JAN/FEB 2009 VOL. 3 NO. 4

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

Coeus eIRB Simplifies Human Research Protocol Submissions

In 2002, Yale University received an award from the National Center for Research Resources. Under the direction of Principal Investigator Stephanie S. Spangler, MD, Deputy Provost for Biomedical & Health Affairs, this award supported the development of an electronic Institutional Review Board (IRB) module. In order to fulfill the goals of the award, Yale joined a consortium of institutions including the Massachusetts Institute of Technology (MIT) as the consortium's lead technical developer. Yale assumed the lead clinical role in the module's development. The end result was the development of an electronic application (Coeus IRB) that supports an IRB module for tracking and monitoring protocol submissions. This Coeus IRB module has been successfully used by Yale's IRBs since 2004. As successful as the module has been for tracking protocols, the ability of the research community to submit protocols electronically to an IRB is a necessary next step in the development effort of Coeus.

Named after the Greek Titan of Intelligence, Coeus eIRB permits Yale researchers to prepare and simultaneously submit research protocols to the Yale Institutional Review Boards (IRBs) and other oversight authorities charged with the protection of research volunteers.

The system's electronic routing feature provides sequential review and approval of the research as required by Yale policy prior to the research being received by the IRB for formal review. In essence, investigators save the time and resources previously expended in writing duplicate protocol submissions to different review groups, delivering protocols, and collecting signatures and the requisite pre-IRB approvals.

Oversight committees utilizing the electronic protocol submission system for their own review, which takes place prior to the formal IRB review, include the Pediatric Protocol Review Committee (PPRC), the Magnetic Resonance Review Committee (MRRC), the PET Center, the Yale Cancer Center's Protocol Review Committee (PRC), the Yale University Radiation and Safety Committee and Yale School of Medicine Department Chairs and/or their designees. Other departments extracting information from the protocol for their operational purposes include the Yale Medical Group, the Yale Center for Clinical Investigation, the Yale School of Medicine's Cancer Data Repository (CaDR), Yale's Conflict of Interest and Conflict of Commitment Committee, and Yale's Information and Data Security office.

This next phase of Coeus is slated to "Go-Live" in early February when researchers within the Yale School of Medicine will be invited to attend training. In preparation, several departments and oversight groups piloted the application this past fall. To learn more about Coeus and how you can increase your efficiency by submitting protocols online, please visit www.yale.edu/coeus.

Yale

Did you know...

Computers may be an allowable charge to a federal award? Computers, which are normally considered to be a Facilities and Administrative cost, may be charged to a federal award if they are used primarily or exclusively (follow sponsor specific requirements) to conduct the research. When purchasing a computer on a sponsored project in support of your research, be certain to follow documentation requirements. For more information regarding the purchase of computers on a federally supported sponsored project review the January 2009 Important Update at: http://www.yale.edu/researchadministration/documents/ImportantUpdateJan09.pdf

REGISTRATION PROCESS FOR NIH PEER REVIEWER REIMBURSEMENT

Beginning Jan. 17, 2009 the NIH is requiring registration of peer reviewers in order to receive reimbursement and honoraria related to their support in an NIH peer review meeting. This registration process replaces the U.S. Treasure Central Contract Registration (CCR) which the NIH used until May 2008. Reviewers who have used the eRA Commons before will find it easy to register. Once the user enters his/her name and password s/he will need to update their Personal Profile with information on residential address, phone number and email. Once complete, the user will be directed to a Secure Payee Reimbursement System to enter his/her social security number and bank routing number.

Some key points to be aware of:

- Registration in the system is required in order to receive disbursement
- Registration does not need to be renewed annually
- Registration information is kept secure and confidential

Reviewers with CCR accounts may cancel their CCR registration. In order to do so, visit the CCR website www.ccr.gov or contact the CCR help desk at (888) 227-2423 or (269) 961-5757.

For additional information and the full announcement please visit: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-033.html.

FUNDAMENTALS OF EXPORT CONTROL LAWS: ONLINE MODULE AVAILABLE

A new web-based module is available for faculty and administrators who would like to become more familiar with the laws and regulations associated with exporting certain technologies (information, software, and items) to foreign entities. Export controls apply to all activities at Yale, not just research. This module provides the course user with specifics regarding the definition of a deemed export, concerns most significant for Yale, regulatory requirements regarding the exporting of certain information or software to foreign entities, and the sanctions that can be applied if the regulations are not followed.

In order to take the course and accompanying quiz visit http://www.yale.edu/training/, navigate to Grant and Contract Financial Administration, and click GCA Training.

If you have any questions regarding access to the module, please contact the Office of Research Administration at www.yale.edu/researchadministration. Questions regarding the module content can be sent to donald.deyo@yale.edu.

CONFLICT OF INTEREST RESPONSIBILITIES

The following is a reminder of the University's policy regarding Conflict of Interest and Conflict of Commitment. The topic of conflict of interest continues to receive considerable attention from members of Congress and the press, and Yale believes it is prudent and timely to reiterate University policies and practices in this area.

Annually, Yale requires all faculty, whether or not they receive external funding, with University appointments of greater than 50% time, and all faculty who hold administrative positions and all personnel who are responsible for the design, conduct, or reporting of research to submit Conflict of Interest/ Commitment Disclosure forms describing their external (*e.g.,* non-Yale) activities and financial interests. This form is reviewed by the University's Committee on Conflict of Interest and Conflict of Commitment (COIC) to determine if such interests or activities present potential or actual conflicts with the individual's teaching, research, clinical, administrative, or other responsibilities at Yale. The COIC also identifies mechanisms whereby conflicts of interest can be managed, reduced, or eliminated.

In addition, University policy and federal regulations similarly require **any individual** identified in sponsored project proposals (must also be identified in Section VII. of Yale's Proposal Summary and Certification Form) by a Principal Investigator as **having responsibility for the conduct, design, or reporting of** the proposed research (usually key personnel but may include others such as graduate students and nurse coordinators), to submit a disclosure form annually as well as whenever the individual acquires additional financial interests or engages in new outside activities that might affect or be affected by the proposed or active research project.

University policy and certain federal and non-federal sponsors require that disclosure forms of research personnel be reviewed in relation to specific sponsored project applications (commonly referred to as a "transactional" review) as well as in relation to an individual's broader University responsibilities. This transactional review, which is also performed by the COIC, is intended 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 potential conflict of interest.

Given the nature of these review requirements and the timing of research proposals, a faculty member may receive a management letter addressing any identified potential conflicts of interest related to his or her overall research, clinical or administrative responsibilities and **may also, from time to time, receive additional management letters** specific to a sponsored project(s). In addition, certain sponsors require that the University notify them of the existence of a conflict of interest related to a specific research project and confirmation that the conflict has been eliminated, reduced below a threshold of significance, 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 assistance, please contact the Conflict of Interest Office at ext. 2-3233.

Did you know...

As the legislatively mandated salary rate cap for NIH, AHRQ, and SAMHSA awards increases so should the amount paid from the award? The salary rate cap in year one of an award should not be maintained through the life of the award if the salary rate cap is adjusted. Adjustments to salary should occur on the effective date of the new salary rate cap. This adjustment will reduce the amount of cost sharing on the part of the University. Effective January 1, 2009, the new salary rate cap for Executive Level I increased to $196,700.

Yale's Institutional Review Board (IRB) offices (HIC/HSC/HSRRC) are responsible for reviewing a sponsored project proposal when it supports the research described in a human subjects protocol. Most sponsors, including the National Institutes of Health (NIH), will not fund a proposal unless the protocol has been reviewed for congruency with the proposal by the IRB. The requirements for human subject congruency review are long-standing. Yale has recently strengthened the process for communication between the appropriate Yale IRB and the Office of Grant and Contract Administration (GCA) to ensure that sponsor requirements and federal regulations are met.

Relevant Terms and Definitions

- ***Human subject protocol:*** a description of proposed human subject activity to be conducted at the University and submitted to the appropriate IRB for review.
- ***Proposal:*** A request for financial support of a research project or activity submitted to a sponsor.
- ***Congruency:*** A review of the protocol and proposal for consistency between the two documents.

Why is a review of protocol to proposal required?

Federal regulations (45 CFR Part 46) require the IRB to review the actual proposal submitted to the sponsor to ensure that the research described in the proposal is consistent with a corresponding protocol(s) submitted to the IRB. Yale is required to certify to a sponsor that the human subject research described in a proposal does not significantly differ from the human subject research described in an IRB-approved protocol (*i.e.*, targeting of vulnerable subjects; additional treatment arms; different drug dosages or method of administration; additional collaborators or performance sites, etc.). Therefore, the IRB must review the actual proposal alongside the IRB protocol(s) to ensure that all research described in the proposal is described in an IRB-approved protocol(s). This congruency review will prevent the use of sponsor funds for unapproved research. The University will not certify to the sponsor that the research has been approved by an IRB and the project funding will not be released until IRB approval and congruency have been verified by GCA.

Is the PI required to submit a copy of the sponsor proposal with the protocol application?

Human subject protocol submission: In order to conduct any human subjects research, Principal Investigators (PI) are required to submit a human subject protocol to the appropriate IRB office. The PI is required to identify the source of financial support on the protocol application, whether it is internally or externally funded. If the project is externally funded, the PI must specify the sponsor name and the proposal number (M/C# located on the Proposal Summary and Certification form, ProSum, and referred to as the ProSum #) on the protocol application. Depending on the method of submission of a proposal to a sponsor, the PI may be required to provide a copy of the proposal.

- ***Proposals Submitted to Sponsors Electronically:*** If the financial support of the research is anticipated to be externally funded and the proposal was submitted electronically (*i.e.*, Grants.gov, FastLane, INSPIRES, Proposal Central), the PI will no longer have to submit copies of the sponsored project proposal with the human subject protocol application. The IRB will receive access to these proposals through GCA.
- ***Proposals NOT Submitted to Sponsors Electronically:*** If the financial support of the research is anticipated to be externally funded and the proposal was **not** submitted electronically (*i.e.*, Grants.gov, FastLane, INSPIRES, Proposal Central), the PI **must** submit a paper copy of the sponsored project proposal that was signed and dated by the authorized GCA official along with the human subject protocol application so that the IRB has the appropriate documentation to conduct the congruency review.
- ***Pending Proposals:*** If the funding source associated with a protocol is "pending" at the time of the human subject protocol submission to the IRB (as is the case for most NIH submissions), the PI should note "Pending" in the appropriate section of the human subject protocol application and provide the ProSum # and Agency name in order for congruency to be done at this time. **Note:** Non-sponsored project (departmental) funds support the research until such time that an award is made.

CONTINUED FROM PAGE 4

If the protocol is approved with "pending" identified as the funding source and no external sponsor has been identified, only University (departmental) funds can support the research. The PI should note University (departmental) funds as the funding source in the protocol application. **Note that no cost transfers to a sponsored project would be permitted since congruency was not established by the IRB.**

When the funding source for human subject research becomes known, the PI must:

- For a new human subject protocol, initiate the human subject protocol review process and provide the appropriate IRB office with the funding source and ProSum # associated with the relevant human subject protocol; or
- For a previously submitted or existing approved human subject protocol, submit an amendment to add the relevant funding source and ProSum # to the protocol and the IRB will conduct the congruency review at that time.

Proposal submissions involving human subjects: PIs are required to submit all proposals to GCA for review, approval, and signature. If the research project involves human subjects, the PI must indicate such on the ProSum and, if known at the time of proposal submission, the IRB protocol number. If an IRB protocol has not been submitted to the IRB for review, approval, and congruency determination, the PI can submit the proposal to GCA indicating "Pending" on the ProSum.

Proposals submitted to the NIH indicating "Pending" will be subject to NIH's "just-in-time" procedure (JIT, the period between peer review determining a funding level and prior to actual funding. JIT does not guarantee funding.). At JIT, GCA is required to verify that appropriate IRB approval, including a congruency determination has occurred. GCA will not submit JIT information electronically without verification that the relevant human subject protocol has been reviewed and approved and congruency between the human subject protocol and proposal has been determined. For those sponsors without a JIT procedure, the Account Set-up Unit will not set up an award without verification that the relevant human subject protocol was reviewed and approved, and congruency between the human subject protocol and proposal was determined.

Please note that it is possible for a proposal to be associated with more than one IRB protocol and for an IRB protocol to be associated with more than one proposal. For certain types of proposals such as career awards, it may be necessary for the IRB to simply verify that the individual projects/protocols noted within a proposal have the appropriate IRB approval. For research training grants, the IRB protocol(s) may not be known at the time of proposal submission and in these cases the PI should note "Pending" on the proposal. At such time that the IRB protocol(s) relating to the work under the training grant are known, the PI should inform GCA and the IRB of the IRB protocol number(s) associated/to be associated with the activities under the training grant.

Yale Resources

IRB Offices

- Human Investigation Committee (HIC): ysmhic@yale.edu; 785-4688
- Human Subject Committee (HSC): human.subjects@yale.edu; 436-3650
- Human Subjects Research Review Committee (HSRRC): 737-2420

Grant and Contract Administration

YSM: grants.med@yale.edu; 203-785-4689

Central: grants@yale.edu; 203-432-2460

Did you know...

Fellows on an individual National Research Service Award (NSRA) must commit full-time effort, normally defined as 40 hours per week or as specified by Yale policies, to the program and its related research activities, and consonant with the NSRA guidelines. As specified in the NRSA guidelines, "Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved Kirschstein-NRSA training program. Fellowship sponsors must approve all instances of employment on research grants to verify that the circumstances will not detract from or prolong the approved training program." For more information on NRSA Guidelines, please refer to the following link: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part10.htm#_Toc54600187

Did you know...

The Office of Research Administration has recently posted two pocket guides on its website: Sponsored Projects pocket guide and the Effort Reporting pocket guide. If you did not already receive a hardcopy guide please visit the following website: http://www.yale.edu/researchadministration/pocketguides.html

RESEARCH ADMINISTRATION TRAINING OPPORTUNITIES

UPCOMING TRAINING EVENTS

- Brown Bag Luncheon Series:
  Movable Equipment Inventory: What Departments Need to Know
  Wednesday, February 11, 2009: NOON – 1:15 PM
  Brady Auditorium, 310 Cedar Street
- Brown Bag Luncheon Series:
  Audits & Assessments: What's the Difference Between the Two and How Do We Learn from the Results?
  Thursday, March 12, 2009: NOON – 1:15 PM
  SCL 110, Sterling Chemistry, Prospect Street
- Fundamentals of Sponsored Projects Administration 2-day training program:
  April 1-2, 2009, 9:00 AM
  Yale West Campus, 137-141 Frontage Road, Orange, CT

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

Contributing Authors

ORA staff

National Institutes of Health

Donald Deyo, ***Ph.D. Director, International Agreements and Export Control Licensing***

Kathleen Uscinski, ***Deputy Director, YSM Human Investigations Committee***

ADDITIONAL TRAINING FOR FACULTY AND ADMINISTRATORS

(Some of the following offerings are web-based)

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

Grant and Contract Financial Administration (GCFA)

- Effort Reporting Principles
- Effort Reporting System Training

Grant and Contract Administration (GCA)

- Hands-on Clinic – Grants.gov

Grant and Contract Administration (GCA)

Office of Research Administration (ORA)

- Sponsored Projects Administration Training for Faculty – online

NEW STAFF MEMBER TO ORA

The Office of Research Administration (ORA) welcomes Ms. Kim Mickey as its new Research Compliance Officer. Kim is a valuable addition to the ORA team bringing with her years of experience in regulatory compliance as it relates to the welfare of animals used in biomedical research, teaching and/or testing at Yale. We are pleased Kim has joined ORA to serve the Yale research community.

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.