OFFICE OF RESEARCH ADMINISTRATION NEWSLETTER

"Yale has a clear obligation to comply with all regulations pertaining to the administration of federal grants, and we will spare no effort to remedy any deficiencies in our practices." *President Rick Levin*

Contributors/Sources

National Institutes of Health

National Science Foundation

Office of Research Administration

Office of Research Compliance and Education

Robert Burger
Office of the Provost

Sara Rockwell
Office of the Dean, Yale School of Medicine

Tracy Rightmer, *Human Research Protections Program*

Make a New Year's Resolution to Plan Ahead

Beginning with application due dates on or after January 25, 2011, the **error correction window** in the eRA Commons to review an NIH, AHRQ, and NIOSH application will no longer be available. All applications must be error free by the specified deadline date. The elimination of the error correction window will not impact the two-business-day application viewing window designed to view assembled application images before a deadline. This viewing window is the only opportunity to view the application as the NIH reviewers will see it. Submitting an application early is the best way to ensure an error-free application. (For additional information see NIH Notice http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-123.html)

Minors Working in Research Laboratories

Yale University supports providing research experiences for students. However, there are federal and state regulations covering the presence of students, particularly minors, in the laboratory. The University has developed a "Minors in University Laboratories" policy to assure compliance with these regulations, address safety concerns, and optimize the student laboratory research experience. Under the policy, youths aged 12 to 17 years may enter a Yale University research laboratory for a one time educational or recruitment purpose. Tours must be conducted with permission of the faculty member responsible for the laboratory and the Department Chair or his/her designee. The faculty member is responsible for proper supervision and for providing any appropriate personal protective equipment for the visitors. Tour participants must be supervised at all times while on the premises, and may not participate in any laboratory activities. **Children under 12 years of age are prohibited from entering laboratory areas under all circumstances.** Minor students between 16 and 18 years may work in a university research laboratory as part of an educational program approved by the Dean or Department Chair of the School and the Office of Environmental Health and Safety (EHS). All minor students must complete the

Did you know that...

PI/PDs or co-PI/PDs who are absent from an NSF supported project for short periods of up to three months must notify the Office of Grant and Contract Administration who in turn must notify the appropriate NSF Program Officer of arrangements for the conduct of the project during the temporary absence? In the event of an absence greater than 30 days, the notification should be sent 30 days before departure and written approval must be granted by the NSF Program Officer. http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_2.jsp#IIB1c

Yale

required safety trainings and adhere to all restrictions imposed by EHS. No persons under the age of 18 may work in a Yale University laboratory unless they are part of an approved program.

For additional information, refer to the *Minors in University Laboratories* Policy. Within the following link is the Application for Student Minors to enter Yale Laboratories and the Parental Consent Form:

http://provost.yale.edu/news-announcements/minors-in-labs

Investigators are also directed to additional policies governing visiting undergraduate and graduate students in Yale Laboratories located at the following URLs.

http://provost.yale.edu/policy-visiting-students-labs
http://www.yale.edu/graduateschool/admissions/nondegreeprograms.html

---

Did you know that...

In general, the Office of Human Research Protection (OHRP) considers private information or specimens collected for research purposes to be identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through locked coding systems? For additional information review the following URL: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm

---

PI Responsibilities Regarding the Reporting of Animal Protocol Changes

A change in an animal activity can be both a "significant change" requiring IACUC review and approval and a "change in scope" requiring notification to the sponsor.

1. Examples considered to be significant include, but are not limited to, changes:

- in the objectives of a study
- from non survival to survival surgery;
- resulting in greater discomfort or in a greater degree of invasiveness;
- in the species or in approximate number of animals used;
- in Principal Investigator;
- in anesthetic agent(s) or the use or withholding of analgesics;
- in the method of euthanasia; and

- in the duration, frequency, or number of procedures performed on an animal.

In the case of a "significant change" investigators are responsible for submitting the proposed change in animal activity to the IACUC for review and approval prior to implementation.

A "change in scope" refers to a change in the direction, specific aims, objectives, or purpose of an approved project. The Principal Investigator (PI) and the Authorized Organizational Official (AOO) are responsible for requesting *prior* approval of a "change in scope". The request must be made in writing to the Grants Management Office (GMO) of the NIH Institute that funds the sponsored project and must be made no less than 30 days before the proposed change. The prior approval request must be signed by both the PI and the AOO.

Award IRB Protocol Congruency: What you don't know can affect your award setup

Federal regulations (45 CFR 46.103(f)) require that Yale's Institutional Review Board (IRB) review all sponsored project applications *along with* the IRB's research protocol application to ensure consistency between the documents. Although this review has always been a requirement, many investigators remain unaware that the Office of Grant and Contract Administration (GCA) cannot release an award if the IRB has not conducted its review and determined that the sponsored project application and the research protocol have consistent aims.

In order to prevent a delay in release of funding, investigators must:
- Provide the IRB with a comprehensive list of ALL funding sources for a particular study; this includes center grants and training grants that support any member of the research team. The IRB understands that all potential funding sources may not be ascertained or finalized at the time a protocol is originally submitted for approval;

- Identify funding sources pending at the time of IRB submission and, if any new sources have been added, submit an amendment to the IRB indicating the addition of the new funding source; and
- Submit an amendment to the IRB if a sponsored project has ended and is no longer funding a particular study.

Special Note for studies conducted at the VA by Yale PIs: Even if a study is being performed solely at the VA, if any of the funding to support the study is in part from a sponsored award to Yale, the funding source must be listed on the protocol.

Where to List Your Funding Sources: If submitting a paper research protocol the funding source is one of the first questions asked on the form. If using the IRB's e-application the funding source will be entered directly into the protocol record. In either application, be sure to list the sponsored award number and the grant and contract proposal number so the IRB staff can obtain the proposal for its review.

Questions about congruency and how to add or remove a funding source, can be directed to the appropriate IRB indicated below.
- Biomedical research: HIC 785-4688, ask for Cathleen Montano
- Social, Educational & Behavioral research: HSC 203.436.3650 or human.subjects@yale.edu

Joining the NIH xTrain

Effective January 1st, 2011 xTrain replaces the paper copies of the PHS 2271 Statement of Appointment form and the PHS 416-7 Termination Notice for NIH institutional research training grants, individual fellowships, and research education and institutional career development awards. After this date paper forms will no longer be accepted.

xTrain is a part of the eRA Commons, an online interface where grantees and NIH staff can access and share administrative grant information. xTrain allows users to electronically process appointment forms and termination notices associated with NIH Kirstein-NRSA training grants and Individual Fellowship awards.

The eRA web page for Institutional Research Training and Career Development Awards includes training materials and instructions for submitting forms electronically. The NIH recommends eRA Commons accounts be established for training grant-eligible students and post doctorates. Investigators may also delegate their xTrain authority to an assistant or department administrator.

To accomplish this a PD/PI logs into eRA Commons at https://commons.era.nih.gov/commons/, selects the Admin tab in the blue navigation bar across the top of the screen, then selects Accounts and Delegate xTrain Authority submenus. The PD/PI then selects the user from the list of Current Institution Users to receive delegation and clicks Assign.

New…

The Office of Grant and Contract Administration is pleased to announce a new webpage dedicated to Institutional Training Grant information. The page developed by ORA, provides easy access to NIH forms, tables, due dates, and program contacts. Also posted is data reflecting all current Yale active NIH training grants, including departmental contacts, number of training slots, and participating faculty. In addition, user tools developed by Yale business administrators, will be available to support new-comers to the process. Informational guides and other support documents are under development and will be rolled out over the coming months. To access this new resource click on the following URL: http://www.yale.edu/grants/institutional_training_grants.

Questions regarding this new page and its content can be directed to Ms. Penny Cook, Director, Strategic Research Initiatives at ext. 5.4797.

Upcoming Research Administration Training/Educational Events

Brown Bag Luncheon Series

• *Proposal Tracking (PT) Update: Learn about new forms, reports, support.
Send questions in advance to ires@yale.edu*

Date: Tuesday, January 18, 2011
Time: 12:00 PM – 1:30 PM
Location: Brady Auditorium

Faculty Forums

• **How to Write a Successful RO1**
Date: Thursday, January 13, 2010
Time: 2:00 PM – 3:30 PM
Location: TBA
*Presenter: Todd Constable: Professor, Diagnostic Radiology, Neurosurgery, Biomedical Engineering.
Director, MRI Research and Co-Director Yale Magnetic Resonance Research Center*

Fundamentals of Sponsored Projects: Administration 2-day training program:

• Date: January 10th and 11th, 2011
Time: 9:00 AM – 4:30 PM
To complete the course attendees must attend both full day sessions.

Additional Training For Faculty And Administrators

Grant and Contract Financial Administration (GCFA)
• Allowability of costs and Cost Transfer Principles
• Effort Reporting Principles (web-based)
• Effort Reporting System Training
• Subrecipient Basics, Monitoring and Tracking (web-based)
• What Research Staff Need to Know About Spending Sponsored Project Funds

Grant and Contract Administration (GCA)
• Hands-on Clinic – Grants.gov
• Fundamentals of Export Controls (web-based)
• Human Research Protection Training (options for training are described at
http://www.yale.edu/hrpp/responsibility/training.html)

*To learn more or to register for the above educational opportunities, visit http://www.yale.edu/training/
Navigate to Grant & Contract Training and click Courses under GCA and GCFA Training.*

Office of Research Administration (ORA)
• Sponsored Projects Administration Training for Faculty (web-based)

*To access this course visit http://www.yale.edu/training/ Navigate to Office of Research Administration
Training and click Courses.*

*The Office of Research Administration and its associated Offices
wish all our readers a happy and joyous holiday season.*

OFFICE OF RESEARCH ADMINISTRATION MISSION STATEMENT

**To coordinate the activities of the various University offices providing support to faculty, staff and
students on sponsored projects, to assure that service provided by those offices is of the highest
caliber and professionalism, and to serve as an effective representative for the research enterprise.**