by-step instructions of PCORI's peer review process
- · Overview of PCORI's peer review process

PCORI encourages you to begin writing your Draft Final Research Report as early as possible so that you are able to promptly submit the report once data analysis is complete. This helps PCORI maintain its goal of providing research information to patients, clinicians, and other stakeholders as quickly as possible.

All awardees submitting Draft Final Research reports after February 1, 2017, must use this new format. If your Draft Final Research Report is due before February 1, 2017 and you have already started working on the report, you are encouraged to consider adhering to the updated instructions for the remainder of the report.

Training & Conferences

OSP & RAIS Resources

Do you have staff that is new to research administration? Schedule a meet and greet with the Office of Sponsored Projects & Research Administration Information Systems. Introduce your staff to their Pre-Award Grant/Contract Administrator, their Post-Award Grant/Contract Accountant, or have them do a demo of Coeus with our Coeus team.

To schedule a meeting, email or call your Pre-Award Grant/Contract Administrator or email the Coeus team at Coeus Help@brown.edu



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

CONFERENCES & PROGRAMS

NCURA National Meetings posted for 2017

- Financial Research Administration (FRA) March 11-13, 2017 | San Diego, CA
- Pre-Award Research Administration (PRA) March 8-10, 2017 | San Diego, CA
- Annual Meeting August 6-9, 2017 | Washington, DC

NCURA Region I Spring Meeting 2017

Conference: May 1- May 3, 2017 | Pre Conference Workshops: April 30, 2017 | Newport, RI

For more details, see http://ncuraregioni.org/spring-meeting.html