OSP News & Updates

Office of Sponsored Projects **6/25/2020** 2020 Volume 2, Issue 7

*he **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 Reminder regarding Signing Documents on Behalf of the University

As a reminder, pursuant to Policy 1104 – Signature Authority, Approval Authority and Access for Financial Transactions, only authorized institutional signatories may sign documents on behalf of Yale. Recently, OSP has learned of certain contracts with outside parties which have been signed by faculty members, rather than by an authorized signatory. Please note that all proposals, awards, and contracts must be reviewed, approved, and signed by OSP and that faculty members do not have the authority to sign contracts on behalf of Yale.

Contracts that may commonly arise and which require OSP review, approval, and signature include Non-Disclosure / Confidential Disclosure Agreements (NDAs/CDAs), Data Use Agreements (DUAs), Sponsored Research Agreements (SRAs), Clinical Trial Agreements (CTAs), Material Transfer Agreements (MTAs), and Collaboration Agreements (whether funded or unfunded). If you need assistance in determining the appropriate signatory for your specific document, please consult the Office of General Counsel's Signature Tool. If you have a question about whether a certain document requires OSP review and/or signature, please contact your assigned Award Manager or Contract Manager.

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2 Reminder regarding Policy 1613 Electronic Signatures…

As a reminder, OSP can accept hard or electronic signatures on documents, but affixed JPEG/copies of signatures are not allowed. Policy 1613 Electronic Signatures specifies the requirements for the use of an authentic electronic signature by Yale employees with signature authority. The policy states, "electronic signatures must use a secure certificate-based electronic signature service that has been approved by ITS. Approved certificate-based electronic signatures are legally binding and equivalent to handwritten signatures."

Refer to the corresponding Procedure 1613 PR.01 Electronic Signatures for more information on the certificate-based signature service that has been approved by ITS for signing legal documents and specific guidance on how it is used. For assistance with the use of electronic signatures, please contact the ITS Help Desk (helpdesk@yale.edu), 203-432-2900, or 203-785-3200.

3 Missing ABS Forms

As a reminder, an Award Budget Setup (ABS) form is required for all new (initial) award setups as well as those award setups requiring more than one grant line in Workday. Please be sure the ABS form is uploaded to the IRES record, so it does not delay the award setup process.

Check out our Frequently Asked Questions regarding award setup on the OSP Website.

4 Exiting Faculty Checklist

Our Exiting Faculty Checklist has been updated. This checklist is designed to be a comprehensive resource for our business offices.

5 OSP Training

OSP is moving more training classes to a Zoom format. Those who attended last week's Financial Reporting and Closeout class had positive feedback and agreed that the session improved their knowledge of the topic, but the personal discussions and usual classroom interactions are lacking when everyone is remote.

Introduction to Sponsored Projects Administration (SPA) training will be held as a Zoom class in July. We are implementing some tools to make the class a bit more interactive and engaging. SPA Registration is now open. Be sure to register even if the class is full in order to put your name on the waitlist for a future

class. Seating is limited and priority will be given to those whose job responsibilities are dependent on taking this class.

Mark your calendars - the July Brown Bag will be held on Tuesday, July 14th at 1:00pm – make note of the later-than-usual time. Topics for the July meeting are still in the planning phase, but we will be including a "What's on Your Mind" segment so please send in your questions in advance to osp.trainings@yale.edu . Zoom links for the meeting will be in sent in the Brown Bag email announcement.

https://bmsweb-h.yale.edu/ords/tms/tms_enrollments.offerings?p_crs_id=7674

6 Highlighted Sponsor Updates

6.1 Statement on NSF Proposal deadlines

NSF issued the following news item on June 16, 2020:

The National Science Foundation is mindful of the challenges many in our country face today. We also are acutely aware that while the research community is dedicated to its work, science may not be at the forefront of everyone's minds during this particular moment in our nation's history. With this in mind, NSF has decided to extend some of our upcoming proposal deadlines where possible. In ...

More at https://www.nsf.gov/news/news_summ.jsp?cntn_id=300767&WT.mc_id=USNSF_51&WT.mc_ev=click

6.2 Special Exception to the NIH/AHRQ/NIOSH Post-Submission Material Policy During COVID-19 Pandemic

Notice NOT-OD-20-123, issued by NIH on June 9, 2020 is below:

The NIH, AHRQ, and NIOSH understand that the emergency declaration related to Coronavirus Disease 2019 (COVID-19) will adversely affect the ability of many applicants to generate preliminary data in time for their grant applications submitted for the current due dates (for January 2021 Council beginning with applications submitted for the May 25, 2020 due date). However, with implementation of the President's Guidelines for Re-Opening America Again, NIH, AHRQ, and NIOSH anticipate that many investigators may be able to generate preliminary data for those applications before peer review. Therefore, this Notice provides an exception to the NIH/AHRQ/NIOSH policy for post-submission materials (NOT-OD-19-083).

For applications submitted for the January 2021 council (beginning with applications submitted for the May 25, 2020 due date for Fall 2020 review meetings), the NIH, AHRQ, and NIOSH will accept a one-page update with preliminary data as post-submission materials for applications submitted under all activity codes, ONLY if the Funding Opportunity Announcement (FOA) used for submission allowed preliminary data in the application. One page of preliminary data will be accepted for single component applications or for each component of a multi-component application.

The deadline for submitting all post-submission materials, including preliminary data, will be 30 days before the study section meeting. Because applications for emergency competitive revisions and urgent competitive revisions undergo expedited review, post-submission materials will not be accepted for those applications.

All other materials listed in NOT-OD-19-083 as acceptable post-submission materials will continue to be accepted if submitted 30 days before the study section meeting.

6.3 eRA Information: Changes in HSS Post-Submission Updates with Forms-F Starting June 13

The following communication was issued by the NIH Office of Electronic Research on June 15, 2020:

As of Saturday, June 13, 2020, all applicants and recipients submitting post-submission updates in the Human Subjects System (HSS) will use the updated FORMS-F PHS Human Subjects and Clinical Trials Information Form. These updates address new requirements for participant-level data on sex/gender, race, ethnicity, and age at enrollment for projects subject to the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects.

Users with records currently in progress will need to modify the records to meet new FORMS-F requirements.

The changes listed below include items released by eRA in March and items released on June 13.

Key FORMS-F Changes to the PHS Human Subjects and Clinical Trials Information Form

- A new Inclusion Enrollment Report title field is now available. The human subjects study title will appear by default for all existing studies and may be changed by the user. For new studies and those with a work in progress study, the title will be blank and need to be filled by the grantee. See Figure 1.

Figure 1: Inclusion Enrollment Report Title Field

- For clinical trials, the "Brief Summary" field will no longer appear in Section 4. Information in this field prior to June 13, 2020 will continue to be available in the PDF images of applications and Research Performance Progress Reports (RPPRs) submitted prior to this change.

- Question 1.4.a. "Does the study involve human subjects/participants" now has a default value of yes and cannot be changed unless the user changes their response to the question "Are Human Subjects Involved?" on the Other Projects Information form. As a study record should be completed only for research involving human participants, the "No" option is no longer available for this question. See Figure 2.

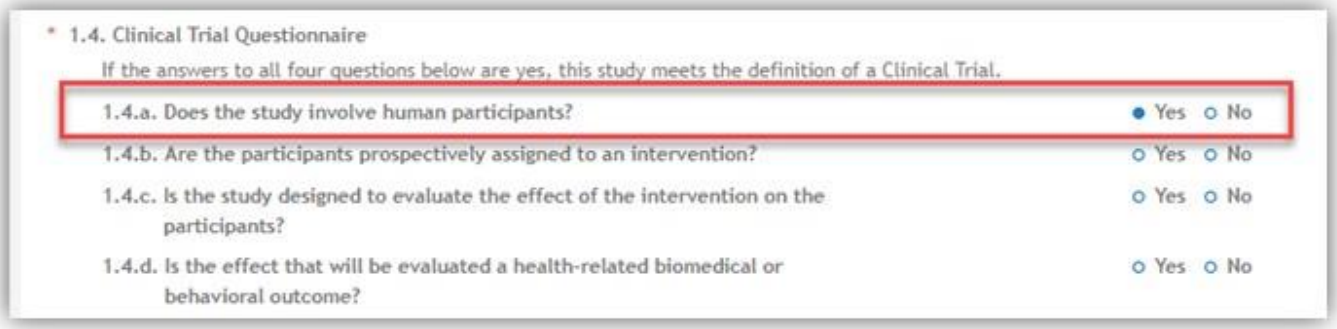

Figure 2: Question 1.4.a of the Clinical Trial Post Submission Study Record

- In Section 2.8 of the *Study Record: PHS Human Subjects and Clinical Trials Information* screen, the language has been changed from 'Enrollment of First Subject' to 'Enrolment of First Participant.'

- A new question has been added to the *Study Record: PHS Human Subjects and Clinical Trials Information* screen — Section 4.6 asks 'Is this an applicable clinical trial under FDAAA.'

- For a full list of significant FORMS-F changes, see the High-level Grant Application Form Change Summary: FORMS-F PDF.

Key Inclusion Across the Lifespan Changes

- Recipients reporting actual enrollment progress for a grant application submitted for due dates January 25, 2019 or later must provide participant-level data on sex/gender, race, ethnicity, and age at enrollment in the Inclusion Enrollment Report of the PHS Human Subjects and Clinical Trials Information Form using HSS.

- Users must use the spreadsheet template available in HSS to submit participant-level data. The column titles must not be altered, and data should be provided using the values modeled in the template. Changes to the template may result in a submission error. See Figure 3.

Figure 3: Download Participant Level Data Template button on the Inclusion Enrollment Report

- Participant-level data must be uploaded in .csv format. Users do not need to separately enter the individual numerical fields in the Actual (Cumulative) Inclusion Enrollment Report table once the .csv file is successfully uploaded. The data provided will populate the actual (cumulative) enrollment table within the system. See Figure 4.

Figure 4: Upload Participant Level Data Attachment button on the Inclusion Enrollment Report

- For more information on the requirement of individual-level participant data on sex/gender, race, ethnicity, and age at enrollment in progress reports for research supported by NIH projects, please see NOT-OD-18-116.

For more information, see:

- Entering Inclusion Data Using the Participant Level Data Template (video and transcript)
- Participant-level Data Template
- The eRA Human Subjects System (HSS) information page
- Information about the PHS Human Subjects and Clinical Trials Information form

[i] *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.*