BROWN

RESEARCH ADMINISTRATION NEWSLETTER

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

JUNE 2018

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

➢ Updated Guidance on Brown's Authorized Signatories is published

We have recently updated the OVPR guidance on obtaining an authorized University signature on agreements related to sponsored research. The list is found under the "How Do I?" section of the OVPR website in the Award Management section here. The office identified as Agreement Owner is the best place to contact for proper handling of any type of contractual document requiring a signature on behalf of Brown University. The Brown University Corporation has delegated these signature authorities to specific titles within the Office of the Vice President for Research. Only these individuals are empowered to execute documents for Brown University. Should you have any questions on this policy please contact us at resadmin@brown.edu.

➢ Brown's Fiscal Year Closure - June 30, 2018

The Year End Schedule has been posted to the Controller's Website: https://www.brown.edu/about/administration/controller/workday-project/year-end-schedule

***OSP requires a lead time of 2 business days prior to Year End Deadlines**

For Example:

- All operational transactions (i.e.: supplier invoices, expense reports, Payroll Accounting Adjustments (PAA's) must be routed to OSP by **July 12th at 4pm** in order to ensure the expenses are approved by the Controller's Office closing schedule of July 16th at 4pm.
- All cost transfer journal entries must be routed to OSP by **July 17th at 4pm** in order to ensure the entries are completed through the business process by the Controller's Office deadline of July 20th at 4pm.

We will do our best to facilitate late submissions, however, we cannot guarantee that late submissions will be posted to FY18 if received after the OSP deadline.

➢ New Team Member in OSP

OSP is pleased to announce the recruitment of Robin Eubank to our Post Award team. Robin previously worked as an auditor with Blum Shapiro for the last fourteen years managing the annual audit process for non-profit and higher education. Robin has an Accounting degree from University of Massachusetts, Dartmouth. Robin's position is a hybrid position - managing the Effort Reporting Process, serving as a Grant/Contract Accountant for a number of departments as well as responsible for several large projects. Please welcome Robin to our office.

Office of Research Integrity

➢ Dissemination Plan for NIH Clinical Trials: HRPP template language

NIH proposals for clinical trials now require additional information, including a dissemination plan that describes how the investigator will fulfill ClinicalTrials.gov registration and reporting requirements for NIH-funded clinical trials. The plan must contain sufficient information to assure the following:

1) the applicant will ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy;

2) informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and

3) the recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

The Brown HRPP offers the below text as suggested language for inclusion in an NIH dissemination plan**:**

The Principal Investigator (PI) will serve as the responsible party for the ClinicalTrials.gov record(s) associated with the study or studies funded by this award. [He/she] will ensure the trial is registered no later than 21 days after IRB approval, in accordance with Brown University Policy. Once a record is established, the PI will confirm the accuracy of record content, resolve problems, and verify and update the record. The PI will also report results and adverse events in ClinicalTrials.gov within 12 months of the primary and study completion dates, respectively. The Brown University Human Research Protection Program (HRPP) monitors and enforces investigator compliance with required registration and reporting in ClinicalTrials.gov. The Brown HRPP assists investigators serving as the responsible party in the registration, record maintenance, and reporting processes, including providing deadline reminders and guidance for resolving errors. As part of the review process, the Brown University Institutional Review Board will confirm that the consent form(s) follow NIH policy by requiring a specific statement relating to the posting of the study or studies on ClinicalTrials.gov.

Please see the new HRPP "Clinical Trials" web page for information about this requirement, Brown's Policy, and the various definitions of a "clinical trial."

➢ Common Rule Change Delayed...except for a few helpful provisions!

The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies are issuing a Final Rule to delay for an additional 6 months (to **January 21, 2019**) the general compliance date for changes recently made to the revised Federal Policy for the Protection of Human Subjects (also known as the "Common Rule").

What does this mean for Brown?
We cannot implement the revised Common Rule changes until January 21, 2019, at which time they will be **required**. This delay gives the federal agencies time to issue long-awaited and much needed guidance to institutions (like Brown) regarding how to implement the required changes. The HRPP is closely monitoring such guidance and will provide tools, templates, and training regarding the forthcoming regulatory changes starting this fall.

Are there any exceptions?
YES! With the announcement of the Final Rule, there was permission granted for institutions to voluntarily implement three burden-reducing provisions starting in mid-July 2018:

(1) Apply the revised definition of "research," which deems certain activities not to be research;
(2) The allowance for no annual continuing review of certain categories of research; and
(3) The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research.

Will Brown implement these three burden-reducing measures before January 2019?
We intend to do so, but want to be thoughtful and systematic in our approach and ensure our research community is well-informed about how these changes impact investigator responsibilities to continue to ensure the ethical conduct of human subjects research at Brown. We may not roll out all three at once, but we do anticipate operationalizing all three burden-reducing measures by fall 2018.

Research Development

➢ Featured Funding Opportunity

Immune Mechanisms at the Maternal-Fetal Interface (R01 Clinical Trial Optional)
FOA: RFA-AI-18-023
LOI Due: September 4, 2018 (optional)
Full Proposals Due: October 4, 2018 (September 26 in OSP/BMRA)
Award Amount: ~$750,000 per year for up to 5 years
The purpose of this FOA is to support individual projects that determine the functional interactions of immune cells present at the maternal-fetal interface, including mechanisms of responses to vaccination, infection, and/or ionizing radiation that protect or impact the fetus and that may influence fetal immune system development. Applications are sought that (1) identify and define immune mechanisms during normal pregnancy, and/or (2) identify and elucidate mechanisms of immune responses triggered by infections vaccinations, and/or ionizing radiation during pregnancy. Projects may include interactions between immune and non-immune cells that support a healthy pregnancy, and/or studies to determine the effects of commensal microorganisms, maternal infectious disease, vaccines, or ionizing radiation on pregnancy outcomes or the developing fetal immune system. **Note: this is a new R01 that is only being offered for one deadline, 10/4/18.**

For more funding opportunities selected with Brown's research community in mind, please visit the Office of Research Development's new Strategic Funding Opportunities website.

➢ Research Development and Grant Writing Newsletter

This newsletter offers strategies on how to compete successfully for research funding and highlights new funding opportunities. Archived editions, going back to 2012, are also available. Access the External Funding Opportunities website and then select 'Research Development and Grant Writing News' in the left hand menu.

Upcoming Proposal Submission Deadlines

Below are upcoming due dates for the most commonly used activity codes for *National Institute of Health (NIH) & Agency for Healthcare Research & Quality (AHRQ)*. There is also a link to the NSF Proposal Deadlines. Please continue to refer to the funding opportunity announcement (FOA) for due date information.

**All Proposals are due to OSP / BioMed Research Administration (BMRA) by the close of the business day unless a time is indicated below. For OSP deadlines that fall on a Friday, complete proposals may be submitted until 9:00 am on the following Monday.*

Click here to view the listing of all the upcoming due dates for NIH.

Activity Code	Program Description	Sponsor Due Date		OSP/BMRA Due Date	
		New Application	Resubmission, Renewal, Revision Application	New Application	Resubmission, Renewal, Revision Application
R01	Research Grants (R01)	October 5	November 5	September 27	October 26
K Series	Research Career Development	October 12	November 12	October 3	November 2
R03, R21, R33, R21/33, R34, R36	Other Research Grants	October 16	November 16	October 5	November 8
R18, U18, R25	Research Demonstration Education Projects	September 25		September 17	
T Series D Series	Institutional National Research Service Awards Other Training Grants	September 25		September 17	
P Series	Program Project Grants and Center Grants	September 25		September 17	
F Series Fellowships	Individual National Research Service Awards	December 8		November 30	
F31 Diversity Fellowships	Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research	December 8		November 30	

Click here to view the listing of all the upcoming due dates for AHRQ.

Grant Mechanism	Type of Application	Sponsor Due Date		OSP/BMRA Due Date	
		New Application	Resubmission, Renewal, Revision Application	New Application	Resubmission, Renewal, Revision Application
R01	Large Research Projects	October 5	November 5	September 27	October 26
R03	Small Research Projects	October 16	November 16	October 5	November 8
K01	Mentored Research Scientist Development Awards	October 12	November 12	October 3	November 2
R18	Large Research Demonstration Projects	September 25		September 17	
F32	Postdoctoral Individual NRSA Awards	December 8		November 30	

NSF Proposal Deadlines:

Click here to view the listing of all the upcoming Due Dates for NSF.

Sponsor /Agency Updates

NIH UPDATE

➢ Transition from Inclusion Management System to New Human Subjects System (HSS) is complete

NIH introduced a new Human Subjects System (HSS) on June 8th which has replaced their Inclusion Management System (IMS).

Earlier this year NIH recently released SF424 Forms E with a new **Human Subjects and Clinical Trials (HSCT) form.** HSS is now the method for making updates to data previously entered on the HSCT form within proposals. Post-submission updates to human subjects and clinical trial-related information (including human subjects protections, participant and enrollment information, and Clinicaltrials.gov registration and reporting information) must be made in HSS via the eRA Commons Status page after June 9, 2018.

NIH recipients completing an RPPR (Research Progress Performance Report) will be prompted to access HSS to update inclusion enrollment reports. Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.

Users (PIs) are currently unable to delegate authority for HSS updates and/or submissions to another user. Delegation authority is expected to be available in a future enhancement of HSS.

For further details and information please see NOT-OD-18-179 and these additional links: HSS Overview and HSS Training.

NSF UPDATE

➢ NSF Newsletter

NSF Proposal & Award Policy Newsletter – May/June 2018

What's Inside:

- Draft PAPPG Published in the Federal Register
- Proposal Submission in Research.gov is Here
- New Account Management System
- Revision of NSF Award Terms and Conditions
- Public Access Expansion Repository
- Faculty Compensation – A Reminder

CDC UPDATE

➢ CDC transitions some prior approval actions to eRA Commons

The Centers for Disease Control (CDC) recently completed a large-scale transition to GrantSolutions, a Grants Management Platform that interfaces with eRA Commons and allows CDC to process applications electronically. As a result, CDC Research Recipients will experience some changes with how they will submit applications for Post Award Amendments. These include most prior approval actions, for example, carryover requests, change of Principal Investigator/Institutions/Organization Name.

- Recipients can now submit all Post Award Amendments using eRA Commons. This functionality is live now, but CDC will accept applications via eRA Commons or your current process through June 24th
- Starting June 25, 2018, recipients must use eRA Commons to submit all Post Award actions.

In addition there are new guidelines for submitting Closeout requests:

- Recipients will continue to submit closeout requests electronically to their assigned Grants Management Specialist until eRA Commons enables the closeout functionality. This is estimated to occur around July 1, 2018.

Training & Conferences

UPCOMING CONFERENCES & PROGRAMS

NCURA National Annual Meeting: August 5-8, 2018 | Washington, DC
Registration now open.

NIH Regional Seminar: October 17-19, 2018 | San Francisco, CA
Registration now open.

NCURA Traveling Workshops: September 5-7, 2018 | San Antonio, TX
For more details, see
http://www.ncura.edu/travelingworkshops/Home.aspx

SRA International Annual Meeting: October 27-31, 2018 | Orlando, FL
Registration now open.

Pre-Award Research Administration (PRA) & Financial Research Administration (FRA): March 11-12, 2019 | Las Vegas, NV Registration now open.

SRA International Basics of Research Administration: July 16-18, 2018 | Milwaukee, WI
Registration now open.

Questions or comments about the Newsletter should be directed to the Office of Research Administration and Information Services– rais@brown.edu