



OFFICE OF RESEARCH ADMINISTRATION

SEPT/OCT 2008 VOL.3 NO. 2

“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*

INSIDE

- 2 **New NIH Tutorial on Objectivity in Research**
- 2 **Adobe Forms Transitions Schedule for Grants.gov submissions**
- 3 **New Responsible Conduct of Research (RCR) Resource Webpage**
- 3 **Yale's Compliance Responsibilities for Research Conducted at Subrecipient Sites**
- 4 **Research Administration Training Opportunities**

NIH Limits Awards under Continuing Resolution

On September 30, 2008, President Bush signed the continuing resolution (H.R. 2638) to fund most of the federal agencies at FY2008 levels through March 6, 2009. On October 2, 2008, the National Institutes of Health (NIH) announced reductions in funding levels for non-competing grant awards under the continuing resolution. Until the final FY2009 appropriation is enacted, NIH will issue non-competing research grants at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). NIH will consider upward adjustments to these levels after the final appropriation is enacted, but expects institutions to carefully monitor their expenditures during this period. To read additional continuing resolution details, visit <http://grants1.nih.gov/grants/financial/index.htm>.

COI Reminder

The Public Health Services (PHS) and the National Science Foundation (NSF) as well as some non-federal sponsors, require that the University have and comply with a conflict of interest policy based on the PHS regulation and NSF policy.

In order to effectively implement the PHS regulations, the NIH has provided specific instructions regarding the implementation of the regulation as it relates to NIH sponsored awards. The following instructions are a reminder to the Yale community of the expectations of the NIH.

At the time of the application/proposal submission: Yale **must** certify that it has a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH. By the time an application/proposal submission is submitted to the NIH, each Investigator (defined as the Principal Investigator **and** any other person who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding. The definition includes the Investigator's spouse and dependent children.) who is planning to participate in the research must have submitted to the Conflict of Interest Office a completed *Conflict of Interest – Conflict of Commitment Disclosure* form of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) (1) that would reasonably appear to be affected by the **research for which funding is sought** from the NIH; and (2) in entities whose financial interests would reasonably appear to be affected by the research.

Prior to spending any funds under an award: Prior to spending **any** funds under an award, Yale must report to the NIH the existence of any conflicting financial interests and assure the NIH that the interest has been managed, reduced, or eliminated in accordance with the PHS regulation. The PHS regulation does not require Yale to report to NIH officials the nature or other details of a reported financial conflict of interest (FCOI); however, Yale is required to make information available, upon request, to the NIH regarding all FCOIs identified by Yale and how those interests have been managed, reduced, or eliminated to protect the research from bias.

Subsequent to the initial report: For any interest that Yale identifies as conflicting

subsequent to Yale's initial report under the award, a report must be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

The NSF policy, though similar to the PHS regulations, differs in that Yale must only report those instances when Yale is unable to satisfactorily manage a conflict of interest.

To further emphasize the importance of complying with the PHS regulation and the commitment to unbiased and objective research, the NIH is including the following language in all NIH awards:

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research,

including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee (Yale) must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee (Yale) under this award.

The following NIH website <http://grants.nih.gov/grants/policy/coi/index.htm> provides additional information.

Questions regarding the application of either the PHS regulation or the NSF policy? Please contact the Office of Research Administration at 432-0108.

NEW NIH TUTORIAL ON OBJECTIVITY IN RESEARCH (ALSO REFERRED TO AS CONFLICT OF INTEREST)

In order to better understand the regulations regarding conflict of interest, the NIH has published a web-based tutorial addressing objectivity in NIH-funded research. This tutorial aims to familiarize and educate the research community with the requirements of and the responsibilities for compliance with federal regulations regarding objectivity in research. The tutorial is

designed for those individuals who are responsible for the design, conduct or reporting of NIH-supported research. The tutorial, along with other important compliance information, may be accessed on the NIH Office of Extramural (OER) Conflict of Interest (COI) web page: <http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.htm>.

ADOBE FORMS TRANSITION SCHEDULE FOR GRANTS.GOV SUBMISSIONS

The NIH has announced the transition schedule for NIH/AHRQ/CDC/NIOSH/FDA from PureEdge to Adobe-based grant application forms for electronic submissions of SF424 Research and Related (R&R) applications. This transition schedule is important to note since Grants.gov will not accept PureEdge applications after the transition dates noted on the schedule. Most electronic submissions to NIH after January 1, 2009 must use Adobe application forms.

Although the overall electronic submission process of finding opportunities, downloading application packages, preparing forms and attachments and submitting applications remains the same, it is important for PIs and administrators to be aware of the following:

- Grants.gov requires a specific version of Adobe Reader in order to open, download, save and submit an Adobe application.
- Active Funding Opportunity Announcements (FOAs) will be transitioning to Adobe – Adobe Forms will replace the PureEdge forms in the December 2008 timeframe.
- Check the FOAs in December to download the new Adobe application forms.

For more information and the detailed transition schedule, visit the NIH's *Resources for Adobe Transition Web Page on the Electronic Submission of Grant Applications* at <http://era.nih.gov/ElectronicReceipt/>.

Did you know that...

...as the legislatively mandated salary rate cap for NIH awards increases so should the amount paid from the award? The salary rate cap in year one of

an award should not be maintained throughout the life of the award if the NIH salary rate cap is adjusted.

NEW RESPONSIBLE CONDUCT OF RESEARCH (RCR) RESOURCE WEBPAGE

The Office of Research Administration (ORA) has launched a new web page to provide a portal to internal and external resources for RCR guidance and training. As interdisciplinary, interdepartmental and inter-institutional research increase, topics such as data management, conflict of interest, collaborative research and authorship need to be at the forefront of discussion and training at all levels of the academic research community.

The various elements of an RCR program are the foundation for ethical research and research training

as required for institutional National Research Service Awards (NRSA). As part of a NRSA proposal, the PI must describe the specific RCR education program trainees will undertake during the award. Additionally, all progress reports must include information on the RCR training program described in the proposal. Included on ORA's RCR web page is guidance on documenting NRSA RCR education. To access the ORA RCR web page visit: <http://www.yale.edu/researchadministration/>.

YALE'S COMPLIANCE RESPONSIBILITIES FOR RESEARCH CONDUCTED AT SUBRECIPIENT SITES

Federal requirements place the responsibility on the grantee organization (Yale) to ensure that subrecipients have appropriate assurances, approvals and certifications in place. This becomes particularly important when research involving human subjects and/or animals occurs at a subrecipient site. Therefore, when Yale is the prime awardee of a sponsored project and intends to subcontract a portion of the research activity that involve the use of human subjects and/or animals to a subrecipient, Yale must be assured of the following:

- The existence of a current Federal Wide Assurance (FWA) and IRB approval for research involving human subjects;
- Certification of required training for all personnel involved with the design, conduct and reporting of research involving human subjects; and
- The existence of a current Animal Welfare Assurance and IACUC approval for research involving animals.

As the prime recipient, Yale must certify to its sponsor compliance for all aspects of work included in the proposed research, including that research taking place at subrecipient sites.

RESEARCH ADMINISTRATION TRAINING OPPORTUNITIES

MANDATORY FACULTY TRAINING

On November 29, 2006, the Provost sent a memo to faculty involved in sponsored projects regarding training. Visit <http://www.yale.edu/researchadministration/documents/here.pdf> to review the memo. Training is required for all faculty involved with a sponsored research project. For access to the on-line training module, visit <https://secure.its.yale.edu/cas/servlet/login?renew=true&service=http://learn.yale.edu/ra/auth121.asp>.

NEW ON-LINE TRAINING MODULE AVAILABLE

Subrecipient Basics, Monitoring and Tracking

A new on-line module for faculty and administrators who would like to become more familiar with requirements and responsibilities relative to sub-awards. Visit <http://www.yale.edu/training/>, navigate to Grant and Contract Financial Administration and click GCEFA Training

UPCOMING TRAINING EVENTS

- Brown Bag Luncheon Series: What's New with the Proposal Summary and Certification Form?
Thursday, October 30, 2008: noon – 1:15 p.m.
Sterling Chemistry Laboratory 225 Prospect St.
Room 110
- Fundamentals of Sponsored Projects Administration
2-day training program:
November 11 – 12, 2008, 9:00 a.m.
Sorry, this class is filled to capacity. Additional offerings will be announced in the near future.
- Allowability of Costs and Cost Transfer Principles
Thursday, November 13, 2008, 1 – 4:00 p.m.
155 Whitney Ave., Room 222
- What Research (Laboratory) Staff Need to Know About Spending Sponsored Project Funds
Wednesday, December 10, 2008, 10:00 a.m.
Sterling Chemistry Laboratory, SCL 160

For details and to register for these events, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Financial Administration and click GCEFA Training.

ADDITIONAL TRAINING FOR FACULTY AND ADMINISTRATORS

Grant and Contract Financial Administration (GCEFA)

- Effort Reporting Principles
- Effort Reporting System Training

Grant and Contract Administration (GCA)

- Hands-on Clinic - Grants.gov

To learn more and/or to register for these sessions, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Financial Administration, then click on the Yale office (as noted below) providing the training.

Contributing Authors

ORA staff

**National Institutes of Health (NIH) Office of
Extramural Research (OER)**

NIH NOT-OD-09-002

NIH NOT-OD-08-117

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 at Yale University and nationally.