The OSP News & Updates, published by the Office of Sponsored Projects, provides OSP updates, quick facts, sponsor/agency updates, guidance and training in all aspects of sponsored projects administration for faculty and department business offices. Please click here for archives. To subscribe, please go to: https://messages.yale.edu/subscribe.

Table of Contents

1. OSP UPDATES
   1.1. MONITORING FINANCIAL AND NON-FINANCIAL REPORTS DUE TO OSP
   1.2. REMINDER – FDP EXPANDED CLEARINGHOUSE PILOT
   1.3. CLEARING OVERDRAFTS ON SPONSORED AWARDS
   1.4. NEW WORKDAY REPORT (BUG 203A REPLACEMENT)
2. OSP STAFF UPDATES
   2.1. OSP EXECUTIVE DIRECTOR
   2.2. OSP CLINICAL AGREEMENTS TEAM
3. SPONSOR-RELATED UPDATES
   3.1. NIH CAUTIONS GRANTEES ABOUT NON-COMPLIANT BIOSKETCHES
   3.2. CHANGING POLICIES IMPACT NIH-FUNDED STUDIES INVOLVING HUMAN SUBJECTS
   3.3. NIH UPDATE: CLARIFICATION REGARDING SALARY SUPPLEMENTATION ON K AWARDS
   3.4. NIH PROVIDES ADDITIONAL GUIDANCE ON “FULL-TIME TRAINING” FOR RUTH L. KIRSCHSTEIN NATIONAL SERVICE AWARDS
   3.5. AUGUST 30: NIH WEBINAR ON RESEARCH PERFORMANCE PROGRESS REPORTS (RPPRS)
   3.6. IMPORTANT NOTICE NO. 140, TRAINING IN RESPONSIBLE CONDUCT OF RESEARCH – A REMINDER OF THE NSF REQUIREMENT
   3.7. UG FAQS AVAILABLE
   3.8. FEDERAL REPORTER

1. OSP UPDATES

1.1 MONITORING FINANCIAL AND NON-FINANCIAL REPORTS DUE TO OSP

The Office of Sponsored Projects will no longer send email notifications to Departments, alerting them when a financial or non-financial report is coming due. Instead, Departments must run the Sponsored Report Tracking (Award Tasks) - Yale to review Awards and Grants that may have required reports, and the due date to OSP (Institutional Due Date). It is highly recommended that the reports are run, at least monthly, to identify any reports coming due. Note the Financial Review Checklist has been updated to reflect this change.

1.2 REMINDER – FDP EXPANDED CLEARINGHOUSE PILOT

Since August 2016 Yale has been participating in the Federal Demonstration Project (FDP) Expanded Clearinghouse Pilot (“Pilot”). Therefore, when Yale is the Pass Through Entity (PTE), the following must
be collected from the participating FDP subrecipient institution(s). Click here for a list of Cohort 1, 2 and 3 Pilot institutions.

- A one-page Letter of Intent (LOI)
- The Scope of Work
- Budget and Budget Justification
- Any other sponsor required information

Yale will no longer collect Subrecipient Information and Compliance (SIC) forms from FDP institutions participating in the Pilot.

When Yale is a subrecipient and the Pass Through Entity is a participant in the Pilot, Yale will no longer complete that institution’s version of a SIC form, but will provide the PTE a completed one-page LOI, if requested.

If a subrecipient is included in a proposal that is not on the FDP Cohort 1, 2 and 3 list, the department must continue to receive the following from the subrecipient:

- A completed and signed SIC form
- The Scope of Work
- Budget and Budget Justification

View OSP’s FDP Subrecipient Pilot webpage for Yale’s fillable LOI and the list of FDP institutions participating in the Pilot. The webpage also includes FAQs, Yale’s SIC form, and the brown bag presentation conducted on August 8 and 9, 2016 which informed the community of the Pilot.

### 1.3 Clearing Overdraft on Sponsored Awards

As a reminder, any overdrafts on awards must be cleared prior to submission of draft financial reports to OSP. Be advised that in removing overdrafts, it is ideal to remove non-labor costs, in instances where they exist.

### 1.4 New Workday Report (BUG 203a Replacement)

A new report replacing the BUG 203a has been created in Workday. Department Business Offices or Business Support Units are required to run the Sponsored Financial Status Report – Yale, review, sign and
return to your OSP Accountant for all awards with a financial report due. For questions on this report please contact osp.financial@yale.edu.

2 OSP STAFF UPDATES

2.1 OSP EXECUTIVE DIRECTOR

As announced by Senior Associate Provost for Research Administration, Pamela Caudill, a special welcome is extended to Lisa Mosley, Executive Director. Lisa started in OSP on Monday, July 24, 2017 and is responsible for providing oversight to the day-to-day operations of the Office of Sponsored Projects. Her direct reports in OSP include:

- Amy Ellis, Associate Director, Proposals
- Cheryl Magoveny, Director, Awards
- Lauren Pite, Associate Director, Subawards
- Donald Deyo, Director, Contracts, Export Controls & Licensing
- Jeffrey Allen, Director, Clinical Agreements
- Nancy Kendrick, Director, Financial Operations
- Cynthia Kane, Director, Business Operations

2.2 OSP CLINICAL AGREEMENTS TEAM

The clinical trial team is excited to announce the addition of Lina McKinney as a Contract Manager. Lina’s first day at Yale University was on July 24th.

Lina most recently worked as an In-House Attorney at Ensign-Bickford Industries where she negotiated a variety of contracts for transactional matters. Prior to working for Ensign-Bickford, Lina was an Associate Attorney at Shipman and Goodwin for 10 years, primarily advising on contractual matters and drafting a variety of agreements. Lina earned a B.A. from Trinity College and her J.D. from Boston University School of Law.

3 SPONSOR-RELATED UPDATES

3.1 NIH CAUTIONS GRANTEES ABOUT NON-COMPLIANT BIOSKETCHES

The Office of Sponsored Projects has received multiple warning letters recently from the National Institutes of Health (NIH) reminding Principal Investigators (PIs) that proposals may be administratively
withdrawn if biosketches have been identified as non-compliant during the receipt, referral and review process. The most common violations identified by the NIH:

- Contributions to Science can include no more than five (5) contributions with four (4) citations for each contribution. Each contribution should be no longer than one half page, including citations.
- Research Support cannot include effort or direct costs.
- The Personal Statement can contain up to four (4) publications or research products that highlight experience and qualifications. Interim research products can be cited, and have specific citation requirements. Please see the NIH FAQs related to Biosketches for more information.

Please remember, PIs and their Designated Business Office personnel are responsible for verifying that the form and content of all biosketches included with the proposal are compliant with NIH guidance and policy.

For additional information please see the following:

NIH Notice NOT-OD-16-004
NIH Notice NOT-OD-16-080
NIH Frequently Asked Questions related to Biosketches
NIH Biosketch Format Pages, Instructions and Samples

### 3.2 Changing Policies Impact NIH-funded Studies Involving Human Subjects

For NIH-funded research involving human subjects, NIH first reminds researchers to become familiar with the new PHS Human Subject and Clinical Trial Information form. For application due dates of January 25, 2018, and beyond, researchers will be required to use an updated application forms package (FORMS-E), which includes the new human subject and clinical trial form. This form requests human subject and clinical trials information at the study level using discrete form fields, which is a change from current practice. Contract proposals will also require this information. More information about the new form can be found here.

Secondly, NIH expanded the clinical trial definition in response to widespread calls from diverse stakeholders for improved reporting of research milestones and outcomes, and for assuring maximal transparency. Clarified and broadened in 2014, the definition encompasses a wide range of trial types: mechanistic, exploratory/developmental, pilot/feasibility, behavioral, and more. If the study involves
human participants, if the participants are prospectively assigned to an intervention, if the study is designed to evaluate the effect of the intervention on the participants, and if the effect that will be evaluated is a health-related biomedical or behavioral outcome then the proposed research meets the NIH definition of a clinical trial.

For additional assistance in determining whether a study would be considered by NIH to be a clinical trial, refer to the definition on the NIH webpage. The webpage includes case studies, FAQs and other resources that can help. The NIH program official or the scientific point of contact listed on the funding opportunity announcement in the application is also available for help.

Thirdly, NIH encourages researchers to familiarize themselves with NIH policy changes related to enhancing stewardship of clinical trials.

NIH made several policy changes to improve the stewardship of clinical trials across the life cycle of the trial. Some changes include:

- the requirement to apply to an FOA that specifically allows for the submission of clinical trial applications for due dates beginning January 25, 2018.
- Good Clinical Practice training expectations for NIH staff, grantees, and contractors that went into effect January 2017.
- updated peer review criteria that will be included in FOAs for clinical trial applications and solicitations for due dates on/after January 25, 2018.
- new Human Subject Information form requirements for clinical trials that will be included in updated application forms (FORMS-E) for due dates on/after January 25, 2018, and contract solicitations published as of January 25, 2018.
- expanded ClinicalTrials.gov registration and reporting to include all NIH supported clinical trials.

Improving the design, efficiency, and transparency of clinical trials is important because it:

- respects our ethical obligation to participants to maximize the use of the knowledge from the trials in which they participate
- facilitates design of clinical trials while reducing unnecessary duplication
- promotes broad, timely, and responsible dissemination of research information and results
- fosters responsible stewardship of the public’s investment in biomedical research
NIH developed a new Clinical Trial Requirements for NIH Grantees and Contractors web page to bring together all the information you need to know. Please review this information carefully. Attention to detail will be critical to ensuring successful funding of your clinical trial awards.

NIH will be putting out a series of reminder policy notices, training opportunities, and other resources in the NIH Guide to Grants and Contracts and the NIH Extramural Nexus.

3.3 **NIH UPDATE: CLARIFICATION REGARDING SALARY SUPPLEMENTATION ON K AWARDS**

Refer to NIH Notice NOT-OD-17-094 for clarification and updates to policies related to Research Career Development (“K”) Awards.

The recipient institution may supplement the NIH or AHRQ salary contribution on "K" awards up to a level that is consistent with the institution's salary scale. *For effort directly committed to the "K" award, salary supplementation is allowable, but must be from non-Federal sources (including institutional sources). Non-Federal or institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the goals of the "K" award. For effort not directly committed to the "K" award, "K" award recipients may devote effort, with compensation, on Federal or non-Federal sources as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator), as long the specific aims of the other supporting grant(s) differ from those of the "K" award.*

Contact your OSP Award Manager with any questions regarding this clarification.

3.4 **NIH PROVIDES ADDITIONAL GUIDANCE ON “FULL-TIME TRAINING” FOR RUTH L. KIRSCHSTEIN NATIONAL SERVICE AWARDS**

NIH Notice NOT-OD-17-095 was issued to clarify and update the guidance on full-time training for Ruth L. Kirschstein National Research Service Awards.

All Kirschstein-NRSA fellows (individual fellowships), and trainees (institutional training grants) are required to pursue their research training full time. Full-time is generally defined as devoting at least 40 hours per week to research training activities, or as specified by the awardee institution in accordance with its own policies.

Beyond the full-time training, NIH recognizes that Kirschstein-NRSA fellows and trainees may engage in part-time employment incidental to their training. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical
employment, so long as those activities do not interfere with, or lengthen, the duration their NRSA training. (See NIH Grants Policy Statement, Section 11.2.10.2 and 11.3.10.2, for more details.)

3.5 AUGUST 30: NIH WEBINAR ON RESEARCH PERFORMANCE PROGRESS REPORTS (RPPRS)

On Wednesday, August 30, from 2:00-3:30 p.m. ET, NIH will be offering a webinar about annual, interim and final Research Performance Progress Reports (RPPRs). NIH will share the latest updates on RPPR policies and process updates. This webinar is designed for principal investigators, signing officials, and delegated officials responsible for the development and submission of progress reports to the NIH.

Registration is open at https://attendee.gotowebinar.com/register/8165062792709498114. (**This webinar is limited to 1000 log-ins so act quickly. We highly recommend group viewing to maximize access.) Prior to the webinar, check out the NIH RPPR web page.

A recording and transcript will be available approximately 5-7 business days following the event on the NIH Grants YouTube channel.

3.6 IMPORTANT NOTICE NO. 140, TRAINING IN RESPONSIBLE CONDUCT OF RESEARCH – A REMINDER OF THE NSF REQUIREMENT

NSF strongly encourages researchers to read Important Notice No. 140, Training in Responsible Conduct of Research - A Reminder of the NSF Requirement, dated August 17, 2017. In accordance with the America COMPETES Act, this NSF Notice reminds institutions of its responsibility for verifying that appropriate training and oversight in the ethical conduct of research to all undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research has been received.

For additional information on the NSF’s implementation of Section 7009 of the America COMPETES Act, Federal Register Notices, NSF-funded resources and Other Resources are available on the NSF Website.

3.7 UG FAQS AVAILABLE

Updated frequently asked questions (FAQs) presented by the COFAR on OMB’s Uniform Guidance at 2 CFR 200 are now available.
3.8 **Federal RePORTER**

Like [NIH RePORTER](#), there is also a federal-wide RePORTER, [Federal RePORTER](#). Active since 2014, Federal RePORTER is a searchable database of about 900,000 scientific awards from 17 federal agencies. To help assess the impact of federal research investment, it also includes publication data. Federal RePORTER is particularly useful for research that extends beyond NIH’s purview. For researchers, it can be used to identify colleagues for collaborations or discover which agencies fund research like their own.

For consistency among agencies, Federal RePORTER includes annual NIH RePORTER data through fiscal year 2016 (if more current information is needed, NIH RePORTER is updated weekly). The Federal RePORTER is working with agencies to allow more frequent updates in the future.

To learn more about Federal RePORTER choose take the Guided tour. Federal RePORTER also offers the following web resources: [About](#), [FAQs](#), [Help](#), and a [User Manual](#).