Yale’s Implementation of the Revised PHS Objectivity in Research Regulations

Last September we reported to you on revised conflict of interest regulations issued by the United States Public Health Service (PHS). This article provides additional information on how the University intends to implement the required changes. The regulations apply both to research sponsored by the National Institutes of Health as well as other funders that mandate compliance with PHS regulations. By law, Yale must implement these PHS regulations no later than August 24, 2012.

In its continuing effort to try to minimize burden on faculty, Yale will raise the threshold for disclosure for faculty who do not receive PHS (i.e., NIH) funding from zero dollars to $10,000. Similarly for faculty and investigators who receive PHS funding, the disclosure threshold based on the PHS regulations will be raised from zero dollars to $5,000.

The revised PHS regulations also impose new disclosure requirements. For example, the PHS regulations require that faculty and others responsible for the design, conduct, or reporting of PHS-supported research disclose all travel related to their institutional responsibilities and professional activities that is paid for by non-Yale sources (with certain exceptions for government entities and US academic institutions), during the period of the supported research. To accommodate the policy and regulatory changes (including new training requirements for PHS funded investigators), the current on-line disclosure is being revised with the assistance of faculty input. To minimize the burden on faculty, the COI training mandated for each PHS funding circumstance will be built into the online disclosure form and process.

As was the case in the past, the regulations include the condition that PHS proposal applications may be submitted only if investigators have a current PHS-compliant disclosure on file. The PHS regulations additionally set forth a number of negative

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consequences for investigators that could result from failure to comply with the regulations; for example, failure
to update disclosures in a timely manner or comply with COI Committee management plans could result in the
need for retrospective reviews of research findings for potential bias and immediate re-training on Yale’s COI
Policy and PHS requirements.

The new PHS regulations and related FAQ’s are available at NIH Financial Conflict of Interest. If you would like
to provide suggestions for improving the University’s COI processes, please send an email to conflicts@yale.edu

Information Security Requirements: What You Should Know

In the course of carrying out its academic, research, and clinical missions, Yale’s faculty, staff and students
collect information that may include both academic, research, protected health and personal related data.
Yale and its employees, under U.S federal and state data privacy and security laws, have an obligation to
implement appropriate safeguards to protect such confidential information residing both inside and outside
of the United States.

In addition, there may be requirements placed by external entities on the use of their data and data sets for the
protection of human subject research within such areas as the Yale School of Medicine, the School of Nursing,
Department of Psychology clinics and Yale University Health Services. These units are covered by the Health
Insurance Portability and Accountability Act (HIPAA), privacy and security rules, and the HITECH Act (Health
Information Technology for Economic and Clinical Health) breach notification requirements.

These data security requirements are complex. Many researchers and departments may not have the required
financial, IT, and human resources to implement and support such requirements. Therefore, when submitting
proposals to external sponsors, budgets should be developed with a full understanding of costs related to IT and
information security roles and responsibilities, and in advance of entering into a sponsored research agreement
with a sponsor. The data security requirement is usually specific to federal contracts and is typically addressed
in the sponsor’s announcement/solicitation. The types of solicitations that may include such a requirement are
Broad Agency Announcements (BAA), Requests for Proposal (RFP) and Requests for Quote (RFQ). The most
often cited references to the requirements are The Health Insurance Portability and Accountability Act (HIPAA)
which falls under The Privacy Act, Federal Information Security Management Act (FISMA), The Family
Educational Rights and Privacy Act (FERPA), and The National Longitudinal Study of Adolescent Health
(Add Health) Project.

If you are preparing a proposal in response to a solicitation with an information and/or data security require-
ment, be sure to consider and include the cost of implementing this requirement in the proposal budget. See
contacts below for budgeting assistance.

Getting Help:
• GCA contact for proposal-related questions including budget building: http://www.yale.edu/grants/contacts/
• Information Assurance & Compliance including HIPAA ‘Security’: http://security.yale.edu/contact.html
  security@yale.edu
• HIPAA ‘Privacy’: hipaa@yale.edu
• ITS Information Security (including assistance with budgeting) at: Ashley.eng@yale.edu; 203.436.5188

Additional Information:
• Federal Agency Policies & Information Security: http://www.yale.edu/grants/policies/
• Legal requirements & data security: http://www.yale.edu/its/secure-computing/data/compliance/

Did you know that...

Every two years the University must conduct a physical inventory of its moveable equipment in order
to ensure that it has properly maintained and accounted for equipment within each unit? This June,
departments can take advantage of the University’s pool of student assistants to help complete their
inventories. For more information see Policy 4209 Equipment or contact Mike Annand at 203.737.7033
or Bob Marchitto at 203.785.3082.
Is Your Informed Consent Language Current?

Effective March 7, 2012, the following language is required in all human participant consent documents for Phase II or III controlled clinical trials with Federal Drug Administration (FDA) oversight, or controlled trials with health outcomes of an FDA regulated device:

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

The Yale HICs have incorporated this language into the informed consent form and compound authorization templates (available on the HRRP forms page).

Note: Registration of clinical trials is also a requirement of ICMJE for manuscripts submitted to biomedical journals. For more information on registering clinical trials, including whether your trial must be registered, review YCCI’s webpage or contact YCCI at 203.785.3482.

Training In The Responsible Conduct Of Research (RCR)

Effective January 4, 2010 all grantees submitting proposals to the NSF must include certification of a plan for responsible conduct of research training of undergraduate students, graduate students, and postdoctoral researchers supported with NSF funding. The University’s plan, National Science Foundation Responsible Conduct of Research Training Plan for Undergraduate/Graduate Students and Postdoctoral Researchers was recently revised and is available on the ORA RCR webpage (click here) for reference and information regarding Yale’s compliance with this requirement.

Also, researchers are reminded that the NIH RCR requirement applies to individuals at all stages of their career who participate in Institutional Training Grants, Individual Fellowship Awards, Career Development Awards, Research Education Grants, Dissertation Research Grants, or other grant programs as identified in the funding opportunity announcement. For additional information review the NIH Requirements for Instruction on RCR. Additional resources specific to Yale are located at the following link ORA RCR webpage.

Yale’s Online “International Toolkit” Goes Live

Yale and the World: Your International Toolkit (http://world-toolkit.yale.edu) gives Yale faculty, students, post-docs, and staff an easy way to access international resources from across Yale’s websites and beyond. The International Toolkit covers a broad range of content, from practical travel tips and tools, to managing procurement and facilities needs overseas, guidance on financial matters and human resources, and more.

Throughout, the International Toolkit provides insight into the various requirements and standards that apply to Yale’s international activities, whether overseas or on campus. Its “Restricted Activities” section features straightforward explanations of challenging legal and regulatory matters and explains where to find help at Yale with structuring international projects to minimize impact while meeting requirements.

Users can browse sections, access country-specific resources, conduct keyword searches, or use the Roadmap tool to filter content by user group and topic. And when a tool will not suffice, the Toolkit’s Contact Us function makes it easy to reach the members of Yale’s International Operations Compliance Committee who are available to help with any international matter.

Did you know that...

If you have a K-award, rebudgeting of salary funds in an NIH-supported research grant for the salaries or fringe benefits of individuals which are freed as a result of a career award, may not be rebudgeted without the prior approval of the NIH awarding IC? See the NIH Grants Policy Statement 8.1.2.16 (http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.htm#_Requests_for_Prior). Rebudgeting requests should be addressed to the named NIH Grants Officer on the Notice of Award and sent to GCA for review and endorsement prior to submission to the NIH.
IRES Proposal Development System Pilot

The IRES Proposal Development system (PD) has arrived! The Office of Grant and Contract Administration’s (GCA) PD, system offers an integrated electronic environment for building, approving, and submission of research proposals. PD was successfully deployed as a Pilot on May 11th, 2012 for the use of select departments (Psychiatry, Child Study, and departments supported by Faculty Research Management Services) that have been working with GCA to validate critical system functionalities. The results of and feedback from the Pilot will assist in the rollout of PD to Yale’s research community.

To learn more about the PD or if you have questions about IRES, please contact us at IRES@yale.edu.

Upcoming Research Administration Training/Educational Events

Brown Bag Luncheon Series

Fly America Act and the Open Skies Agreement
- Date: June 22, 2012
- Time: 12:00 – 1:30 PM
- Location: Brady Auditorium

An Introduction to Sponsored Projects Administration
- Date: July 10, 2012
- Time: 8:30 AM – 4:30 PM
- Location: 47 College Street, Room 212A

Research Compliance Principles for Administrators (Offered quarterly)
- Date: July 19, 2012
- Time: 8:30 AM – 1:00 PM
- Location: 47 College Street, Room 212A

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)

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 or to register for the above educational opportunities, 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.