OSP News & Updates

Office of Sponsored Projects **10/28/2021** 2021 Volume 4, Issue 2

*The **OSP News & Updates**, published by the Office of Sponsored Projects, is a bi-weekly subscription-based newsletter that provides OSP and sponsor updates and reminders, quick facts, guidance and training in all aspects of sponsored projects administration. Subscribe to OSP News & Updates*[i]

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1 Updates to 1306 FR.01 – Cost Sharing Approval Request and Creation of a New F&A Rate Reduction/Waiver Form 1306 FR.02

The Cost Sharing Approval Request Form has been updated with two significant changes.

- The section to request an F&A waiver, previously included on 1306 FR.01, has been moved to its own form, 1306 FR.02.
- Cost centers and/or COAs will no longer be required on the form

Please make sure that you are submitting the most current version of the form to avoid having the request returned. If you should have questions, please contact your OSP award or contract manager.

- https://your.yale.edu/policies-procedures/forms/1306-fr01-cost-sharing-approval-request
- https://your.yale.edu/policies-procedures/forms/1306-fr02-facilities-and-administrative-fa-rate-reductionwaiver-request

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2 NSF System Updates – Proposal & Award Policies & Procedures Guide (NSF 22-1)

Effective October 4, 2021, the National Science Foundation (NSF) made a number of system updates for proposals submitted in Research.gov, FastLane, and Grants.gov in accordance with the implementation of the *Proposal & Award Policies & Procedures Guide* (PAPPG) (NSF 22-1). Please see the list of PAPPG (NSF 22-1) significant changes and clarifications for all of the updates.

Updates to NSF-approved Biographical Sketch and Current and Pending Support Formats

- The NSF-approved biographical sketch and current and pending support formats were updated to incorporate revisions in the PAPPG (NSF 22-1) and must be used for proposals submitted or due on or after October 4, 2021.
- The current formats are posted on the NSF biographical sketch and current and pending support websites. Updated system-related Frequently Asked Questions (FAQs) are also available: FAQs on using SciENcv and FAQs on using NSF fillable PDF. SciENcv documents created using the previous version (i.e., NSF 20-1) prior to October 4th are automatically converted in SciENcv to the current version after October 4th.
- Biographical sketch format updates include increasing the page limit from two to three pages.
- Current and pending support format updates include the addition of new sections for information on objectives and overlap with other projects to help NSF and reviewers assess overlap/duplication.
- Biographical sketches and current and pending support information also must be uploaded with Change of Principal Investigator (PI) and Add/Change co-PI requests in FastLane.
- When notifying NSF that active other support has changed since the award was made, or since the most recent annual report, current and pending support information must be uploaded in annual and final project reports in the Research.gov Project Reporting System.
- Research.gov, FastLane, and Grants.gov will generate a compliance error message if a proposer or grantee attempts to upload a prior version of the biographical sketch or current and pending support formats on or after October 4th.

Removal of Blank Pages from the Current and Pending Support Fillable PDF

- Research.gov, FastLane, and Grants.gov will remove any pages which do not contain data entered by users (i.e., blank pages) from the NSF-approved current and pending support fillable PDF.
- The trimming service is triggered in Research.gov and FastLane during document upload and during proposal submission in Grants.gov.

- The trimming service only applies to the NSF-approved current and pending support fillable PDF and not to any other uploaded PDFs. Current and pending support PDFs generated in SciENcv do not include blank pages.

The current and pending support fillable PDF document is paginated, and the PDF page numbers will not be updated during the trimming process. This means that it is possible for the trimmed PDF to have skipped page numbers corresponding to the blank pages removed from the fillable PDF.

3 November 5th R01 Proposal Deadline Activities and Reminders

In preparation for the NIH R01 deadline on Friday, November 5th, please note the following:

Thursday, November 4th Proposal Review and Submission Activities

The Proposal Team will:

- review proposals in the order received.
- approve and submit (if no changes are required) or return the proposal for corrections, all proposals received by OSP before 2:00 p.m. on November 4th, 2021. Proposals received after 2:00 p.m. may not be reviewed until Friday, November 5th, 2021.

Friday, November 5th Proposal Review and Submission Activities

- Proposals will continue to be reviewed in the order received. Please ensure that proposals are submitted to OSP as early as possible to allow sufficient time to resolve issues (including system issues) and make corrections. Proposals ***will not be reviewed out of order for any reason***.
- If a last-minute submission is expected, let your OSP Proposal Manager know as soon as possible.

Satisfying Compliance Requirements and Other Reminders

- If there is effort/salary for personnel from departments outside of the responsible cost center, that Department Business Office must be included in the PD route to review and approve the effort in the proposal.

- All PIs/PDs (PI, Multiple PIs,) of an application must complete Sponsored Projects Administration Training for Faculty. The training and quiz can be accessed by clicking on the following link: https://bmsweb.med.yale.edu/tms/tms_enrollments.offerings?p_crs_id=1073&p_std_id=#

- The PI and other Yale proposal personnel must complete, prior to submitting the proposal to the sponsor, the following:
  - Patent Policy Acknowledgement and Agreement (all Yale individuals listed in the proposal)
  - Current External Interests Disclosure form (only individuals identified in the proposal as being responsible for the conduct, design, or reporting of the research)
  - Current VA MOU, if applicable

- The following resources may be of assistance in the preparation of a proposal:
  - Yale Frequently Needed Facts https://your.yale.edu/research-support/office-sponsored-projects/resources/frequently-needed-yale-facts
  - NIH Page Limits http://www.grants.nih.gov/grants/forms_page_limits.htm

On behalf of the OSP Proposal Team, we appreciate your cooperation and collaboration in facilitating the timely and accurate submission of proposals.

4 eRA Enhancements: New Errors for Non-Compliance with Clinical Trial Registration and Reporting at Time of Award and in RPPR

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals.

Enhancements to clinical trial registration and reporting checks are to be released today, October 1, in the Human Subjects System (HSS). The new checks will now result in an error for grant recipients upon submission of a Research Performance Progress Report (RPPR) when clinical trial registration (required 21 days after enrollment of first participant) and/or results reporting (required 12 months after trial actual primary completion date) is overdue.

- Currently, grant recipients receive a warning if they are not in compliance with clinical trial registration at 21 days after the enrollment of the first participant. They will also now see a new error if they are more than 30 days past this date.
- Similarly, the current warning for results reporting will change to an error; grant recipients will now receive an error when results are overdue by more than 12 months after the trial's actual primary completion date.

- If the required registration or results reporting information is overdue by more than 30 days after enrollment of first participant for the registration or by more than 12 months after the trial's actual primary completion date for results reporting at the time of (RPPR) submission, grant recipients will receive an error, and if the requirements are not met at time of award, it will prevent the award.

The clinical trial registration error for RPPR submission or red bar to award will be resolved once the recipient completes the required registration and provides the NCT# (Clinicaltrials.gov identifier) on the Human Subjects Clinical Trial Information (HSCT) form. The reporting error or award bar will be resolved after results are submitted in Clinicaltrials.gov. When registration or reporting are in progress, recipients may submit an exception document to resolve the error.

Here are the details on the compliance checks. These will be visible to users in RPPR in eRA Commons.

Compliance Checks for Clinical Trial Registration and Results Reporting

Compliance checks during RPPR submission

- **Display a warning message if the enrollment of the first participant was more than 21 days and less than or equal to 30 days ago and no NCT number was provided.**

  Warning message: *Enrollment of first participant for <Study Title> was* ***more than 21 days ago and less than or equal to 30****, but a Clinicaltrials.gov identifier (NCT) has not been provided. Please complete Clinicaltrials.gov registration and use the Human Subjects link in G.4 to add the NCT number in the PHS Human Subjects and Clinical Trial Information Form item 1.5.*

  An exception would be provided if one of the following conditions is satisfied:

  - If no subject is enrolled (enrollment of first subject under Sec 6.3 of the Human Subjects Trial Information Form is null or set to anticipated).
  - If the recipient uploads a valid registration receipt as an attachment under Sec 5.1 Other Clinical Trials related attachments of the Human Subjects Trial Information Form. The file name should contain 'CTgov_registration_receipt' (without quotations; file name not case sensitive).
  - If the parent application was submitted in response to a Basic Experimental Studies Involving Humans (BESH) FOA.

- **Changed warning message to an error if the actual primary completion date was more than 12 months ago and the results have not been reported to Clinicaltrials.gov.**

  Error message: *The study <study title> Primary Completion date is more than 12 months in the past and results have not been submitted to Clinicaltrials.gov. The responsible party should submit results in Clinicaltrials.gov or should have an approved extension to submit the results on a later date.*

  An exception would be provided if one of the following conditions is satisfied:

  - If the recipient uploads a valid Clinicaltrials.gov certification or extension receipt under Sec 5.1 Other Clinical trials related attachments of the Human Subjects Trial Information Form. The file name should contain 'CTgov_extension_receipt' (without quotations; file name not case sensitive).
  - If the parent application was submitted in response to a BESH FOA.

- **Display a new error message if the first participant was enrolled more than 30 days ago and no NCT number has been provided.**

  Error message: *Enrollment of first participant for <Study Title> was more than 30 days but a Clinicaltrials.gov identifier (NCT) has not been provided. Please complete Clinicaltrials.gov registration and use the Human Subjects link in G.4 to add the NCT number in the Human Subjects and Clinical Trial Information Form item 1.5*

  An exception would be provided if one of the following conditions is satisfied:

  - If recipient uploads a valid registration receipt under Sec 5.1 Other Clinical Trials related attachments of the Human Subjects Trial Information Form. The file should contain 'CTgov_registration_receipt' (without quotations; file name not case sensitive).
  - If no subject is enrolled (enrollment of first subject under Sec 6.3 of the Human Subjects Trial Information Form is null or set to anticipated).
  - If the parent application was submitted in response to a BESH FOA.

Note: The above warnings and errors will be triggered only if the studies were submitted in FORMS-E or later form versions and Clinical Trial Code is set to 'Yes.'

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5 OSP Training

Visit the OSP Grants and Contract TMS training website to review the OSP course descriptions or to register for a class. *(VPN required).* Registrations close several days prior to class.

Instructor-Led Training (ILT): Upcoming Classes

- November 16: Clinical Trial Budgeting
- November 16, 17, 18: IRES Proposal Development (PD)
- January 10: Introduction to Sponsored Projects Administration (SPA)

Online self-paced learning

The following OSP training courses are available online. After completing the course, if you have any questions about the course content email osp.trainings@yale.edu and we will forward your question to the appropriate subject matter expert.

- Allocating Allowable Costs - Online
- Clinical Trials: Create a Clinical Trial Record in PD
- Cost Transfer Principles - Online ***Revised***
- Direct Charging of F&A Type Costs on Sponsored Awards - Online
- Export Compliance (CITI Program) - Online
- IRES Proposal Tracking (PT) Overview - Online
- NIH K Award Fundamentals - Online ***New***
- Subrecipient Basics and Monitoring - Online
- What Research Staff Need to Know About Spending Sponsored Projects Funds - Online

NCURA Webinar Videos

View videos of recent NCURA (National Council of University Research Administrators) webinars by visiting the OSP Research Administrator Training website.

- **Audits: What's Hot**
  This webinar provides an in-depth look at audit issues is provided through a combination of audit trends, a review of Federal audit reports, and a discussion of day-to-day best practices.
- **In-N-Out: Here's What PI Transfers are all About**
  This webinar takes an in-depth look at the PI transfer process and provides you with questions to ask and the things to look out for in order to be prepared to handle a PI that is either coming in or leaving from their institution.

- **Participant Support Costs: An Overview of Dos and Don'ts**
  This webinar will help you understand what participant support costs are and why they are special. Discussions include: the rules and regulations governing participant support costs; how to budget, set up, and manage participant support costs; and audit considerations.
- ***Coming Soon:*** **Cost Transfers: Tackling the Challenges**

[1] *Thank you to all who have contributed to this newsletter. Please direct questions or suggestions regarding newsletter content to Tracy Coston at osp.communications@yale.edu or tracy.coston@yale.edu. Use the following link to unsubscribe to OSP News & Updates. For archived issues, visit OSP News & Updates archives.*