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)

Email: RAIS@brown.edu | Subscribe / Unsubscribe: https://listserv.brown.edu/?SUBED1=RESEARCH_ADMIN_NEWS&A=1

### INSIDE THIS ISSUE

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coeus Update</td>
<td>1</td>
</tr>
<tr>
<td>Sponsor/Agency Updates</td>
<td>4</td>
</tr>
<tr>
<td>NIH / AHRQ/NIOSH/HHS Update</td>
<td>4</td>
</tr>
<tr>
<td>NSF Update</td>
<td>5</td>
</tr>
<tr>
<td>Other Federal Updates</td>
<td>6</td>
</tr>
<tr>
<td>Research Administration Updates</td>
<td>7</td>
</tr>
<tr>
<td>Office of Research Integrity</td>
<td>7</td>
</tr>
<tr>
<td>Research Development</td>
<td>10</td>
</tr>
<tr>
<td>Research Administration Information Systems</td>
<td>11</td>
</tr>
<tr>
<td>Office of Sponsored Projects</td>
<td>11</td>
</tr>
<tr>
<td>Upcoming Proposal Submission Deadlines</td>
<td>12</td>
</tr>
<tr>
<td>Training &amp; Conferences</td>
<td>13</td>
</tr>
<tr>
<td>OSP &amp; RAIS Resources</td>
<td>13</td>
</tr>
<tr>
<td>Upcoming Conferences &amp; Programs</td>
<td></td>
</tr>
</tbody>
</table>

### Coeus Update

#### NIH Additional Investigator(s) Questionnaire Update

The Additional Investigator(s) questionnaire is used to identify any additional individuals, other than the PI, who are responsible for the design, conduct, or reporting of research on the project. This identification is necessary to meet the 2011 Public Health Service (PHS) regulations on “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (“the PHS COI regulations”) - 42 C.F.R. Part 50, Subpart F.

The questionnaire has been updated to be required when submitting a proposal to one of the PHS foundations or agencies that have adopted the PHS COI regulations. Please see Special Requirements for PHS Investigators on Brown’s Conflict of Interest Policy Website for further details.

#### Coeus / NSF – Grants.gov Submission Validations Document Updated

RAIS has reviewed NSF’s Automated Compliance Checks dated 1/30/17 and has updated our NSF – Grants.gov validation listing to include all the validations on the list and identify which compliance checks are validated by Coeus and which compliance checks need to be manually checked.


#### New Guidelines on NSF / Grants.gov Submissions through Coeus

RAIS has reviewed NSF’s new compliance requirements and Automated Compliance Checks dated 1/30/17. The recommended platform for each submission type is noted in the table on the next page.
## NSF Submissions – Recommended Platforms

<table>
<thead>
<tr>
<th>Type of Submission</th>
<th>Submission Platform</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Collaborative Applications</strong> – proposals in which investigators from two or more organizations wish to collaborate on a unified research project.</td>
<td>FASTLANE</td>
<td>Grants.gov does not support the functionality to submit collaborative proposals to Fastlane.</td>
</tr>
<tr>
<td>Applications Submitted to the <strong>Directorate for Computer &amp; Information Science &amp; Engineering (CISE)</strong></td>
<td>FASTLANE</td>
<td>CISE requests that <em>Collaborators and Other Affiliations Information</em> should be submitted using the spreadsheet template found at <a href="https://www.nsf.gov/cise/collab">https://www.nsf.gov/cise/collab</a>. This excel spreadsheet is not transmittable via Coeus.</td>
</tr>
<tr>
<td>Proposal Type &gt; <strong>GOALI</strong> - Grant Opportunities for Academic Liaison with Industry</td>
<td>FASTLANE</td>
<td>RAIS is actively working on implementing the new NSF Cover Page and will communicate with the research community as soon as it available in Coeus.</td>
</tr>
<tr>
<td>Proposal Type &gt; <strong>RAISE</strong> - Research Advanced by Interdisciplinary Science and Engineering</td>
<td>FASTLANE</td>
<td>RAIS is actively working on implementing the new NSF Cover Page and will communicate with the research community as soon as it available in Coeus.</td>
</tr>
<tr>
<td>Proposal Type &gt; <strong>FASED</strong> - The Facilitation Awards for Scientists and Engineers with Disabilities</td>
<td>FASTLANE</td>
<td>RAIS is actively working on implementing the new NSF Cover Page and will communicate with the research community as soon as it available in Coeus.</td>
</tr>
<tr>
<td>Graduate Research Fellowship Program / Doctoral Dissertations / Postdoctoral Research Fellowships</td>
<td>FASTLANE</td>
<td>Opportunities are not posted to Grants.gov.</td>
</tr>
</tbody>
</table>
| **Applications that require *Directorate Specific Forms***  
  a. **Biological Sciences (BIO) Classification Form**  
     (For applications submitted to the Directorate for Biological Sciences) | COEUS however, FASTLANE can be used | For proposals requiring Directorate Specific Forms - the Directorate Specific Forms have not been programmed in Grants.gov. They need to be uploaded as a Proposal File Update in Fastlane when using Coeus. (See section below – Proposal File Updates for NSF / Coeus Submissions) |
|  b. **Project Data Form**  
     (For applications submitted to the Division of Undergraduate Education (DUE)) |  
| All Other Applications | COEUS | |

* If a FastLane application is prepared, please be aware that a Coeus record is also required.
Proposal File Updates for NSF / Coeus Submissions

- When performing a Proposal File Update (PFU) in Fastlane after a NSF / Coeus Submission, you will be required to complete the “Collaborative Status” question on the NSF Cover Page. That question does not get populated on proposals inserted into Fastlane from Coeus. Select “Not a collaborative proposal” radio button.

- In order to allow time for the Proposal File Update to be confirmed as received at NSF before 5 pm, it is best to have the proposal submitted before 12 noon on the due date. Submission of a proposal with file update after 3 pm may not qualify as a fully compliant with the deadline due date.

Grants.gov Forms Updated in Coeus

Grants.gov recently renewed the existing forms and have renewed and updated all the Research & Related (R&R) Budget Forms.

Form Renewals – OMB Expiration Date update to October 31, 2019:

- Project/Performance Site Location(s)
- Research & Related Other Project Information
- Research & Related Personal Data
- Research & Related Senior/Key Person Profile (Expanded)
- SF424 R&R Multi Project Cover
- SF424 (R&R)

All Research & Related Budget forms have been updated to reflect a new Summary line; Line K (Total Costs (Line I) and Fee (Line J). The Budget Justification has been moved to Line L.

Updated Research & Related Budget Forms & OMB Expiration Date update to October 31, 2019:

- RR_SubawardBudget10_10_1_4-V1.4
- RR_SubawardBudget10_30_1_4-V1.4
- RR_FedNonFed_SubawardBudget_1_3-V1.3
- RR_SubawardBudget_1_4-V1.4
- RR_FedNonFed_SubawardBudget30_1_3-V1.3
- RR_Budget10_1_4-V1.4
- RR_Budget_1_4-V1.4
- R&R Renewal: RR FedNonFed Budget V1.2
Sponsor / Agency Updates

<table>
<thead>
<tr>
<th>NIH/ AHRQ/ NIOSH/HHS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristics and Outcomes of R01 Competing Renewal Applications</strong> (&quot;Type2s&quot;)</td>
</tr>
<tr>
<td>NIH recently completed an analysis around Type 2 competing renewal R01 applications to determine the strongest correlation of success. In this article, Dr. Michael Lauer, NIH's Deputy Director for Extramural Research, highlights the trends and characteristics that make for a successful competing renewal application. To learn more see the &quot;Open Mike Blog&quot;: <a href="https://nexus.od.nih.gov/all/2016/12/22/r01-type2-characteristics-outcomes/?utm_source=nexus&amp;utm_medium=email&amp;utm_content=nihupdate&amp;utm_campaign=dec16">https://nexus.od.nih.gov/all/2016/12/22/r01-type2-characteristics-outcomes/?utm_source=nexus&amp;utm_medium=email&amp;utm_content=nihupdate&amp;utm_campaign=dec16</a></td>
</tr>
<tr>
<td><strong>New Appendix Policy for NIH/AHRQ/National Institute for Occupational Safety and Health (NIOSH Applications)</strong></td>
</tr>
<tr>
<td>NOT-OD-17-035</td>
</tr>
<tr>
<td>This Notice reminds the scientific research community of the recent policy for allowable Appendix materials in applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017.</td>
</tr>
<tr>
<td><strong>Allowable Appendix Materials:</strong></td>
</tr>
<tr>
<td>- <em>For all applications:</em></td>
</tr>
<tr>
<td>o Blank informed consent/assent forms</td>
</tr>
<tr>
<td>o Blank surveys, questionnaires, and/or data collection instruments</td>
</tr>
<tr>
<td>o Other items only if they are specified in the FOA as allowable</td>
</tr>
<tr>
<td>- <em>For applications proposing clinical trials (unless the funding opportunity announcement (FOA) provides other instructions for these materials):</em></td>
</tr>
<tr>
<td>o Clinical trial protocols</td>
</tr>
<tr>
<td>o Investigator's brochure from an Investigational New Drug (IND) application, as appropriate for the goals of the research proposed in the application.</td>
</tr>
<tr>
<td>No other items are allowed in the Appendix. Relocating disallowed materials to other parts of the application will result in a noncompliant application (<a href="https://nexus.od.nih.gov/all/2016/12/22/r01-type2-characteristics-outcomes/?utm_source=nexus&amp;utm_medium=email&amp;utm_content=nihupdate&amp;utm_campaign=dec16">NOT-OD-11-080</a>).</td>
</tr>
<tr>
<td><strong>Important eRA Commons Software Updates</strong></td>
</tr>
<tr>
<td>Final RPPR Section D.1 Added</td>
</tr>
<tr>
<td>- Section D.1 asks “What individuals have worked on the project?” This information will be the list of people who have worked on the project since the previous progress report. It does not include all the individuals during the lifetime of the award.</td>
</tr>
<tr>
<td>New Design of the Status Information Screen for Principal Investigators (PIs) and Signing Officials (SOs)</td>
</tr>
<tr>
<td>The Status Information screen has a new look and feel. The screen is an important source of information for PIs and SOs for such things as scores, summary statements, NIH contacts, reference letter status, etc.</td>
</tr>
<tr>
<td>- Categories of information are organized into collapsible/expandable sections</td>
</tr>
<tr>
<td><strong>Interim-Research Performance Progress Reports (I-RPPR)</strong></td>
</tr>
<tr>
<td>Effective February 2017, NIH will require that organizations submit an &quot;Interim RPPR&quot; while their renewal application (Type 2) is under consideration.</td>
</tr>
<tr>
<td>- If the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.</td>
</tr>
<tr>
<td>- If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPPR.</td>
</tr>
</tbody>
</table>
FAQs and additional information will be included on the NIH RPPR website [https://grants.nih.gov/grants/rppr/index.htm](https://grants.nih.gov/grants/rppr/index.htm) as the information becomes available.

**Notice of the Final Rule to the Federal Policy for the Protections of Human Subject (Common Rule)**

**NOT-OD-17-040**

The U.S. Department of Health and Human Services (HHS) and fifteen other Federal Departments and Agencies have published the final rule to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. The final rule is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs).


HHS released a Press Release about the final rule on January 18, 2017, that can be accessed at: [https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html](https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html)

---

**NSF UPDATE**

**Fastlane Changes to Support Policy Updates in the Proposal & Award Policies & Procedures Guide (PAPPG)**

**Effective January 30, 2017**, the National Science Foundation (NSF) will implement the following changes in FastLane to support the policy updates in the [Proposal & Award Policies & Procedures Guide](https://www.nsf.gov/pubs/2017/nsf17117/nsf17117.jsp) (PAPPG) (NSF 17-1) and to run new and enhanced automated compliance checks on proposals:

**Proposal Submission**

- New types of proposals will be incorporated into the PAPPG with new required supporting documents and automated proposal compliance checks.

  - **Grant Opportunities for Academic Liaison with Industry (GOALI):** The new GOALI automated compliance checks will require that at least one Co-Principal Investigator (PI) exists on the proposal and the “GOALI-Industrial PI Confirmation Letter” is uploaded at the time of proposal submission. All automated compliance checks applicable to Research proposals will apply to GOALI proposals.

  - **Research Advanced by Interdisciplinary Science and Engineering (RAISE):** The new RAISE automated compliance checks will require that a “RAISE-Program Officer Concurrence Email” is uploaded at the time of proposal submission, the proposal award budget is less than or equal to $1 million, and the proposal duration is less than or equal to 5 years. All automated compliance checks applicable to Research proposals will apply to RAISE proposals.

- **The Facilitation Awards for Scientists and Engineers with Disabilities (FASED) type of proposal will be included on the FastLane dropdown menu. All automated compliance checks applicable to Research proposals will apply to FASED proposals.**

**Deadline Submission**

- Organizations that are unable to submit a proposal prior to a deadline due to a natural or anthropogenic disaster will be required to submit a new Single Copy Document, “Nature of Natural or Anthropogenic Event,” when attempting to submit a late proposal using the “Special Exception to the Deadline Date Policy” box on the NSF Cover Sheet.
Updated References and Terminology

- The PAPPG (NSF 17-1) has been modified in its entirety, to remove all references to the Grant Proposal Guide (GPG) and Award & Administration Guide (AAG). The document will now be referred to solely as the NSF Proposal & Award Policies & Procedures Guide and is sequentially numbered from Chapter I-XII. All system references and links to the GPG and AAG will be updated to corresponding references and links in the PAPPG (NSF 17-1).
- “International Travel” type of proposals will be renamed to “Travel” and will be expanded to include domestic and international travel.
- “Facility/Center” type of proposals will be renamed to “Center/Research Infrastructure.”

Enhanced Automated Compliance Checks

- In addition to the new compliance checks for the GOALI, RAISE, and FASED types of proposals, FastLane will run enhanced automated compliance checks across several proposal types and will generate errors or warnings when the submission or deadline validation compliance checks are not met.
- Checks are run during “Check Proposal,” “Forward to Sponsored Projects Office (SPO),” and “Submit Proposal.” The complete list of FastLane automated compliance checks effective January 30, 2017, is available [here](#).

Note About Proposal File Update (PFU):
The automated compliance checks also apply when a PFU is performed on a proposal. The compliance checks will be run on all sections of the proposal, regardless of which section was updated during the PFU. Proposers should be aware that if a proposal was previously submitted successfully, a PFU performed on the proposal will be prevented from submission if the proposal does not comply with the compliance checks in effect at the time.

Note About Grants.gov:
*Please see Coeus Update section for updated Information on [New Guidelines on NSF / Grants.gov Submissions through Coeus](#).
Grants.gov-submitted proposals are not compliance-checked by the FastLane system and therefore do not undergo the same set of automated compliance checks at submission as those submitted directly via FastLane. If NSF receives a proposal via Grants.gov that is not compliant, it will be returned without review.

For system-related questions, please contact FastLane User Support at 1-800-673-6188 or fastlane@nsf.gov Policy-related questions should be directed to policy@nsf.gov.

### Other Federal Updates

#### American Innovation and Competitiveness Act Signed
This legislation maximizes basic research opportunities, reduces administrative burdens for researchers, encourages scientific entrepreneurship, and promotes oversight of taxpayer-funded research.

**Highlights of the American Innovation and Competitiveness Act:**

- Maximizing Basic Research
- Administrative and Regulatory Burden Reduction
- Science, Technology, Engineering, and Mathematics
- Innovation and Technology Transfer

Source and further legislative details can be found at [https://www.aip.org/fyi/2017/president-obama-signs-cures-act-competitiveness-act-and-ndaa](https://www.aip.org/fyi/2017/president-obama-signs-cures-act-competitiveness-act-and-ndaa)
Research Administration Updates

Office of Research Integrity

 Responsible Conduct of Research (RCR) Training

Brown Ethics And Responsible Conduct Of Research Education (BEARCORE) Spring 2017
The BEARCORE program is administered by the Office of Research Integrity and fulfills National Institute of Health (NIH) and National Science Foundation (NSF) Responsible Conduct of Research (RCR) training requirements. This in-person course is offered to students and trainees from a variety of academic fields, biomedical and non-biomedical, who are funded by NIH and NSF. The Spring 2017 course offering is currently open to enrollment and starts on Monday, March 20th. Registration and course details can be found here.

RCR FAQs

Who is required to take RCR training?
(1) All trainees, fellows, participants, and scholars receiving support through an NIH training grant, career development award (individual or institutional), research education grant, or dissertation research grant must receive face-to-face RCR instruction.
(2) The NSF requires that the institution provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.

How often does RCR training need to be completed?
The NIH requires that RCR training be completed at least once during each career stage (i.e., undergraduate, graduate, postdoctoral, and faculty levels), and at a frequency of no less than once every four years. NSF defers to each institution to determine the frequency of RCR training for its NSF-supported trainees, and Brown encourages NSF trainees to follow the same training frequency requirements as those required by NIH. Once you complete the face-to-face course of instruction with a minimum of 8 contact hours to satisfy the initial RCR training requirement, you may then complete refresher courses to comply with the career stage requirement and/or the requirement to complete re-training no less than once every four years.

What RCR trainings are offered at Brown?
Brown currently offers the following NIH and NSF compliant RCR courses:

- The Division of Biology and Medicine RCR Training Sequence (BioMed RCR Training). This course is offered annually each fall.
- The School of Public Health offers a Responsible Conduct in Research course each fall.
- The BEARCORE course is held annually each spring.

RCR Refresher courses

- BioMed offers refresher training for postdoctoral researchers and fourth-year predoctoral students each spring and fall. More information can be found here.
- You can also meet the refresher training course requirements via the BEARCORE program. More information can be found here.

To register for the Spring 2017 BEARCORE course or if you have any questions about RCR, please contact Jules Blyth at juliane_blyth@brown.edu or 401-863-3295.
*NEW* Brown University Export Control and U.S Sanctions Policy

ORI recently released a new Brown University Export Control and U.S. Sanctions Policy, which replaces the University's former Export Control Policy. The purpose of the policy is to help ensure compliance with export controls by heightening awareness and understanding of export control laws and regulations; highlighting how they apply in a university setting; and describing each individual's compliance responsibilities and available resources.

All faculty, staff, visiting scientists, postdoctoral fellows, students, and anyone who is paid by or otherwise engaged by Brown to conduct research, teach, or provide services at or on behalf of the University (collectively, “University personnel”), must comply with U.S. export controls and with the new policy. In addition, University personnel are required to adhere to University procedures established to maintain institutional compliance with governing laws and regulations. ORI will be publishing a comprehensive Export Control Compliance Manual in late January, which describes in detail the procedures Brown has implemented to promote compliance with the new policy.

Winter Export Control Brown Bags

ORI is hosting two Export Control Brown Bags in February. Both sessions are open to all faculty, students, and staff and space is limited.

Introduction to Export Controls. *(Beginner session, no prior knowledge of export control regulations required)*

**Tuesday, February 7, 2017, 12 pm - 1 pm (Conference room in the Rock)**

- This session serves as an introduction to export control regulations and how they apply in a university setting. What are the major regulatory schemes? Why do we need to comply? What types of activities conducted at a university might be subject to export controls? What academic exceptions can we use to conduct our everyday work without worrying about export controls? We will answer these questions and welcome your questions as well.

Export Controls Applied. *(Advanced Session – prior knowledge of export control regulations required)*

**February 15, 2017, 12 pm - 1 pm (Horace Mann, Room 103)**

- This session builds upon a basic knowledge of export control regulations. Using real life case studies, we will explore situations and activities at the university that could trigger export controls. We will focus on potential export control red flags and what needs to be done to avoid potential violations. This is an interactive, discussion-based session; participants are encouraged to bring questions and/or real or hypothetical scenarios that can be discussed with the whole group.

Space for each class is limited. To RSVP, please email Jules Blyth (Juliane.Blyth@brown.edu). Bring your lunch; we will provide snacks, water, coffee, and tea.

**Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) Accreditation Site Visit**

The Brown University animal care program will undergo a triennial re-accreditation visit by the AAALAC on February 16th and 17th. Brown has maintained continuous accreditation since 1971.

A site visitor team of AAALAC council members will review the animal care and use program, including housing and research facilities, the veterinary program, and the IACUC program. The reviewers will visit all the animal housing areas, review our program description and policies, review Institutional Animal Care and Use Committees (IACUC) protocols, and meet with University officials and IACUC members. They will also request to visit various research laboratories to speak to researchers and review animal research.

The research community has been provided with a Self-Assessment checklist to help laboratories prepare for the visit. In addition, the IACUC will be providing outreach and education while performing its semi-annual inspections over the next several weeks leading up to the site visit.

If you have any questions about the site visit, do not hesitate to contact the Animal Research Protection Program at 863-3050 or IACUC@Brown.edu.
Brown University joins SMART Institutional Review Board (IRB)!

For investigators pursuing NIH funded clinical research involving multiple sites, coordination of IRB review can be challenging. Streamlining this process has been a major concern for NIH and a high priority for Brown’s Human Research Protection Program.

Brown University is pleased to announce that we are now one of 95 (and growing!) institutions that have joined SMART IRB, a platform designed to ease common challenges and burdens associated with initiating multi-site research by leveraging a pre-negotiated master IRB Reliance Agreement. SMART IRB enables member institutions to minimize duplicative IRB review while maintaining appropriate oversight. The platform can be used for a range from large, complex clinical trials to two-site collaborations. It is also designed to provide a roadmap to implement the NIH [Policy on the Use of Single Institutional Review Board for Multi-Site Research](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM580078.pdf) which goes into effect on September 25, 2017.

As part of SMART IRB, institutions may choose to rely on another IRB to review, approve and oversee a research study:

- The Reviewing IRB takes on oversight responsibilities associated with that study for its duration
- Relying institutions provide local information about state law, study team member training and qualifications, and conflicts of interest
- Investigators and institutions retain their responsibilities for the protection of human subjects, compliance with applicable laws, regulations, ethical standards and the terms of the institution’s Federal Wide Assurance (FWA)

Additional details are available in the [SMART IRB Standard Operating Procedures](https://www.smartirb.org/) on “Establishing Reviewing IRBs and Relying Institutions” and “Initial Review Submission and Review Process.” See the [Resources page](https://www.smartirb.org/).

For more information, feel free to contact Brown University’s SMART IRB official point of contact, Susan Carton-Lopez, at Susan_Carton-Lopez@Brown.edu or 401-863-9206.

Why Register Your Study on ClinicalTrials.gov?

[ClinicalTrials.gov](https://clinicaltrials.gov/) ("CT.gov") is a registry of clinical trials that was first launched in 2000, as a result of 1997 legislation that required the Department of Health and Human Service (DHHS) to broaden public access to information about funded trials on “drugs for serious or life-threatening diseases and conditions.” While initially the registry was only open to certain NIH-funded clinical trials, several policies and laws have been enacted in the intervening years to expand the requirements for submitting registration and summary results information of clinical trials to ClinicalTrials.gov.

**Broad definition of “clinical trial”**

The definitions of “clinical trial” and requirements for registration are now so broad that it behooves NIH-funded investigators to understand the requirements and how to determine whether their research falls under any of the NIH definitions of “clinical trial” that determine registration requirements. The consequences of failure to register a trial include potential civil or criminal actions, civil monetary penalty actions, and grant funding actions, as well as the inability to publish in medical journals.

In September 2016, the US DHHS issued a final rule for [Clinical Trials Registration and Results Information Submission (42 CFR 11)](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM580078.pdf), which clarifies and expands the definition of an Applicable Clinical Trial, and provides a checklist for evaluating whether a particular study is an applicable clinical trial in accordance with [Food and Drug Administration Amendments Act (FDAAA 801)](https://en.wikipedia.org/wiki/FDA Amendments Act). For purposes of this final rule, the definition of applicable clinical trial is “a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes.” [Source: 42 CFR 11.10(a); 81 FR 65139]
Requirements for non-Applicable Clinical Trial studies

Whether or not an NIH-funded trial is subject to FDAAA 801 by meeting the definition of an Applicable Clinical Trial, it still may be required to be registered on CT.gov based on the final policy issued by NIH in September 2016. This policy is effective for applications for funding submitted on or after January 18, 2017, and applies to “all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation.”

For example, NIH-funded Phase 1 clinical trials of a Food and Drug Administration (FDA)-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including Applicable Clinical Trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to CT.gov.

Clinicaltrials.gov registration & Publication

To publish in any of the medical journals listed on the International Committee of Medical Journal Editors (ICMJE) website, investigators are required to have registered their trials with an appropriate registry, such as CT.gov, prior to enrolling participants. The ICMJE definition of a clinical trial that requires registration is:

“any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.”

Informed consent

Studies that are registered on CT.gov should include a statement in the information consent document notifying prospective participants of the availability of information about the study in the registry. You can find more information about this on the HRPP website (see Appendix C and D), or by contacting HRPP staff directly at 863-3050 or at IRB@brown.edu.

Research Development

➢ 2017 Write Winning Grants Workshops in 3 separate sessions!

Registration due by Monday, February 13 for the Grant Writing Workshop, presented by Grant Writers Seminars & Workshops, LLC in the Kasper Multipurpose Room.

Monday March, 6: Write Winning Grants - 8:30-5pm Register here
Tuesday, March 7: NSF CAREER Awards - 8:30-noon Register here
Tuesday, March 7 Career Development Awards (K Awards) - 1-5pm Register here

Learn How To:

• Identify, write and submit successful research grants
• Identify the basics of research grant applications: funding sources, grant construction, and successful submission to funding agencies
• Appreciate and understand the NIH/NSF peer review process so you can submit your best grant applications

Space is limited for each workshop and will be provided on a first come, first served basis. Individual registration is required for EACH session. Register by Monday, February 13, 2017. Registration after February 13th will be wait listed.

Sponsored by the Office of BioMed Faculty Administration, the School of Public Health and the Office of the Vice President for Research.
Campus Visits by Program Officials
The Research Development Team is available to assist in coordinating campus visits by program officials. If you have already scheduled a visit or are planning one, please let us know by contacting Amy.Carroll@brown.edu. We would like to take full advantage of having program officials on campus and ensure that as many faculty and staff have an opportunity to meet with them as possible.

OVPR Internal Funding Opportunities
Grant Resubmission Awards
Deadline: Rolling
- Provide up to $15,000 for investigators to improve an already highly-rated proposal for re-submission. Apply via UFunds.

Research Development and Grant Writing Newsletter
The January 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

RAIS Welcomes New Staff Member
We would like to introduce Kerri Camera, who has joined RAIS, as a Research Services Business Analyst to assist in supporting the research administration information systems at Brown. She will be working with OVPR and departments as we continue our InfoEd implementation. Before joining RAIS she served as the Grants/Financial Coordinator in the Department of Pathology and Laboratory Medicine, and prior to joining Brown she held positions involving system implementations, data quality review, and reporting. Kerri holds a Bachelor of Arts from Rhode Island College and a Master of Arts from Liberty University.

Please join us in welcoming Kerri to RAIS.

InfoEd Project Update
Our first InfoEd module, Conflict of Interest (COI), was implemented in December, 2016. This module has replaced the legacy COI reporting system and will be used for submission of all COI Assurance and Reporting forms. In February, a separate communication will be sent to faculty and researchers who are required to complete an Annual COI Assurance and Reporting form.

The Lab Animal module, which will be used to submit IACUC protocols, is scheduled to be implemented this summer, and will be followed by proposal development and human subjects. Throughout the implementation period, updates on our progress will be provided on the project website, or you may subscribe to the InfoEd Project Listserv.

We invite everyone from the research community to share ideas, questions, and concerns throughout the course of the InfoEd project via the website's feedback link. We appreciate your support as we implement InfoEd, and we look forward to improving efficiency and reducing administrative burden for our research community.

Office of Sponsored Projects

OSP Welcomes New Staff Member
OSP is excited to welcome Tanitia Sello to the Post Award team as a Grants/Contracts Accountant II. Tanitia previously worked at the Boston Athenaeum as the Director of Finance, CFO and at Brown as Director of Finance/Budget and Operations of the Graduate School. Tanitia holds a M.Sc. Business Management from the University of East Anglia, Norwich England. Welcome, Tanitia!
Upcoming Proposal Submission Deadlines

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

*All Proposals are due to OSP / 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.

<table>
<thead>
<tr>
<th>Activity Code</th>
<th>Program Description</th>
<th>Sponsor Due Date</th>
<th>OSP/BMRA Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>New Application</td>
<td>Resubmission, Renewal, Revision Application</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Application</td>
<td>Resubmission, Renewal, Revision Application</td>
</tr>
<tr>
<td>R01</td>
<td>Research Grants (R01)</td>
<td>February 5</td>
<td>March 5</td>
</tr>
<tr>
<td>K Series</td>
<td>Research Career Development</td>
<td>February 12</td>
<td>March 12</td>
</tr>
<tr>
<td>R03, R21, R33, R21/33, R34, R36</td>
<td>Other Research Grants</td>
<td>February 16</td>
<td>March 16</td>
</tr>
<tr>
<td>R18, U18, R25</td>
<td>Research Demonstration Education Projects</td>
<td>past</td>
<td>past</td>
</tr>
<tr>
<td>T Series D Series</td>
<td>Institutional National Research Service Awards Other Training Grants</td>
<td>past</td>
<td>past</td>
</tr>
<tr>
<td>P Series</td>
<td>Program Project Grants and Center Grants</td>
<td>past</td>
<td>past</td>
</tr>
<tr>
<td>F Series Fellowships</td>
<td>Individual National Research Service Awards</td>
<td>April 8</td>
<td>March 31</td>
</tr>
<tr>
<td>F31 Diversity Fellowships</td>
<td>Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research</td>
<td>April 13</td>
<td>April 5</td>
</tr>
</tbody>
</table>

Click [here](#) to view the listing of all the upcoming due dates for AHRQ.

<table>
<thead>
<tr>
<th>Grant Mechanism</th>
<th>Type of Application</th>
<th>Sponsor Due Date</th>
<th>OSP/BMRA Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Large Research Projects</td>
<td>February 5</td>
<td>March 5</td>
</tr>
<tr>
<td>R03</td>
<td>Small Research Projects</td>
<td>February 16</td>
<td>March 16</td>
</tr>
<tr>
<td>K01</td>
<td>Mentored Research Scientist Development Awards</td>
<td>February 12</td>
<td>March 12</td>
</tr>
<tr>
<td>R18</td>
<td>Large Research Demonstration Projects</td>
<td>past</td>
<td>past</td>
</tr>
<tr>
<td>F32</td>
<td>Postdoctoral Individual NRSA Awards</td>
<td>April 8</td>
<td>March 31</td>
</tr>
</tbody>
</table>

Click [here](#) to view the listing of all the upcoming Due Dates for NSF.
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 participate in a demo of Coeus with RAIS.

To schedule a meeting, email or call your Pre-Award Grant/Contract Administrator or email Coeus_Help@brown.edu

UPCOMING 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](http://ncuraregioni.org/spring-meeting.html)

NSF Grants Conference 2017

- Conference: June 5 – 6, 2017 | Louisville, KY

NIH Regional Seminar (Spring & Fall 2017)

- **Spring**: May 3-5, 2017 | New Orleans, LA
- **Fall**: October 25 – 27 | Baltimore, MD

For more details see [NOT-OD-17-026](#).

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