

# 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*

## INSIDE

- 2 Accreditation of the Yale University Human Research Protection Program
- 3 National Science Foundation: ARRA Terms and Conditions
- 3 Research Administration Training Opportunities

## I submitted my annual Conflict of Interest Disclosure form and there were no problems, so why is my award being held up for a “transactional” review? What is a transactional review?

Annually, Yale requires its faculty to submit a Conflict of Interest/Commitment Disclosure form identifying potential conflicts of interest. This form is reviewed by the University’s Conflict of Interest Committee with respect to potential financial conflicts of interest an individual may have in light of their teaching, research and administrative responsibilities. As a result of these reviews, a faculty member may receive a management letter addressing any identified conflicts of interest related to their overall research, clinical, and administrative responsibilities.

In addition, University policy and certain federal agencies and non-federal sponsors require that the Principal Investigator’s and certain other individuals’ annual financial disclosure form (as well as any additional financial interests become apparent) be reviewed in relation to specific sponsored project applications. This application specific review is referred to as a “**transactional**” review. The transactional review must be done in order to determine if a significant financial interest exists that could directly and significantly affect the design, conduct, or reporting of the proposed research, thus creating a conflict of interest.

Lastly, certain sponsors require that they be notified of the existence of a conflict of interest and whether the conflict has been eliminated or managed. The University is not initially required to disclose the nature of the conflict but may be required to do so upon further inquiry.

Yale is committed to ensuring objectivity in research and we remind faculty of the central role they have in assuring compliance with University policy and federal regulations. For further information regarding conflict of interest requirements, please review the following documents:

- Yale University Policy on Conflict of Interest and Conflict of Commitment  
<http://www.yale.edu/provost/html/coi.html>
- ORA Newsletter COI Update  
<http://www.yale.edu/researchadministration/documents/ORANewsletterseptoct2008.pdf>

For additional information, please contact the Conflict of Interest Office at 432-8029 or 432-1018.

### Contributors/Sources

ORA Staff  
National Institutes of Health  
National Science Foundation  
John Maloney, *Manager, Sponsored Programs, Grant and Contract Financial Administration*  
Council on Governmental Relations  
Patricia Lindahl, *Project Manager, Accreditation of Human Research Protection Program*

Yale University has long maintained a robust Human Research Protection Program (HRPP) under the oversight of Stephanie Spangler, MD, the Deputy Provost for Biomedical and Health Affairs. The HRPP helps to ensure the protection of research participants across the various University departments and committees that have a unique responsibility in the initiation, conduct and/or oversight of human research. The HRPP recognizes that the protection of research participants transcends traditional departmental jurisdictions and is not the sole responsibility of any single office. Many administrative and academic departments work collaboratively with research personnel and others engaged in research to ensure that the rights and welfare of research participants are upheld. They include, for example, the Office of the Provost, the Office of Research Administration, the Office of Grant and Contract Administration, the Conflict of Interest and Conflict of Commitment Committee, the Yale IRBs, the Yale Center for Clinical Investigation, the Yale Cancer Center, the Pediatric Protocol Review Committee, the YNHH and Yale Radiation Safety Committees, the Protocol Review Committee of the Magnetic Resonance Research Center, and departmental representatives.

The University is seeking accreditation of its HRPP through the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

The AAHRPP, founded by the Association of American Medical Colleges, the Association of American Universities, the Consortium of Social Science Associations, and others requires an institution to demonstrate its commitment to protecting research participants by meeting or exceeding published standards in five areas; the institution, research review units, investigators and research teams, sponsored research agreements, and community outreach. These standards are based on strong ethical principles and federal regulations related to the conduct of human

research. The standards are met when the group of specific elements, or detailed requirements that support the overarching standard is demonstrated via interviews, written institutional policy, practice, guidelines, or other documents.

Spearheaded by the Yale Institutional Review Boards (IRBs), Yale created an HRPP Project Team in the Winter of 2008 to prepare for the application for accreditation. The project team directed by Susan Bouregy PhD, CIP and Kathleen Uscinski, MBA, CIP, is charged with collecting and/or creating policies, procedures, guidelines, checklists and other written material that are needed to demonstrate satisfaction of the AAHRPP standards. These documents are the responsibility of the various departments that are accountable for human research related processes and tasks. The HRPP Project Team works cooperatively with the departments and oversight committees noted above to review currently published and draft policies, procedures and guidelines related to human research. The documents are compared to the elements and standards published by AAHRPP. Gaps were identified and discussed with each “policy owner” and revisions were recommended and developed. The outcomes are improved policies and procedures that ensure that human research is conducted pursuant to strict ethical standards and applicable federal, state, and local regulations.

As part of the application process, research investigators, members of oversight Committees, Deans, Directors and Chairs may be interviewed by AAHRPP to demonstrate their working knowledge of Yale policies related to human research. There will be multiple introductory sessions aimed at insuring that those responsible for the protection of human research participants are conversant in their knowledge of these policies and procedures and their roles and responsibilities. Changes as well as additions to Yale policies are distributed through mass emails and will eventually be posted to the new HRPP website.

### ***Did you know that...***

*The Federal Demonstration Partnership (FDP) is a cooperative initiative designed to reduce administrative burden of federal grants. FDP is comprised of members from 9 federal agencies and 106 institutions (Yale included). As an FDP member, Yale’s grants from the participating agencies include special terms and conditions designed to reduce administrative burden. It is important to check the FDP terms and conditions as it relates to grants sponsored by one of the participating federal agencies. The following FDP matrix can assist in better understanding those requirements: <http://www.nsf.gov/bfa/dias/policy/rtrc/priorapproval.pdf>*

On May 8, 2009, the National Science Foundation (NSF) posted its American Recovery and Reinvestment Act (ARRA) Terms and Conditions (NSF Document # arra0509) that will apply to any NSF award made using funds from the ARRA. The terms are available at the following url:  
[http://www.nsf.gov/pubs/policydocs/arra/arratc\\_509.pdf?govDel=USNSF\\_109](http://www.nsf.gov/pubs/policydocs/arra/arratc_509.pdf?govDel=USNSF_109).

Building on the standard NSF award conditions, Yale is required to meet the reporting requirements specified in ARRA. Those requirements include but are not limited to the following:

- Submit quarterly reports. The failure to submit timely reports may result in NSF taking administrative action, including disallowance of costs or the suspension or termination of the award.
- ARRA funds must be separately tracked and monitored from any non-ARRA funding. Specifically, any ARRA funds received as a supplement to an existing award will not be additive to that award and must be reported on separately.
- ARRA-related terms and conditions are required to be incorporated into any subrecipient agreements, as appropriate.
- NSF will monitor ARRA funds, and, if, after 12 months, no allowable expenditures have been incurred, NSF may consider reducing or terminating the award and reallocating the funds.

In a departure from ARRA requirements, NSF requires reports within ten calendar days after each **calendar** quarter. The Council on Governmental Relations (of which Yale is a member) has asked the NSF to consider implementing a ten **business** days rule.

### *Did you know that...*

*Principal Investigators of an NIH institutional training grant are expected to identify effort and may have the associated salary paid for by the training grant? Mentors in support of the trainees are not required to indicate effort in the grant application.*

## Research Administration Training Opportunities

### UPCOMING TRAINING EVENTS

- *Brown Bag Luncheon Series: Corporate Contracts at Yale: Terms and Conditions*  
Tuesday, June 23, 2009  
noon–1:15 PM  
The Anlyan Center, Congress Avenue  
N107 auditorium
- *Fundamentals of Sponsored Projects Administration 2-day training program*  
July 22 & 23, 2009  
9:00 AM – 4:30 PM  
155 Whitney Avenue  
Conference room 222, 2nd floor

For details and to register for these events, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Training and click on Courses under GCA and GCEA Training.

*(continued on next page)*

## **ADDITIONAL TRAINING FOR FACULTY AND ADMINISTRATORS**

### ***Grant and Contract Financial Administration (GCEA)***

- Allowability of Costs and Cost Transfer Principles
- Effort Reporting Principles
- Effort Reporting System Training
- Subrecipient Basics, Monitoring and Tracking – web based

### ***Grant and Contract Administration (GCA)***

- Hands-on Clinic – Grants.gov
- Fundamentals of Export Controls – web based

### ***Office of Research Administration (ORA)***

- Sponsored Projects Administration Training for Faculty – web based

*To learn more and/or to register for these sessions, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Training, then click on Courses under GCA and GCEA Training.*

### **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.**