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)

**Research Administration Updates**

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

In the space between award receipt and acceptance by the Office of Sponsored Projects (OSP) there can be a period of negotiation. The Principal Investigator (PI) and Department Research Administrators will be notified if an award contains terms and conditions that must be modified before acceptance by the University.

**Negotiating Report Due Dates**

On occasion, we have received Award Notices which require submission of final financial reports prior to the end date of the award. OSP will contact the sponsor to request that report submission be extended to a minimum of 60 days after the project end date. The sixty day period allows for a thorough review of financial expenses allocated/charged to the award.

**Final Financial Reporting Practice**

When a final financial report is due prior to the project’s end date there is a high risk of under-reporting expenditures as all allowable costs would not have posted to the financial accounting system.

- OSP’s standard final financial reporting practice involves the following steps:
  - OSP generates a closeout “rough draft” financial report after the financial accounting system close for the month the award ends. Brown’s financial books close normally between 5-8 business days of the subsequent month.
  - The rough draft report is then forwarded to department for review/adjustments and certification. The Department Research Administrator will verify expenses, review OSP notes, explore variances and make adjustments to the financial detail.
  - OSP will submit a copy of the Final Financial Report to the sponsor in advance of the sponsor due date whenever possible. OSP retains a copy of the report in the award file for three (3) years from the date of...
substitution unless otherwise instructed by the sponsor. If a sponsor requires a longer retention period such as 4 or 7 years, OSP will accommodate this time frame.

—are Reminder - New Sponsored Funding Opportunities Database
As of August 31, PIVOT, the grant funding search engine jointly sponsored by the Library, the Graduate School and Office of the Vice President for Research (OVPR), is no longer be available. SPIN has replaced PIVOT and can be access via the following link: [http://libguides.brown.edu/grants/spin](http://libguides.brown.edu/grants/spin).

Please see a quick guide on Accessing SPIN+ and How to Videos. For additional information, instructional videos, and webinars on SPIN see [http://libguides.brown.edu/grants](http://libguides.brown.edu/grants).

—are Form and Policy Changes Impacting NIH-funded Studies Involving Human Subject
If you are conducting NIH-funded research that involves human subjects, or are considering applying to NIH for support of such research, there are some important form and policy changes that may affect you.

New PHS Human Subject and Clinical Trial Information Form
For application due dates of January 25, 2018, and beyond, you will be required to use an updated application forms package (FORMS-E), which includes the new human subject and clinical trial form. This form requests human subject and clinical trials information at the study level using discrete form fields, which is a change from current practice. Contract proposals will also require this information. Learn about the new form here.

NIH Policy Changes Related to Enhancing Stewardship of Clinical Trials
To improve the stewardship of clinical trials across the life cycle of the trial, NIH made a number of policy changes which include:

• A requirement to apply to a Funding Opportunity Announcement (FOA) that specifically allows for the submission of clinical trial applications for due dates beginning January 25, 2018.
• Good Clinical Practice training expectations for NIH staff, grantees, and contractors that went into effect January 2017.
• Updated peer review criteria that will be included in FOAs for clinical trial applications and solicitations for due dates on/after January 25, 2018.
• New Human Subject Information form requirements for clinical trials that will be included in updated application forms (FORMS-E) for due dates on/after January 25, 2018, and contract solicitations published as of January 25, 2018.
• Use of a single Institutional Review Board (IRB) for non-exempt, multi-site clinical trials for application due dates on/after January 25, 2018.
• Expanded ClinicalTrials.gov registration and reporting to include all NIH supported clinical trials

Please visit the [Clinical Trial Requirements for NIH Grantees and Contractors web page](http://libguides.brown.edu/grants) for more information.

—is Streamlining the Subaward Issuance Process at OSP
As part of OSP’s involvement with the [FDP Expanded Clearinghouse](http://library.brown.edu/grants) pilot project to re-engineer the process for issuing and monitoring federal subawards, Brown University joined and began to utilize the Clearinghouse’s repository of shared data on 127 subrecipients (subaward) partners.

What was the Benefit to Pilot Project?

• Streamlined the requirements and number of forms needed to meet federal guidance on subrecipient monitoring.
  o From a population of over 130 individual forms, a single set of standard questions and data elements was defined as the essential subrecipient monitoring information.
• Streamlined the process of gathering information on Subrecipients each time a new sub or modification was requested.

Partly due to this activity, OSP’s subaward issuance timelines have greatly decreased since the summer of 2016.
Today, the **Expanded Clearinghouse** now contains 164 individual entity profiles. It is a quick stop for the collection of subrecipient information. The goal is to expand the number of participants to include the remaining members of FDP and beyond. Please check out the Brown Profile page and do recommend the site to your research collaborators. A screen shot of the Brown Audit tab appears below.

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### Office of Research Integrity

- **Expanded Interpretation: Definition of Clinical Trial for NIH-funded Research**

In 2014, the NIH clarified and broadened its definition of “Clinical Trial” as part of its initiative to enhance transparency and stewardship of clinical trials funded by its institutes. Along with the new definition, several requirements for NIH-funded clinical trials were introduced and have been implemented (e.g., Good Clinical Practice (GCP) training, reporting on CT.gov); others will be implemented in January 2018 (e.g., Single Institutional Review Board review, FORMS-E and Funding Opportunity Announcement (FOA) requirements discussed in the OSP section of this newsletter).

What may have come as a surprise to investigators this month is what feels like an expanded interpretation of the Clinical Trials definition initially rolled out in 2014. On August 8, Michael Lauer, MD, Deputy Director for Extramural Research at NIH, announced a [new tool to guide investigators in determining whether their research fits into the expanded definition of Clinical Trial](https://www.brown.edu/). This new guidance, which includes four questions to ask about the research and a series of illustrative case studies, makes it clear that the expanded definition encompasses mechanistic and exploratory/developmental research that had not previously been considered to be clinical trials. Brown University and many other institutions are pushing back against this interpretation.

Many Brown investigators with studies that meet the expanded clinical trial definition were already contacted early this year about the GCP training requirement. In light of this recent update from NIH and expanded interpretation/application of the definition, Brown’s Human Research Protection Program (HRPP) is currently conducting another review of active NIH-funded research and will contact investigators whose research we believe fits this expanded interpretation.

All investigators who are currently receiving NIH funding should take a moment to answer these four questions:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is yes, then your research meets the NIH definition of a clinical trial.
More detailed information, including case studies and FAQs, can be found on the NIH’s webpage on the definition and a new Clinical Trial Requirements for NIH Grantees and Contractors web page.

➢ **Institutional Review Board Submissions: Freeze Period for Transition to New Regulations**

The Brown HRPP is gearing up to implement the revised human subjects regulations, 45 CFR 46, also known as the Common Rule. The revised regulations were released on January 19, 2017 and nearly all of the new provisions will become effective as of **January 20, 2018**. The one part of the new regulations with a later effective date of January 20, 2020, involves a mandate for the use of a single IRB for collaborative research involving human subjects.

Beginning December 20, 2017, there will be a freeze on all new protocol submissions to the HRPP. During this freeze period:

- We ask that investigators work with HRPP staff to finalize any submissions that are currently under review – failure to obtain approval for existing submissions prior to January 20, 2018 will, unfortunately, result in closure of the submission and require re-submission under the revised regulations.
- The HRPP will be evaluating currently active protocols to determine if they meet new exemption or expedited criteria under the revised regulations (and, therefore, may be subject to reduced administrative burden for investigators!)
- The HRPP intends to complete all continuation reviews for current studies that expire in January 2018 in late December/very early January, which may result in a slight change in anniversary date moving forward.
- The HRPP will consider exceptions to the freeze period for urgent situations, such as Just in Time requests, to be evaluated on a case-by-case basis.

Regular IRB operations will continue under the new policies, procedures and regulations as of January 20, 2018.

➢ **North Korea Travel Ban**

**Effective September 1, 2017,** the Department of State has declared all U.S. passports invalid for travel to the Democratic People’s Republic of Korea (North Korea) unless the travel meets certain criteria, as specified at 22 CFR 51.64.

Due to risk of arrest and long-term detention, travel to North Korea is not advised. For anyone who is proposing to travel to North Korea on a non-U.S. passport OR on a U.S. passport that has been specially validated for travel to North Korea, please note the following:

- U.S. persons (including U.S. residents) are generally prohibited from engaging in transactions or dealings involving persons whose property and interests in property are blocked pursuant to North Korea-related authorities.
- Exports of goods and services to North Korea are generally subject to export controls administered by other agencies, including the Department of Commerce and the Department of State. A license is required for the export or re-export to North Korea of almost all items (all items subject to the Export Administration Regulations (EAR) other than food or medicines designated as EAR99).
- You must contact the University’s Export Control Officer to determine if any export or Office of Foreign Assets Control (OFAC) licenses are required for your trip to North Korea.

Please use this link to view the OFAC summary information on the North Korea sanctions program.

➢ **Forthcoming Amendments to the Cuban Asset Control Regulations (CACR)**

In June, President Trump issued a memorandum instructing various departments and agencies to adjust current regulations regarding travel to and transactions with Cuba. Within the next few weeks, we are expecting the OFAC in the Department of the Treasury to issue an amendment to the CACR. The amendment will primarily affect individual people-to-people travel to Cuba; however, OFAC has indicated that it may also impact certain categories of educational travel.

Additionally, the President instructed the Department of State to issue a list of entities and sub-entities that are under the control of the Cuban military, intelligence, or security services. Under the revised regulations, direct financial transactions with those entities or sub-entities on the list will be prohibited.

We will provide a full update to the research community once the amendments have been issued. In the meantime, we
encourage anybody traveling to Cuba in a Brown capacity and any Department or Center with ongoing educational programs in, and exchanges to, Cuba, to contact the Export Compliance Team with any questions.

- **Updated Animal Holding Policy & Request Form**
The Institutional Animal Care and Use Committee (IACUC) recently approved revisions to its Policy on Holding of Animals not covered by an active Animal Care and Use Protocol and the corresponding Holding Request Form. Importantly, all investigators should be aware that NIH (and some other sponsors) prohibit charging animal costs to federal awards while animals are under the Holding Policy and not associated with an active study protocol. The Holding Policy is not intended to be used as a stop-gap solution for investigators who failed to submit three-year renewals in accordance with stated deadlines.

- **Transfer of Animals between Protocols at the End of a Study**
The Animal Research Protection Program encourages the transfer of animals from one active protocol to another at the end of a study (when appropriate) as one way in which our program adheres to the 3Rs (specifically, Reduction of the number of animals used). We remain highly committed to ensuring this process is encouraged and does not impose unnecessary administrative burden.

In order to facilitate such transfers, the donating protocol must list “donation” or “transfer” as an endpoint for the animals. If donation/transfer is one potential endpoint, we encourage you to include this in your protocol at the time of initial submission even if the recipient protocol is not yet known to avoid the need to amend later. The recipient protocol and PI will then specify in his/her own protocol, either at the time of submission or later via an amendment, which protocol is donating the animals and how the animals will be used under the receiving protocol.

Please note that the IACUC may not independently approve a transfer of United States Department of Agriculture (USDA)-covered species that would involve an animal having multiple major survival surgeries across protocols (i.e., one surgery under the donating protocol, and the second under the receiving protocol). For USDA-covered animals, such transfers require approval from the agency following a request from the IACUC. Such a request is time-intensive and approval by the USDA can take several months.

**Research Development**

- **OVPR Internal Research Funding Opportunities 2017-2018**
The Office of the Vice President for Research (OVPR) is pleased to announce the availability of research funds for the 2017-2018 Academic Year. Research Seed Awards, Salomon Awards, and Grant Resubmission Awards are competitive grants distributed directly to faculty researchers and administered by OVPR. Complete guidelines on these and other opportunities are available on the Internal Funding Opportunities page of the OVPR website.

**OVPR Research Seed Awards**
*New* Letter of Intent (LOI) (required)
Deadline: Monday, September 25, 2017, 5 p.m. (via Seed LOI google form)
Proposal due: Monday, October 16, 2017, 5 p.m. (via UFunds)
- Help faculty more successfully advance competitive research proposals by supporting the generation of preliminary data, pursuing new directions or collaborations in research, and other endeavors.
- Investigators may propose projects in one of two categories. Category 1 - projects of any type with budgets up to $50,000 for one year; Category 2 - projects supporting a new collaboration between two or more disciplines with budgets up to $100,000 for one year.
- Any Brown faculty member whose research is administered through Brown is eligible. Brown faculty members whose research is administered through affiliated institutions, emeritus, adjunct, and visiting faculty, as well as post docs, are not eligible to lead projects, but may be included on the research team.
- Proposal: 250-word abstract, 5-page project description, Curriculum Vitae (CV), budget, chair’s letter
OVPR Salomon Faculty Research Awards
Proposal due: Monday, November 20, 2017, 5 p.m. (via UFunds)

- Support excellence in scholarly work by providing up to $15,000 for one year for selected faculty research projects deemed to be of exceptional merit.
- 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 apply. Faculty who have received a Salomon grant in 2015 or later are not eligible to apply. Preference will be given to junior faculty who are in the process of building their research portfolio.
- Proposal: 250-word abstract, 3-page project description, CV, budget, chair’s letter

OVPR 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.

Please contact Margaret Manning at Research_Opps@brown.edu or 863-5145 with any questions.

- Limited Submission Reminder, Upcoming Internal Deadlines

NIH Centers of Biomedical Research (COBRE):
Deadline: 9/18/17

For the most current list of all upcoming opportunities, please visit the Limited Submission webpage here on the OVPR website. Please contact Margaret Manning at Research_Opps@brown.edu or 863-5145.

- Research Development and Grant Writing Newsletter

The August issue is now available online; this newsletter offers strategies on how to compete successfully for research funding and highlights new funding opportunities.
Research Administration Information Systems

➢ Update on NIH “Forms-E” Grant Application Forms

Effective Date:
Applicants must use FORMS-E application packages for due dates on or after January 25, 2018. NIH will begin posting funding opportunities with the new FORMS-E packages beginning October 25th.

What’s Changing:
• Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple forms into a new PHS Human Subjects and Clinical Trials Information Form.
• Expansion and use of discrete form fields for clinical trial information to ensure proper oversight
• Removal of Human Subjects Section and Human Subject related attachments on various forms:
  o PHS 398 Career Development Award Supplemental Form
  o PHS 398 Cover Page Supplement
  o PHS 398 Research Plan
  o PHS 398 Research Training Program Plan
  o PHS Fellowship Supplemental Form
• Updated R&R Other Project Information form to incorporate the addition of two human subject exemption codes (7 and 8) in preparation for implementation of Common Rule
• Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms
• Updated OMB Expiration Dates across various forms

Resources:
• High-level Summary of Form Changes in FORMS-E Application Packages
• Annotated Preview of FORMS-E Grant Application Form Changes
• A Walk-through of the PHS Human Subjects and Clinical Trials Form (9 min. video)

Coeus Update to Support the New Forms:
RAIS is in the process of testing the new FORMS-E in the Coeus Test environment:
• New Versions of the PHS Forms - We are reviewing the new versions and hope to have those implemented by the end of October.
• New Form - PHS Human Subjects and Clinical Trials Information Form – These forms are currently under development and we plan to implement once the development and testing is completed.

➢ Grants.gov is Transitioning to using Grants.gov Workspace for Grant Submission

On December 31, 2017, Grants.gov will retire its legacy, downloadable PDF application packages and make a full transition to Grants.gov Workspace. Grants.gov Workspace is a shared, online environment managed by Grants.gov where multiple users can simultaneously work on different forms within an application package.

While most of our Federal grant applications are submitted System-to-System (S2S) via Coeus; if you have a submission that cannot be submitted by Coeus, the following options will be available:

1. Grants.gov Workspace - A shared, online environment managed by Grants.gov where multiple users can simultaneously work on different forms within an application package
2. ASSIST – For NIH Applications only - NIH’s web-based service for the preparation, submission and tracking of grant applications. Must be used for NIH multi-project applications.
3. Fastlane – For NSF Applications only - FastLane is the NSF’s online website for research related functions.

*In the coming months, RAIS will be providing more details about the Grants.gov Workspace process to the Research Community.
# 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.

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<th>Program Description</th>
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Click [here](#) to view the listing of all the upcoming due dates for AHRQ.

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<td>Application</td>
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**NSF Proposal Deadlines:**

Click [here](#) to view the listing of all the upcoming Due Dates for NSF.
## Sponsor /Agency Updates

### NIH Update

- **New Features for xTRACT**
  
  Several new features were added to xTRACT in an August 24, 2017 software release. xTRACT is the Extramural Trainee Reporting and Career Tracking system and is accessed via eRA Commons. It allows applicants, grantees and assistants to create research training tables for progress reports and institutional training grant applications.

  Users will now be able to upload participating trainee information in batches, by providing a file separated by tabs that contain certain information for each trainee. For each row of information in the file, a participating trainee will be either inserted or updated as appropriate. The following information should be included for each trainee listed in the upload file:

  - The Trainee’s Commons User Id
  - Trainee Type (Pre-Doc, Post-Doc, or Short-Term)
  - In-Training Indicator ("Y" for yes, or "N" for no)
  - Start Date (in MM/ YYYY format)
  - End Date (in MM/YYYY format)
  - Research Topic (up to 200 characters)
  - Commons ID of first associated Faculty Member
  - Commons ID of second associated Faculty Member

  You may choose to create your file using a spreadsheet application, and then saving the file as a “tab-delimited” text document.

  Similar to the participating trainee upload described above, users will also be able to perform a batch upload of participating student information. The information included in the upload file will follow the same format as participating trainees, with one exception: the only allowable values for Student Type are Pre-Doc and Post-Doc (no short-term).

  See the [Online Help for xTRACT](#) for additional details and screenshots.

### NSF Update

- **Training in Responsible Conduct of Research**
  
  The National Science Foundation (NSF) requires that each institution submitting a proposal certify that it has a plan to provide appropriate training and oversight in the ethical conduct of research to all undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research. The institutions are responsible for verifying that the training has been received. This is in accordance with the 2007 America COMPETES Act.

  See [NSF Notice No. 140](#) for more information.

- **NSF Proposal and Award Policy Newsletter**
  
  The NSF Proposal and Award Policy August/September 2017 newsletter is now available.

Coeus Update

➢ Best Practice for Processing Subaward Budgets in Coeus

When Brown’s proposal has other entity(s) that will be subawardees, the correct Grants.gov subaward budget forms must be used or there will be a Grants.gov error upon submission and the proposal will not be sent to the agency. Only the subaward budget forms directly from the specific grant opportunity package should be used.

To obtain the correct version of the Subaward form, you should first locate the Funding Opportunity on Grants.gov.

- Once located, click on the Opportunity Number to View the Grant Opportunity
- Click on the Package tab to navigate to the Grant Application package
- Click the Apply link in the “Actions” Column
- Click the Submit button
  (You will need to enter an email address or check the No checkbox under “Notification of any changes” section)
- Click the Download Package button to open the PDF package

From the Grant Application PDF, click the checkbox for the Optional form – R&R Subaward Budget Attachment and then click on the form name to open that form.

From the opened R&R Subaward Budget Attachment form, click the Click here to extract the R&R Subaward Budget Attachment button.

Please note that some grant opportunity packages are using the R&R Subaward Budget Attachment(s) Form that is version 1.3 and some are using version 1.4. Form sets can also change in the future. If you use the subaward form directly from your opportunity package you will not have to worry about what form to use, or if it is incorrect.

* Be sure to send those extracted subaward forms to your subaward contact and confirm that they are returning the proper forms to you.
**National Institute of Standards and Technology (NIST) PREP Proposals Update**

NIST PREP Proposals- currently NIST PREP proposals cannot be sent via Coeus S2S (system-to-system). They will need to be sent via the Grants.gov forms package which can be downloaded directly from [Grants.gov](https://grants.gov) by searching that specific funding opportunity.

Coeus is unable to populate the Award Number field on the CD-511 mandatory form.

![Screenshot of CD-511 form](image)

Also, please note that these submissions have a 60-character maximum project title allowed. Titles longer than 60 characters will generate an error.
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.

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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 Traveling Workshops

- **October 11-13** | West Palm Beach, FL
For more details, see [http://www.ncura.edu/Education/TravelingWorkshops.aspx](http://www.ncura.edu/Education/TravelingWorkshops.aspx)

NIH Regional Fall Seminar

- **Seminar: October 25 – 27** | Baltimore, MD
For more details, see [NOT-OD-17-026](#)

NSF Fall Grants Conference

- **Conference: November 13-14** | Phoenix, AZ
For more details, see [https://nsfgrantsconferences.com/fall-17-conf/](https://nsfgrantsconferences.com/fall-17-conf/)

Questions or comments about the Newsletter should be directed to the Office of Research Administration Information Systems – [RAIS@brown.edu](mailto:RAIS@brown.edu)