

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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DHHS issues a Final Rule on Financial Conflict of Interest (FCOI)

On August 25, 2011, The U.S. Department of Health and Human Services (DHHS) issued a final rule that amends the Public Health Service (PHS) regulation on *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought* (42 CFR Part 50, Subpart F), commonly referred to as the “FCOI regulations”. Grantee institutions, such as Yale, must be in full compliance with all of the revised regulatory requirements no later than August 24, 2012.

The Office of Research Administration (including the Conflict of Interest Office, and the Office of Research Compliance and Education) is partnering with General Counsel and the Provost’s Office to execute various COI policy and procedural changes needed to comply with the new FCOI Regulations. Some of the changes include but are not limited to:

- A new *de minimis* threshold (generally, \$5,000 vs. \$10,000) for disclosure of Significant Financial Interests (SFIs) (*Exclusions apply only to government and U.S. higher education institutions and organizations affiliated with U.S. higher education institutions; there are no exclusions for services provided to not-for-profit organizations such as the American Cancer Society.*);
- A new SFI category – all travel regardless of dollar threshold that is related to the investigator’s institutional responsibilities that is reimbursed or sponsored by sources other than Federal, state, or local government agency, an U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education must be disclosed (*When Yale implements the new PHS requirements on August 24, 2012, investigators will be required to disclose travel that occurred during the previous 12 months. Additional guidance will be forthcoming.*);
- Disclosure of FCOI details by an investigator who transfers to Yale from another institution at which the investigator had a FCOI on a PHS sponsored award;
- Required COI training of investigators prior to their engaging in PHS-funded research and, thereafter, every 4 years, or when an instance of non-compliance occurs, or when the Institution’s policy changes with respect to disclosure requirements;

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Compliance and Education

Did you know that...

On September 1, 2011, the University published Policies for Postdoctoral Appointments addressing issues such as paid time off and sick time? The policies can be viewed by clicking the following URL: http://www.yale.edu/postdocs/documents/PD_policy.pdf

- Failure of investigators to meet disclosure requirements or otherwise comply with new regulations, or failure of Institutions to act timely on disclosures will require a retrospective examination of the facts to determine if any research results were “biased” and, if so, what mitigation plans need to be put in place;
- FCOIs must be reported to the PHS awarding component and must include a description of the SFI, the nature of the FCOI and the details of the management plan. All FCOIs reported to the sponsoring agency must be updated on an annual basis;
- A new requirement to provide Public accessibility of FCOI review results related to PHS-funded projects; and
- For Yale subrecipients, in the absence of a sub-recipient having a PHS compliant policy, Yale policy must flow down its Policy; however, disclosure need only relate to the specific award in question.

To learn more about the FCOI regulations the National Institutes of Health (NIH) will hold a free 90-minute webinar entitled, “What NIH Grantees Need to Know About the 2011 Revised Financial Conflict of Interest Regulation” on November 30 at 2:00 p.m. EST. The webinar, designed for investigators and administrators will include an overview of the final rule, a discussion of investigator and institutional responsibilities, and a 15-minute Q&A period. For more information, visit: http://grants.nih.gov/grants/policy/coi/fcoi_webinar_20111130.htm

Lastly, in the coming months additional guidance regarding Yale’s implementation of the FCOI regulations will be provided to the Yale community. Should you have any immediate questions, please contact conflicts@yale.edu.

License Requirements for Interactions with Embargoed or Sanctioned Countries

On September 13, 2011 the Office’s of Grant and Contract Administration and the General Counsel issued a memorandum describing requirements for licensure for interactions with Iran, Syria, Sudan, Cuba, North Korea and Myanmar. The United States currently maintains embargoes and comprehensive sanctions on each of these countries and prohibits, without licensure, many academic, clinical, and research activities.

Faculty members are reminded that many beneficent academic and clinical interactions with people or institution in these countries may require licensure. Examples include:

- Paying locals to translate
- Bringing home artifacts from an archeological dig, even if approved by Customs
- Sending or receiving routine objects, such as bandages or furniture
- Taking your computer or phone into the country, even if they contain no data
- Advising local professionals on disease prevention
- Sending or receiving samples: biological tissue, rocks, leaves
- Providing clinical services on-site or through consults by phone or Internet
- Holding a Q&A session at a conference

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Did you know that...

Because of the Open Skies Agreement you may not have to fly an American Carrier if the trip is supported with federal funds? A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an “Open Skies” Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States. When making reservations consider a foreign carrier but only if an “Open Skies” Agreement exists otherwise the airfare may be disallowed on the federal award.

LICENCE REQUIREMENTS FOR INTERACTIONS WITH EMBARGOED OR SANCTIONED COUNTRIES (CONTINUED)

There are exceptions, which vary from country to country. Generally, receipt of informational materials (books, newspapers) does not require a license. Personal travel does not require a license in some of the six countries. Communicating previously published information (as in a lecture) is generally allowed, but a discussion or Q&A session, where new information might be provided, may require a license.

Any questions about this and other export controls issues should be directed to one of the following individuals noted below. Additional information is also available on the websites of the Office of General Counsel and the Office of Grant and Contract Administration.

<http://www.yale.edu/grants/policies/exportcontrols.html>

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ORA Newsletter Survey

As this Newsletter approaches its five year anniversary, we are asking our readers to comment on the content and future direction of this publication.

The ORA Newsletter was launched in 2006 with the purpose of providing up-to-date information on topics of interest to principal investigators, project directors, and staff who manage sponsored

programs. We focus on compliance issues that support the University's research, education and service mission, advise you about important communications from sponsors, and provide you with information on our training opportunities for faculty, staff and administrators.

We hope that you will take a few minutes to complete our survey online:

<http://www.surveymonkey.com/s/XVWKBJC>

Did you know that...

Yale's Office of Institutional Research (OIR) publishes an Ongoing Book of Numbers as well as a Fact Sheet on frequently asked statistical questions about the University administration and community?

Bookmark this useful resource <http://www.yale.edu/oir/index.html>.

Upcoming Research Administration Training/Educational Events

How to Write a Compelling Grant Abstract: A Hands-On Skill Building Workshop

Date: December 7, 2011

Time: 3:00 – 4:30 PM

Location: 60 College Street, LEPH 101

Presenter: Elena Kallestinova, PhD, of the Yale Graduate Writing Center, will lead a hands-on workshop devoted to improving your ability to write a compelling grant abstract (both lay abstracts and technical abstracts). NOTE: Due to limited space, faculty will be given preference for this session.

An Introduction to Sponsored Projects Administration

Date: December 13, 2011

Time: 8:30 AM – 4:30 PM

Location: 47 College Street, Room 212A

Research Compliance Principles for Administrators (Offered quarterly)

Date: December 6, 2011

Time: 8:30 AM – 1:00 PM

Location: 47 College Street, Room 212A

What Research Staff Need to Know About Spending Sponsored Project Funds

Date: January 19, 2012

Time: 10:00 AM – 12:00 PM

Location: Sterling Chemistry Laboratory (SCL), 225 Prospect St, Room 123

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 (offered quarterly)

Grant and Contract Administration (GCA)

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

To learn more or to register for the above educational opportunities with the exception of Sponsored Projects Training for Faculty, visit <http://www.yale.edu/training/>. (Follow link to GCA and GCFA Training and then to Funding/ Grantsmanship Training Programs).

To learn more or register for Sponsored Projects Administration Training for Faculty (web-based) visit <http://www.yale.edu/training/>. Navigate to Office of Research Administration Training and click Courses.

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.