Update Your Web Browser by Nov. 30 to Continue Using eRA Commons, ASSIST, IAR & iEdison

Posted on October 31, 2016 by NIH Staff

eRA is strengthening the security of its modules on November 30 by moving to the ‘https only’ secure connection for websites, as mandated for all federal agencies. With the implementation of this security protocol, older internet browsers may not work, and you may need to update your browser to access any eRA module, including eRA Commons, ASSIST, IAR and iEdison.

An October 26 eRA email bulletin lists the web browsers and versions that will continue to work after the security upgrade. While these versions will continue to work past November 30, for an optimal experience when using eRA modules, we encourage you to use the browsers and software versions listed in the eRA browser compatibility statement. (Note that eRA uses Google Chrome, Mozilla Firefox and Internet Explorer to develop and test its modules for browser compatibility.)

RELATED

Reviewers Soon to Have Easier Accessibility to Encrypted CDs
October 1, 2008
In "eRA News"

eRA Thanks Users for Their Patience
June 1, 2009
In "eRA News"

NIH Announces New Business Process for Reporting Identified Financial Conflict of Interest for Grants and Cooperative Agreements Beginning
October 10, 2008
September 1, 2008
In "eRA News"

This entry was posted in Top Stories by NIH Staff. Bookmark the permalink [https://nexus.od.nih.gov/all/2016/10/31/update-your-web-browser-era/].
eRA Browser Compatibility

eRA is committed to delivering secure web modules that are compliant with web standards, and we aim for cross-browser compatibility. To ensure this, our development teams must use the capabilities and improved security and performance provided by the most up to date browsers, since older versions are typically no longer supported by their development company and therefore vulnerable.

We strive to verify our web modules work properly and efficiently with a reasonable range of browsers.

The following information will help ensure you have the best experience when using eRA modules such as eRA Commons, ASSIST and Internet Assisted Review (IAR).

Currently, our modules are developed and tested for compatibility using the following browser versions:

- Internet Explorer 11.x
- Mozilla Firefox 49.x
- Google Chrome 54.x

Resolving Browser Issues
If you are experiencing a problem using one of the browsers mentioned above, please contact the eRA Service Desk for assistance.

These four are the other browser versions that will work with the security upgrade, but are not included in the in the eRA Browser Compatibility statement:

- Chromium®
- Opera® version 12 and later
- Safari® as of OS X Mavericks
- Microsoft® Edge™ and Internet Explorer® 11 on Windows® 10
Is Prior Approval Required to Change the Level of Effort for Key Personnel on a Grant Award?

Posted on November 22, 2016 by NIH Staff

Yes, the PD/PI and other Senior/key personnel named in the notice of award must devote a measurable level of effort to the project. If the level of effort is reduced by 25 percent or more from what was approved in the initial competing year award, prior approval from NIH would be required. (See NIH Grants Policy Statement Chapter 8.1.2.6). With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH does not require prior approval for the reduction in effort for Senior/key personnel named in the notice of award during a no-cost extension.

RELATED

- During a No-cost Extension, Is There a Minimum Effort Requirement for Key Personnel Named in the Notice of Award, Other than the PI?
  November 22, 2016
  In "You Ask, We Answer"

- How Does NIH Determine Which Senior/Key Personnel are Named on the Award?
  January 31, 2013
  In "You Ask, We Answer"

- During a No-Cost Extension, is Prior Approval Still Required if Senior or Key Personnel Withdraw from a Project?
  August 25, 2014
  In "You Ask, We Answer"

This entry was posted in You Ask, We Answer by NIH Staff. Bookmark the permalink [https://nexus.od.nih.gov/all/2016/11/22/is-prior-approval-required-to-change-the-level-of-effort-for-key-personnel-on-a-grant-award/].

3 THOUGHTS ON “IS PRIOR APPROVAL REQUIRED TO CHANGE THE LEVEL OF EFFORT FOR KEY PERSONNEL ON A GRANT AWARD?”
8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The recipient is required to submit a prior approval request to the GMO if:

- The PD/PI or other Senior/Key Personnel specifically named in the NoA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months).

Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting Yes in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
New eRA Commons Option for Prior Approval of Applications Requesting $500,000 or More in Direct Costs

Posted on October 31, 2016 by NIH Staff

It is a longstanding NIH policy that a principal investigator (PI) needs to seek prior approval from NIH before submitting a grant application with direct costs of $500,000 or more for a single budget year. You now have the option to electronically submit these prior approval requests through eRA Commons. As per current practice, the PI will first reach out via email or phone to the Program Official (PO) at the Institute/Center (IC) to discuss the request. From there, the PO can then choose to invite the PI to initiate the prior approval request through eRA Commons. Read more about how this works in the October 2016 eRA Items of Interest, and stay tuned for two tutorial videos on this process, coming soon.

RELATED

Want to Withdraw an Application? Now, Do it Electronically in eRA Commons August 30, 2016 In "New Resources"

Submitting and Tracking Administrative Supplement Requests Electronically January 31, 2012 In "Application Submission"

Moving Forward with Special Council Review August 20, 2012 In "blog"

This entry was posted in Top Stories by NIH Staff. Bookmark the permalink [https://nexus.od.nih.gov/all/2016/10/31/new-era-commons-option-for-500k-in-direct-costs/].
NIH eRA Items of Interest - October 2016

Friday, October 14, 2016

Prior Approval – $500K

A principal investigator (PI) needs to seek prior approval from the NIH before submitting a grant application with direct costs of $500K or more for a single budget year.

NIH has been developing a way to provide you with an option to electronically submit these prior approval requests through eRA Commons. And effective Sept. 15, this option is a reality.

Here is how it works:

The Invite to Initiate a $500K Request
The PI will reach out via email or phone to the Program Official at the Institute/Center (IC) with whom they have been working concerning the $500K request, per current practice. The PO can then choose to invite the PI to initiate the prior approval request through eRA Commons. The initiation of the request will trigger an email notification to the PI and to the email address listed for receiving the Notice of Award (NoA) on the Institutional Profile screen.

PI Action
Upon being notified, the PI will go into eRA Commons and go to the Prior Approval tab along the top navigation menu. The PI will find two options and should click List my Requests. The PI will find the $500K Request under the column Request Type, with a status of “In Progress PI,” and should click the “Modify” link.

The Prior Approval Request $500K screen will open. The screen is pretty straightforward with a few required fields, such as Project Title, FOA number, and Anticipated Submission Date. The PI will need to provide a short justification (just 500 characters) for the request, with up to 10 supporting documents allowed. Depending on the business processes of the institution, the PI can route the request to the SO for review, or submit directly to NIH.

SO Action
Since the notice to submit the prior approval request is sent to the NoA address as well, the SO should login to eRA Commons and go to the Prior Approval tab. SOs should use the Search for Requests button and select the $500K Request under the Request Type drop down. The SO has the ability to view the request, or if they choose, recall it, thus giving them the ability to modify it and submit it.

Next Steps
If the request is approved by the Program Official at the IC, the PI will receive an email from the Program Official. When the error free application is received by NIH, this
application will be matched with the $500k approval from the IC and the application will move through the normal process.

For the moment, this is an option for the submission of $500K requests. However, as we continue to move from all paper processes to a formal electronic environment, this option may become a requirement as we seek solutions that provide accountability, transparency and improved reporting capabilities.

There are other features (status and history), which you can read about in the Prior Approval section of the eRA Commons Online Help.

For more information, please see Guide Notice NOT-OD-17-005. Also, coming soon will be two new video tutorials on Prior Approval. One focuses on the request to withdraw an application, and the second demonstrates the process of $500K requests as described above.

URL: https://era.nih.gov/news_and_events/era_item_October_2016.htm
NIH Operates Under a Continuing Resolution

Notice Number: NOT-OD-17-001

Key Dates
Release Date: October 7, 2016

Related Announcements
NOT-OD-16-046

Issued by
National Institutes of Health (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the "Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act" (Public Law 114-223) signed by President Obama on September 29, 2016. This Act (CR) continues government operations through December 9, 2016 at 99.504 percent of the FY 2016 enacted level.

Continuing the procedures identified under NOT-OD-16-046 and consistent with NIH practices during the CRs of FY 2006 – 2016, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2017 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2016 (see NOT-OD-16-044 and NOT-OD-16-048) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see NOT-OD-16-059) and the Ruth L. Kirschstein National Research Service Award stipend levels and tuition/fees (see NOT-OD-16-062).

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
OMB Approval for SF424 R&R Forms Used Federal-wide Underway - Continue to Use Current Forms Until Further Notice

Notice Number: NOT-OD-16-120

Key Dates
**Release Date:** June 30, 2016

Related Announcements
NOT-OD-16-004

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose

NIH and AHRQ grant application form packages include both agency-specific forms (typically labeled PHS) and federal-wide forms (typically labeled Research & Related or R&R). Although our agency-specific forms were recently approved for use through October 31, 2018 (FORMS-D, NOT-OD-16-004), the forms used federal-wide are on different clearance cycles and have recently expired or will expire soon.

Applicants and grantees should continue to use the application form packages (FORMS-D) posted with our funding opportunity announcements despite the expiration dates noted on each form.

Grants.gov is working with the Office of Management and Budget (OMB) on the federal-wide form clearance and expects OMB approval for proposed form changes later this summer. Once approval is in place, we will provide information on data collection changes and implementation plans.

We anticipate the proposed form updates to have minimal user impact for most NIH and AHRQ grant programs.

**Forms Expiring as of June 30, 2016 (OMB Clearance 4040-0001)**

- SF424 R&R
- SF424 R&R Multi-project Cover
- Research & Related Other Project Information
- Research & Related Senior/Key Person Profile (Expanded)
- Research & Related Budget
  - R&R Subaward Budget Attachment Form 5 YR 30 ATT
- Research & Related Budget 10YR
  - R&R Subaward Budget Attachment 10 YR 30 ATT
- R&R Multi-project 10 Year Budget
  - R&R Multi-Project Subaward Budget Attachment Form 10 YR 30 ATT
- SBIR/STTR Information

**Forms Expiring as of September 30, 2016 (OMB Clearance 4040-0010)**

- Project/Performance Site Locations

Inquiries

Please direct all inquiries to:

NIH Grants Information
Email: grantsinfo@od.nih.gov (preferred method of contact)

Policy on Funding Opportunity Announcements (FOA) for Clinical Trials

Notice Number: NOT-OD-16-147

Key Dates
Release Date: September 16, 2016

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

Policy Statement

NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. This means that the NIH will no longer accept clinical trial applications through "parent" FOA announcements or through other FOAs that are not specifically designed to accept clinical trials. The purpose of this policy is to improve our ability to identify proposed clinical trials, ensure that key pieces of trial-specific information are submitted with each application, and uniformly apply trial-specific review criteria.

Background

Over the past few years, the NIH began taking steps to enhance its management and oversight of clinical trials. One recommendation NIH is implementing is the use of clinical trials-specific FOAs. Some NIH Institutes and Centers already require clinical trials to be submitted in this manner, and this will now be implemented across the NIH. The NIH recognizes that there is great breadth and diversity to the types and topics for clinical trials, and the Institutes and Centers will retain the flexibility to determine how best to design funding opportunities for clinical trials for their communities.

Scope and Applicability

This FOA policy will apply to all applications involving one or more clinical trials (see definition), including applications that involve a combination of studies that are clinical trials as well as studies that are not. These latter “hybrid” FOAs include applications that will involve a combination of trial and non trial aims. These and other types of trial applications will also be submitted to clinical trial-specific FOAs if the combination studies involve a NIH defined clinical trial.

Effective Date

The target effective date for the NIH Policy on Funding Opportunity Announcement (FOA) for Clinical Trials is September 27, 2017. All applications with receipt dates on or after the effective date with plans to conduct clinical trials must be submitted in response to a clinical trial-specific FOA. After that date, applications planning a clinical trial that are submitted to a non-clinical trial FOA will be returned without review.

Inquiries

Please direct all inquiries to:

NIH defines clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html and http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

Notice Number: NOT-OD-16-148

Key Dates
Release Date: September 16, 2016

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

Policy Statement

This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).¹

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

Background

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of a research involving human subjects.²

Scope and Applicability

This Policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.³ GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6.⁴ GCP training may be achieved through a class or course, academic training
program, or certification from a recognized clinical research professional organization. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training.

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

Effective Date

This policy is effective as of January 1, 2017

Inquiries

Contact the program official at the funding NIH IC

Or

Clinical Trials Program
Office of the Director (OD)
Office of Extramural Programs (OEP)
Office of Extramural Research (OER)
National Institutes of Health (NIH)
Email: oepmailbox@od.nih.gov

2 Required Education in the Protection of Human Research Participants, see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
3 A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html.
4 Acceptable GCP courses include the NIAID GCP Learning Center website (http://gcplearningcenter.niaid.nih.gov) and National Drug Abuse Treatment Clinical Trials Network (https://gcp.nihtraining.com/).
New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-129

Key Dates
Release Date: August 12, 2016

Related Announcements
NOT-OD-16-130
NOT-OD-11-064
NOT-OD-11-080

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice alerts the scientific research community of plans to eliminate most appendix materials for applications submitted to the NIH, AHRQ or NIOSH for due dates on or after January 25, 2017. Application instructions will be updated by November 25, 2016 to reflect this change.

The Notice also clarifies:

- Status of appendix materials in peer review
- Allowable appendix materials
- Consequences for submitting disallowed appendix materials

The NIH, AHRQ, and NIOSH strive to ensure fairness in peer review for all grant applicants by specifying the types and amount of application material that are accepted for peer review. At the same time, these agencies appreciate both the need for applications to provide sufficient information to allow for an informed, expert review process and the importance of limiting the burden on peer reviewers.

Elimination of most appendix materials is intended to rectify inequities in the peer review process that can arise from submission of inappropriate or excessive appendix materials by some applicants and consideration of appendix materials in peer review by some, but not all reviewers.

Policy

Appendix materials in peer review

All information submitted with an application except the cover letter, assignment request form and appendix information are assembled into a single application image for funding consideration. The different sections within the application image are specified in the application instructions and correspond to the standard review criteria.

Therefore:

- All information required for the peer review process must be contained within those designated sections of the application image, unless the Funding Opportunity Announcement (FOA) specifies otherwise.
- Information that expands upon or complements information provided in any section of the application -- even if it is not required for the review -- is not allowed in the appendix unless it is listed in the allowed appendix materials (below). (NOT-OD-11-080)

Unless the FOA requires that certain information be included in the appendix, failure of reviewers to address appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review (NOT-OD-11-064).

**Allowable appendix materials**
Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017, the only allowable appendix materials are:

- For applications proposing clinical trials (unless the FOA provides other instructions for these materials):
  - Clinical trial protocols
  - Investigator's brochure from Investigational New Drug (IND), as appropriate

- For all applications:
  - Blank informed consent/assent forms
  - Blank surveys, questionnaires, data collection instruments
  - FOA-specified items.
    - If appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

**Consequences for submitting disallowed appendix materials**
Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

**Inquiries**

Please direct all inquiries to:

Division of Receipt and Referral  
Center for Scientific Review (CSR)  
National Institutes of Health  
Telephone: 301-435-0715  
Email: csrdrr@mail.nih.gov

Sally A. Amero, Ph.D.  
NIH Review Policy Officer  
Email: ReviewPolicyOfficer@mail.nih.gov

Francis D. Chesley, Jr., M.D.  
Director, Office of Extramural Research, Education, and Priority Populations  
Agency for Healthcare Research and Quality  
Telephone: 301-427-1521  
Email: Francis.Chesley@ahrq.hhs.gov

Viji Potula, Ph.D.  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
Telephone: 404-498-2551  
Email: VPotula@cdc.gov
Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017

Notice Number: NOT-OD-16-130

Key Dates

**Release Date:** August 12, 2016

**Implementation Date:** Applications submitted for the January 25, 2017 due date and thereafter.

Related Announcements

NOT-OD-16-129
NOT-OD-12-111
NOT-OD-12-141

Issued by

National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice simplifies and consolidates current NIH and AHRQ policy concerning post-submission materials, and extends this policy to NIOSH. Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event. The policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application.

Policy

**Allowable Post-Submission Materials for All Applications**

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application (see NOT-OD-12-111)
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in NOT-OD-12-141 for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application,** which must include only:
  - List of authors and institutional affiliations
  - Title of the article
  - Journal or citation (if available)
Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

**Institutional Training and Training-related Grants** (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news - since the training grant application was submitted - of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

**Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications:** in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH/AHRQ/NIOSH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

**Applications submitted to Requests for Applications (RFAs):** the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

**Conference Grant Applications (R13, U13):** a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

*Any other types of post-submission materials are not likely to be accepted.*

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH/AHRQ/NIOSH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH, AHRQ, or NIOSH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the FOA for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send his/her concurrence to the PD/PI.
who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Post-submission materials can only be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

**Inquiries**

Please direct all inquiries to:

Division of Receipt and Referral  
Center for Scientific Review (CSR)  
National Institutes of Health  
Telephone: 301-435-0715  
Email: csrdr@mail.nih.gov

Sally A. Amero, Ph.D.  
NIH Review Policy Officer  
ReviewPolicyOfficer@mail.nih.gov

Francis D. Chesley, Jr., M.D.  
Director, Office of Extramural Research, Education, and Priority Populations  
Agency for Healthcare Research and Quality  
Telephone: 301-427-1521  
Email: Francis.Chesley@ahrq.hhs.gov

Viji Potula, Ph.D.  
Office of Extramural Programs  
National Institute for Occupational Safety and Health  
Centers for Disease Control and Prevention  
Telephone: 404-498-2551  
Email: VPotula@cdc.gov

---

**Weekly TOC for this Announcement**  
NIH Funding Opportunities and Notices
NIH Implementation of Final Research Performance Progress Reports (Final RPPR)

Notice Number: NOT-OD-17-022

Key Dates
Release Date: November 23, 2016

Related Announcements
NOT-OD-15-111
NOT-OD-15-014
NOT-OD-14-092
NOT-OD-14-084
NOT-OD-14-079
NOT-OD-14-026
NOT-OD-13-113
NOT-OD-13-035
NOT-OD-13-061
NOT-OD-12-083

Issued by
National Institutes of Health (NIH)

Purpose

The National Institutes of Health intends to replace the Final Progress Report (FPR) with the Final Research Performance Progress Report (Final RPPR) through a new eRA Commons module effective January 2017.

Background

NIH implemented the interim RPPR in 2012, based on a policy memorandum from the Office of Management and Budget and Office of Science and Technology Policy (OSTP) to the heads of executive departments and agencies establishing the uniform RPPR for use by agencies supporting research and research-related activities. The RPPR replaced previous interim performance reporting formats used by NIH and other agencies.

In order to keep its promise, the Research Business Models (RBM), an Interagency Working Group of the Social, Behavioral & Economic Research Subcommittee of the Committee on Science (CoS), charged NSF and NIH to serve as the co-chairs of an interagency workgroup tasked with developing a standard format for use in reporting final progress on Federally-funded research projects and research-related activities, taking into consideration the lessons learned from implementation of the interim RPPR. This interagency workgroup completed its task and on November 16, 2016, published a Federal Register notice announcing the updated standardized RPPR to be used for final performance progress reporting.

NIH Implementation

For NIH, the Final Research Performance Progress Report (F-RPPR) will replace the Final Progress Report (FPR) for closeout effective January 1, 2017. On or after that date, NIH will no longer accept FPRs. Generally, the format will be the same as the current interim/annual RPPR, making it easier for recipients to navigate through the F-RPPR based on familiarity with the existing format of the annual RPPR. However, a significant change with implementation of the F-RPPR, is that in order to maximize public transparency, NIH will not maintain the current Type 2 policy which in accordance with NIHGPS Chapter 8.6.2 states that "whether funded or not" the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. It is important to note that the discontinuance of this longstanding policy aligns NIH's final performance...
reporting requirement with the requirements imposed by other Federal research awarding agencies thus reducing the administrative burden associated with a unique NIH reporting requirement.

Therefore, as a standard policy, NIH will request that organizations submit an "Interim-RPPR" while their renewal application (Type 2) is under consideration. In the event that 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. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.

Also, in accordance with NIH's implementation of the F-RPPR, recipients will be required to adhere to the new requirement to report on Project Outcomes. This section will be made publicly available, thus allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

As mentioned, NIH is aligning its reporting requirement with other Federal research agencies and therefore will not be making any changes to the deadline for submitting the final report- i.e., the Final RPPR or Interim-RPPR must be submitted via eRA Commons no later than 120 calendar days from the period of performance end date. If a recipient fails to comply with this reporting requirement, NIH may take one or more enforcement actions, such as a decision not to make a non-competing continuation award, consistent with NIHGPS Chapter 8.5.2. NIH also plans to maintain the business rule in the RPPR module enabling institutional signing officials (SOs), at their discretion, to delegate submission of the Final RPPR or Interim-RPPR to the Program Director/Principal Investigator (PD/PI).

Note: Implementation of the Final RPPR for Small Business Innovation and Research (SBIR) and Small Business Technology Transfer (STTR) grants will occur approximately 2 months after implementation for all other NIH grants due to unique final reporting requirements under the Small Business Administration's SBIR/STTR Policy Directive.

FAQs and additional information pertaining to NIH's implementation of the F-RPPR will be available on the NIH RPPR website.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research
grantspolicy@od.nih.gov
Requirement for the Appropriate Signatures on NIH Forms and Official Documentation

Notice Number: NOT-OD-16-071

Key Dates

Release Date: February 25, 2016

Related Announcements
None

Issued by
National Institutes of Health (NIH)

Purpose

National Institutes of Health grants and cooperative agreements are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Recipients are required to adopt and enforce policies that minimize the opportunity for improper research and financial conduct on the part of their organization, employees and collaborators. In upholding the high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients, NIH requires the signature of the AOR on the application as certification of compliance for the applicant organization.

The purpose of this Guide Notice is to inform NIH applicants and recipients that as of the effective dates reflected in table below, NIH will no longer accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information (i.e., Authorized Organizational Official (AOR), Signing Official (SO), Business Official (BO), Principal Investigator (PD/PI)).

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Effective on and after</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competing application</td>
<td>June 1, 2016</td>
</tr>
<tr>
<td>Non-competing continuation</td>
<td>June 1, 2016</td>
</tr>
<tr>
<td>RPPR</td>
<td>June 1, 2016</td>
</tr>
<tr>
<td>JIT/Pre-Award Materials</td>
<td>June 1, 2016</td>
</tr>
<tr>
<td>Post-Award materials (e.g., Trainee</td>
<td>June 1, 2016</td>
</tr>
<tr>
<td>Appointment Forms, Termination Notices,</td>
<td></td>
</tr>
<tr>
<td>etc. . . )</td>
<td></td>
</tr>
</tbody>
</table>

For a complete detailed list of all eRA Commons roles, please refer to Definitions of roles in eRA Commons.

Inquiries

Please direct all inquiries to:

Division of Grants Policy
Office of Policy for Extramural Research Administration (OPERA)
National Institutes of Health
Telephone: 301-435-0949
Email: GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices