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.

Table of Contents

1. sIRB Plans for NIH Grant Applications
2. General Reminders from the Proposal Team
3. Upcoming Process Change Regarding IRES Record Deletions
4. IRES PD, PT, COI – Outage Application and Database Upgrade
5. OSP Training
   5.1. Brown Bag Meeting
   5.2. Upcoming OSP Classes
6. Recent NIH Notices
   6.1. Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY2020
   6.2. Revised NIAID Policy Defining the Institute’s Use of the Mentored Research Scientist Career Development (K01) Award

1 SIRB PLANS FOR NIH GRANT APPLICATIONS

NIH requires use of a single Institutional Review Board (sIRB) to conduct ethical reviews of NIH funded multi-site research where domestic sites follow the same protocol. Applicants are expected to include a plan for the use of a sIRB in the grant applications. For details, see Section 3.2 of the PHS Human Subjects and Clinical Trials Form Information Application Guide. Templates of sIRB plans that investigators can download and tailor to their needs are posted on the Yale Human Research Protection Program website.

In general, the plan for the use of a sIRB should include the following elements:

- Description regarding how you intend to comply with the sIRB policy;
- Name of the IRB that will serve as the IRB of record;
- Statement that all identified participating sites have agreed (or will have to agree if sites have not been selected at the time of the grant application) to rely on the proposed sIRB;
- Statement that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and
participating sites (the actual reliance agreements should NOT be included with the grant application);

- Brief description of a communication plan between the sites and the IRB;
- Description of which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.

Yale utilizes commercial IRBs to serve as the sIRB. Letters of support and help with sIRB review fee estimates for the budget can be obtained by submitting the online form: Request for Letter of Support for sIRB. Questions about sIRB requirements can be sent to hrpp@yale.edu.

2 GENERAL REMINDERS FROM THE PROPOSAL TEAM

The OSP web site provides guidance for departments on roles and responsibilities for principal investigators, department business office staff and OSP managers when creating research proposals. Located under the Proposals tab, you can find the document under Roles and Responsibilities. It includes a checklist to assist with the proposal preparation process.

As a general rule, OSP will not review proposals for the following:

- PMCID (PubMed Central reference number)
- Page limitations
- Font size
- Salaries of personnel
- Sponsor specific requirements
- Also, the proposal cannot be reviewed by OSP if the PD route has not yet been received by the proposal manager or required personnel are missing from the route

3 UPCOMING PROCESS CHANGE REGARDING IRES RECORD DELETIONS

In August, the process to delete IRES proposal records will be changing. We will no longer delete IRES records but instead will mark them as incomplete so that they become inactive in the system. In addition, a new form to request the Inactivation of a record will be deployed. Once available, all inactivation requests will be going to IRES support via the new form. At that point any questions related to record inactivation requests can be directed to ires@yale.edu.
4  IRES PD, PT, COI – OUTAGE APPLICATION AND DATABASE UPGRADE

Beginning at 5pm on Thursday, August 15, 2019 IRES-PD, PT, COI and all related reporting will be unavailable due to an application and database upgrade. All systems will be available again for use at 7am on Monday, August 19, 2019. Any proposals that are due either Thursday, August 15th or Friday, August 16th must be received by OSP prior to noon on Thursday, August 15th to be reviewed and submitted before the system shuts down at 5pm. Please contact your proposal manager with any questions or concerns.

If you have any questions or concerns regarding the shutdown, please contact IRES@yale.edu. Research Enterprise Operations apologizes for the inconvenience and appreciates your patience and understanding during this time.

5  OSP TRAINING

5.1  BROWN BAG MEETING

Join us for the August 15th Brown Bag session. Visit the TMS Brown Bag webpage to register and view the event details.

Topics for the August meeting include:

• General Information and Updates
• More on Data Usage Agreements
• Fundamental Research
• New Procedure: Inactivate an IRES Record
• IRES v15 Live Walkthrough (demo)
• And more...

5.2  UPCOMING OSP CLASSES

OSP classes are designed for Research Administrators and those in DBOs (department business offices) who manage sponsored projects. Attend a class to learn more about the issues you deal with in your office or take a refresher to stay up-to-date. Register to attend an OSP training class.
**Introduction to Sponsored Projects Administration:** This course is designed to be an overview of the sponsored projects process from pre-award to post award and closeout and relevant for those who manage some part of the award process. Attendees include those new to research administration or those who would like a refresher or an overview of the entire life-cycle of an award. Topics covered include:

- Award basics and terminology
- Preparation, submission, negotiation and acceptance
- Award setup and managing an award
- Reporting obligations, award closeout and audits

**Cost Transfer Principles:** This module provides individuals with an understanding of Yale’s policies and procedures regarding labor and non-labor cost transfers associated with sponsored awards including:

- Federal regulations related to cost transfers
- Sponsor and University Policy
- The process to properly and efficiently prepare, document, approve and submit a cost transfer

**Subrecipient Basics and Monitoring:** This course is designed to review the process of managing a subaward including:

- Understand the roles and responsibilities of individuals involved in the subaward process
- Be able to differentiate between a subrecipient and a vendor relationship
- Gain a greater awareness and understanding of Yale’s policies and procedures regarding subrecipients
- Understand the requirements and expectations for subrecipient monitoring and the processing of invoices
- Know where to find resources to assist in the subaward process

### 6 RECENT NIH NOTICES

#### 6.1 REQUIREMENT FOR ORCID iDS FOR INDIVIDUALS SUPPORTED BY RESEARCH TRAINING, FELLOWSHIP, RESEARCH EDUCATION, AND CAREER DEVELOPMENT AWARDS BEGINNING IN FY2020

In [Notice Number: NOT-OD-19-109](https://not.od.nih.gov/notices/not-od-19-109.html), NIH, AHRQ, and CDC announce that individuals supported by research training, fellowship, research education, and career development awards will be required to have ORCID iDs (Open Researcher and Contributor Identifiers) beginning in FY 2020.
Background and Related Information

ORCID iDs are unique, persistent digital identifiers that distinguish individual investigators and can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. These free identifiers are assigned and maintained by the non-profit organization ORCID.

In response to recommendations from the Advisory Committee to the NIH Director and the National Science and Technology Council’s Working Group on Research Business Models that federal agencies adopt tools and approaches to simplify applicant reporting and improve the tracking of career outcomes, NIH introduced the option for PD/Pis and other users to associate an ORCID identifier with their eRA Commons Personal Profile in 2017. Since that time, more than 30,000 eRA Commons Profiles have been linked to ORCID iDs.

In addition, more than 7,000 journals now use ORCID iDs and, with the permission of users, can automatically populate ORCID user accounts with their citations when they publish. Federal grant applicants can also link their ORCID accounts with SciENcv (Science Expert Network Curriculum Vitae), to simplify the creation of biosketches for grant applications.

Implementation

The requirement for ORCID identifiers will be implemented through the appointment process for those appointed to institutional awards and through the application process for those applying for individual awards.

In October 2019, the requirement for ORCID identifiers will be incorporated into the appointment process for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including the following:

T03, T15, T32, T34, T35, T37, T42, T90/R90, TL1, TL4, TU2, K12/ KL2, R25, R38, RL5, RL9

At the time of appointment, the xTrain system will check whether appointees have ORCID iDs and appointments will be not be accepted for agency review unless an ORCID iD is linked to the individual’s eRA Commons Personal Profile.
Beginning with receipt dates on or after January 25, 2020, the requirement for ORCID identifiers will be enforced at the time of application for individual fellowship and career development awards, including the following:

- F05, F30, F31, F32, F33, F37, F38, F99/K00, F12, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00

eRA system validations will check whether applicants have ORCID iDs and applications will not be accepted unless an ORCID iD is linked to the PD/PI's eRA Commons Personal Profile.

At this time, prospective applicants for individual fellowship and career development awards are encouraged to follow the ORCID link from their Personal Profiles in the eRA Commons, where they can either link their eRA profiles to existing ORCID accounts or create ORCID profiles and link them back to the eRA Commons. Similarly, PD/PIs of institutional research training, career development and research education awards are urged to begin alerting potential appointees to do the same.

### 6.2 REVISED NIAID POLICY DEFINING THE INSTITUTE’S USE OF THE MENTORED RESEARCH SCIENTIST CAREER DEVELOPMENT (K01) AWARD

**Notice Number: NOT-AI-19-061** was issued to revise the Institute’s K01 submission policy.

Beginning with the October 12, 2019 application due date and beyond, NIAID will support Mentored Research Scientist Career Development Award (K01) (**PA-19-126** and its reissues) only in the areas of epidemiology and data science*. This includes but is not limited to computational modeling, bioinformatics, big data and advanced statistical analyses in the prevention, treatment, discovery, prediction or forecasting of infectious, immunologic and/or allergic diseases. A predominance of the specific aims proposed must be in one or more of these research area(s).

* NIH defines data science as the interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are developed and used to extract knowledge and insights from increasingly large and/or complex sets of data.

---

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](OSP News & Updates archives).