

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

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Contributors/Sources

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NIH Will Not Approve of Grant Continuations Unless Compliance with Public Access Requirement Has Been Demonstrated

Since 2008, the National Institutes of Health (NIH) public access policy has requested that the public have access to the published results of NIH funded research. Notice-OD-12-160 (at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-160.html>), published on November 16, 2012, informed grantees that in Spring, 2013, at the earliest, NIH will not process non-competing continuation grant awards if publications arising from that award are not in compliance with the NIH public access policy. This change will take effect together with NIH requiring the use of the Research Performance Progress Report (RPPRs) for all Streamlined Non-competing Award Process (SNAP) and Fellowship awards in the Spring of 2013.

(see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-142.html>)

NIH advises PDs/PIs to use their My NCBI account to track compliance of their publications now, and to ensure all publications arising from their awards are posted to PubMed Central in accordance with the policy.

The Yale University Medical library has established a website to assist Yale staff, faculty and researchers in complying with the NIH Public Access Policy.

The following tutorials are also available (see links within Notice-OD-12-160 above).

- Get Started with My NCBI: Access My NCBI, Register, and Sign In
- Manage Compliance with the NIH Public Access Policy in My NCBI
- Use a Delegate to help manage your My NCBI account and public access compliance
- Using My NCBI to associate your papers with your PD/PI's award

Did you know that...

The National Institutes of Health (NIH) plans to transition all multi-project applications to electronic submissions using the SF 424 (R&R) form set by the end of December 2013? The NIH will publish pilot funding announcements for due dates between January and September 2013 and transition the P01, P20, P50, R24, U24, U19 mechanisms by September 25, 2013, and the G12, P30, P40, P41; P42, P51, P60, R28, U10, U41, U42, U45, U54, U56, UC7, UM1 mechanisms by January 25, 2014.

See <http://grants.nih.gov/grants/guide/notice-files/not-od-12-161.html>

NIH Clarifies PHS COI Rules Regarding the Reporting of Third Party Travel

On November 29, 2012 Jill Pagliuca, Director, Conflict of Interest Office, released a Memorandum (at <http://coioffice.yale.edu/node/83/attachment>) outlining NIH's clarification regarding the reporting of third party paid travel as part of required conflict of interest disclosures.

The clarification states that:

- Only third party paid travel with an aggregate amount exceeding \$5,000 per year from any single entity must be disclosed. **Previously, ALL third party paid travel regardless of the amount was subject to disclosure.** It is expected that applying this clarification will significantly decrease the number of travel disclosures investigators are required to make.
- Investigators must disclose the **past 12 MONTHS** of third party paid travel **related** to their Yale responsibilities. **Previously, Yale's practice required disclosure for only the past 30 days.**
- The disclosure of third party paid travel **related** to the investigator's Yale responsibilities applies to the investigator, his/her spouse, and dependent children.

PHS Investigators should read the Memorandum carefully to determine what steps they need to take to be in compliance.

The Most Frequently Asked Questions about the PHS COI Disclosure Process

According to the PHS, Conflict of Interest regulations are designed to increase accountability, add transparency, and enhance regulatory compliance and effective Institutional management of investigators' financial conflicts of interest. Revised regulations went into effect on August 24, 2012. Below are answers to frequently asked questions about Yale's COI disclosure process and the location of additional resources to assist with the application of the PHS regulations to proposals and awards.

1. *To whom does the PHS Conflict of Interest regulation apply?*

The PHS regulation applies to all PHS Principal Investigators (PIs) and anyone designated by the PI (regardless of title or position) as responsible for the design, conduct, or reporting of research either funded or proposed for funding by the PHS awarding agencies (e.g., NIH).

In addition, subrecipient investigators and consultants who have been designated by the PI as responsible for the design, conduct or reporting of the research are also subject to the regulations.

2. *As the PI, how do I determine who is responsible for the design, conduct or reporting of research?*

PIs should consider the role, rather than the title, of those involved in the research and the degree of independence with which those individuals work. The risk of limiting the definition of investigator to titles or designations (e.g., senior/key personnel, faculty) is that there is the potential for an unidentified financial conflict of interest (FCOI) to exist that may compromise the research.

3. *As an investigator (PI or someone designated by the PI as responsible) on a PHS award, when must I complete the new External Interests Disclosure form?*

You (and anyone else identified by the PI as being responsible for the design, conduct or reporting of research, also referred to as an "investigator") must complete the new PHS-compliant External Interests Disclosure form when:

- a PHS application is submitted (new, competing renewal, non-competing continuation, supplement); or
- if new PHS funding is received on or after August 24, 2012 as a result of an application submitted prior to August 24, 2012 in which you are identified as an investigator.

Note: A new investigator added to an existing PHS award must have a current PHS-compliant External Interests Disclosure form on file, reviewed by the COI Office, and if appropriate, must have a signed management plan in place prior to participating in the PHS research.

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According to PHS regulations, all investigators must complete and submit their External Interests Disclosure form prior to proposal submission or receipt of new funding, whichever comes first. Likewise, if any financial conflicts of interest (FCOIs) are identified, the award cannot be set up until the investigator agrees in writing to the management plan, and the COI Office has reported the FCOI to the sponsor.

4. How do I submit the new External Interests Disclosure Form?

To submit an External Interests Disclosure:

- Click here ([at https://secure.its.yale.edu/cas/login?service=https%3A%2F%2Ffires.yale.edu%2Flogin.asp](https://secure.its.yale.edu/cas/login?service=https%3A%2F%2Ffires.yale.edu%2Flogin.asp))
- Log in with your NetID and Password
- On the next screen left side bar, click on “External Interests”, then click on “Update”
- The “Welcome” screen box should appear in the center of the screen
- Click the button at the bottom right hand side of the Welcome screen box that reads either “Update Disclosure” or “Edit/Submit Current Disclosure” or “Create My Disclosure”
- Let the questions guide you through the disclosure process (**Tip: Remember to answer “Yes” to Pre-Screening Question #2b, and the form will navigate you to the PHS disclosure pathway.**)

5. When am I required to disclose a newly acquired significant financial interest (SFI)? Annually?

A new SFI, whether it is reportable third party paid travel, or stock, consulting fees, etc. for you, your spouse, or dependent children must be reported when the aggregate value exceeds \$5,000 and within 30 days of receiving/acquiring the SFI. (**Note:** Stock and/or stock options from a non-publicly traded company must be disclosed at \$0 value.) Failure to do so, according to PHS regulations, will require Yale to conduct a retrospective review to determine whether the undisclosed significant financial interest biased the research. If after your initial PHS External Interests Disclosure no additional SFIs are received or acquired, then only an annual disclosure is required.

Additional Resources

To assist investigators and department business offices with the application of the PHS regulations to proposals and awards, GCA has created a PHS and NSF COI Resource Repository website located at: <http://www.yale.edu/grants/FCOI/index.html> that includes a Summary for Investigators of the PHS COI changes. External Interests Disclosure information and requirements are available on the Conflict of Interest Office’s website located at: <http://coioffice.yale.edu/information-revised-phs-coi-regulations>.

As always, please call upon the staff of the Office of Grant and Contract Administration (GCA) and the Conflict of Interest Office (COI) to assist you with questions regarding PHS or NSF requirements. If you encounter technical problems while completing your disclosure form, or have questions regarding navigating the disclosure form, please contact the COI Call Center at (203) 737-5954.

IACUC Posts Transportation Guidelines for Animals

The Institutional Animal Care & Use Committee (IACUC) and the Office of Grant and Contract Administration (GCA), in collaboration with the Office of Cooperative Research (OCR) and the Yale Animal Resource Center (YARC), have recently updated *Yale Policy 4442: Transportation of Animals (Inter-institutionally)* governing the export and import of rodents and other live vertebrate animals. This policy ensures the proper transfer of animals in a safe and appropriate manner.

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Did you know that...

The National Science Foundation (NSF) has revised its Merit Review Criteria (See http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/nsf13_1.pdf). Changes will affect the project summary and project description sections of proposals and are effective for proposals submitted, or due, on or after January 14, 2013. Annual and final reports will also be affected.

Policy 4442 states that unless animals are being transferred under the terms and conditions of a collaborative research agreement (CRA), sponsored research agreement (SRA), federal subaward, or other appropriate agreement, a License or Material Transfer Agreement (MTA) must be utilized to import or export animals to or from the University.

Import Procedure

Investigators importing animals from non-commercial and/or unapproved vendors such as Jackson Laboratories, Taconic Inc., or the Mutant Mouse Regional Resource Center should either utilize a Request to Introduce Rodents Form available on the YARC website at (<http://info.med.yale.edu/yarc/qa/introduc.htm>) or contact the YARC Purchasing Agent at 785-2526 because the transfer of animals for these types of repositories are governed by the policies of the specific vendor.

Should an investigator be contacted directly by a vendor that a specific MTA or Condition of Use Agreement (COU) is required, they should contact GCA's at MTAs@yale.edu prior to transfer. GCA will coordinate with YARC to negotiate the required agreement.

Investigators who would like to receive materials from an academic or non-profit institution, governmental agency, or for-profit company are required to complete an Incoming MTA web-based form (<http://www.yale.edu/grants/mta/incoming.html>) and submit it to GCA. This form provides the necessary background information in order to ensure that Yale complies with the organization's MTA terms.

Export Procedure

Investigators wishing to export mice to an academic or non-profit institution, or governmental agency should complete an Outgoing MTA web-based form (<http://www.yale.edu/grants/mta/outgoing.html>) and submit it to GCA. GCA will confirm that there are no restrictions in transferring the mice, limitations on the recipient's use, or costs related to the transfer of the mice. GCA employs standard agreements such as the Uniform Biological Material Transfer Agreement (UBMTA), the NIH Simple Letter Agreement (SLA), or the NIH Transfer of Organisms Agreement (MTA-TO) in order to expedite these types of transactions.

License Agreements to export rodents to for-profit companies are required to protect the University's intellectual property rights in the animals, to ensure that Yale is not transferring animals with any third party rights that would violate existing agreements, and to negotiate appropriate licensing fees. Investigators wishing to export rodents to a for-profit company should contact John Puziss, Director of Technology Licensing, OCR.

If animals are to be exported under an existing agreement, such as a grant, SRA, CRA or subaward, YARC should be notified of the specific agreement. They will coordinate with OCR/GCA to ensure the rodents are being appropriately transferred.

Note: Graduate students, post-docs, research scientists, or visiting scientists, working in an investigator's research group wishing to take rodents to another institution (and possibly another laboratory here at Yale) must do so under an appropriate License Agreement or MTA.

It is important to contact either OCR or GCA as early as possible to allow for the required time to draft, negotiate and sign agreements. License agreements and incoming and outgoing MTAs may require a few days or weeks to process especially if Yale is required to contact a third party or if the incoming agreement contains terms that conflict with University academic policies. Animals may not be transferred until the appropriate agreement has been fully executed by both investigators and institutions.

Yale University Contacts:

Institutional Animal Care and Use Committee (IACUC) Office

Website: <http://iacuc.yale.edu/>

Email: IACUC@yale.edu

Tel: 1-203-785-5992

Yale Animal Resource Center (YARC)

Website: <http://medicine.yale.edu/yarc/index.aspx>

E-mail: Jennie Smith, Animal Import/Export Coordinator, jennie.smith@yale.edu

Tel: 1-203-785-2526

Office of Cooperative Research (OCR)

Website: <http://www.yale.edu/ocr/>

Email: John Puziss, Director of Technology Licensing, john.puziss@yale.edu

Tel: 1-203-785-6209

Office of Grant and Contract Administration (GCA)

Website: <http://www.yale.edu/grants/mta/index.html>

Email: Don Wiggin, MTA Manager, donald.wiggin@yale.edu, MTAs@yale.edu

Tel: 1-203-785-6313

IRES Proposal Development

Over the summer Yale's new web-based Integrated Research Enterprise Solution (IRES) Proposal Development (PD) module was effectively piloted in Psychiatry, Child Study Center, and departments supported by FAS Faculty Research Management Services (FRMS). Pilot participants built and electronically submitted over two hundred proposals using the new PD module. During the pilot, proposals were routed and approved online by faculty from locations across the US and internationally (e.g., China and Greece).

The PD module provides PIs and administrators an online portal for preparing, submitting, and tracking grant proposals. Features of the new PD module include:

- Ability to electronically create, assemble and route proposals for review, approval, and submission
- Access proposals from any networked computer (via Yale VPN) or Smartphone
- Pre-population of PI and department information
- Ability to attach supporting documents and compliance information
- Facilitates direct submittals to Grants.gov

IRES began with the implementation of the Proposal Tracking (PT) module as a first phase to capture, store and manage preliminary proposal and award information. Progress continues as the PD module is implemented in waves across the University, beginning Fall 2012 through 2013.

If you have questions about IRES, please contact us at IRES@yale.edu.

Good Clinical Practice (GCP) Module

Individuals seeking training in Good Clinical Practice (GCP) for clinical research can now access the Collaborative Institutional Training Initiative (CITI) Good Clinical Practice (US FDA Focus) web-based program through Yale's Training Management System (click on <http://yale.edu/training/> and scroll down to CTSA/YCCI).

The GCP course contains modules that address GCP requirements, investigator responsibilities in drug and device studies, safety monitoring and reporting. Each module includes an introduction, topic-specific content, references and resources, and quiz questions. Review of the required materials and completion of the quizzes will take about 15-20 minutes per topic. You do not have to complete the course all in one session. A minimum aggregate score of 80% is required in order to successfully complete the GCP(US FDA Focus) Course.

Sponsors or funding agencies may require researchers who conduct clinical research to demonstrate knowledge of good clinical practices. The CITI GCP (US FDA Focus) Course can be used to meet this requirement.

Questions about course content can be directed to susan.anderson@yale.edu. Having trouble with access? Contact researchadmin@yale.edu.

Research Administration Training Opportunities

UPCOMING TRAINING EVENTS

Introduction to Sponsored Projects Administration

Date: January 8, 2013

Time: 8:30 AM – 4:30 PM

Location: 47 College St, Suite 212A

This one day program will walk participants through the basics of sponsored projects administration from proposal preparation to award closeout. Topics include: Regulatory Compliance, Proposal Preparation, Budget Basics, Proposal Review and Submission, Award Negotiation and Acceptance, Sponsored Award Setup, Financial Management of Sponsored Awards and Financial Reporting and Award Closeout. The department of a registrant canceling within 24 hours of the course or who is a “no show” will be charged a cancellation fee of \$50.

Research Compliance Principles for Administrators

Date: January 30, 2013

Time: 8:30 AM – 12:30 PM

Location: 47 College Street, Room 212A

This 1/2 day program is designed to walk attendees through the principles of research compliance focusing on what business administrators should know about research involving animals, human research studies, conflict of interest, environmental health and safety, export controls, and the basic requirements of subawards. A prerequisite for this course is “Introduction to Sponsored Projects Administration. The department of a registrant canceling within 24 hours of the course or who is a “no show” will be charged a cancellation fee of \$50.

Additional Training for Faculty and Administrators

Grant and Contract Financial Administration (GCFA)

- Cost Transfer Principles and Access
- Effort Reporting Principles (System Training)

Grant and Contract Administration (GCA)

- Hands-on Clinic – Grants.gov (on request)
- Hands-on Clinic – Fastlane (on request)
- Fundamentals of Export Controls (web-based)

Office of Research Administration (ORA)

- Sponsored Projects Administration Training for Faculty (web-based)
- CITI Responsible Conduct of Research (RCR)

*To learn more or to register for ORA sessions, visit <http://www.yale.edu/training/>,
Navigate to Office of Research Administration.*

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.