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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, 2006

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NIH Issues Dual Use Research of Concern Policy

The National Institutes of Health (NIH) issued its policy for oversight of life sciences "Dual Use Research of Concern" (DURC) on August 28, 2013 (NOT-OD-13-107, NIH Policy on Mitigating Risks of Life Sciences Dual Use Research of Concern). As required by the US Government policy issued on March 29, 2012, NIH has identified the manner in which it will conduct reviews and the requirements it will place on projects that involves one or more of 15 listed pathogens and toxins that are being used in projects with specified experimental aims that may result in research products, technology or information that could be misused to pose particular risks.

NIH's approach is consistent with the Federal policy. The NIH will conduct an administrative review of all current and future awards to determine if they involve research that could be considered a DURC. If they do, a condition of award will be added requiring the institution to submit a letter from the Institutional Biosafety Committee or another appropriate review body, indicating its assessment of the DURC status of the research proposed, including the reason for its determination, and cosigned by the institutional official. If the institution determines that the research is a DURC, an assessment of the risks and benefits of the research must also be included.

If an institution determines that the research is not a DURC, NIH will conduct a subsequent analysis and make a final determination. If a project is determined to be a DURC a risk mitigation plan will be required. If during the course of the research, the research becomes a DURC, the grantee is required to inform the NIH immediately of the change in the DURC status and develop a risk mitigation plan as well. The institutional determination that research is a DURC must be reassessed at least annually and the outcome included in the annual progress report. For DURC research, NIH requests that grantees share with the Program Official for review any resulting manuscripts within at least 10 business days prior to planned journal submission. NIH also requests that grantees share with the Program Official any meeting Abstracts summarizing research activities supported by this grant that are intended for presentation at scientific conferences at least 10 business days prior to anticipated submission.

To review the complete policy, it is located at:
www.grants.nih.gov/grants/guide/notice-files/NOT-OD-13-107.html

International Collaborations and Export Controls

Yale employs foreign nationals; collaborates with international partners on research, education and services; and hosts foreign visitors and international students in connection with international exchange programs as well as other academic, research

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and collaboration agreements. Yale also hosts international visitors, both long and short term, in the most welcoming manner possible while also assuring compliance with U.S. laws and regulations. However, access to restricted or export controlled technology, commodities, defense articles and defense services by an unauthorized foreign person could result in severe criminal or civil penalties for the University and any University employee involved with the export violation.

Most research activities at Yale will not be affected by export controls. The primary reason is the so-called Fundamental Research Exclusion. As is the case with most Yale research, this exclusion covers basic and applied research that results in publications and open dissemination of research results, as is typically found in academic research. However, research activities that have limitations on the right to publish or restrictions on the participation of foreign students or researchers or use of certain controlled equipment would most likely be subject to export controls.

Other important exclusions involve information that is in the public domain (essentially any information in the public domain is not subject to export controls) or information disclosed in routine education activities. Questions regarding export control requirements can be directed to Donald Deyo, Director of Export Control Licensing at *Donald.Deyo@yale.edu*.

HRPP: Expanding Researcher Support

The Human Research Protections Program (HRPP) strives to provide meaningful and timely information and support to researchers submitting human participant protocols to the HIC/HSC. In addition to HRPP's educational program, HRPP maintains a daily regulatory analyst phone support system, general email accounts that are monitored daily, and a "Submit Your Question to the HRPP" link on the HRPP website located at: *http://www.yale.edu/hrpp/questions.html* (scroll to the bottom of the page to submit your question) in further support of the community.

During the spring of 2012 the HRPP launched a formal consultation service for investigators and research staff. Investigators and research staff can set up a meeting at the HRPP Office, the researcher's office, another location (e.g., the library on the main campus), by extended phone conversation, or by email. Since the initiation of the service, the HRPP has provided 127 formal consultations. The service has been used by undergraduate and graduate students, fellows, research coordinators, Clinical Trials Office staff, faculty new to Yale, faculty new to human subjects research, and experienced faculty who have questions about complex research design.

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Did you know that…

The NIH "encourages" Individual Development Plans for all Grad Students and Post-Docs?

In a notice posted July 23, 2013, NIH announced its "encouragement" of institutions to use Individual Development Plans (IDPs) for all graduate students and post-doctoral research fellows engaged in research supported by NIH. They are encouraging the adoption of IDPs by October 1, 2014 and ask investigators to include a description of the implementation of this encouraged activity in Research Performance Progress Reports (RPPR) on/after October 1, 2014. It was noted by the NIH that for those institutions that currently use IDPs, NIH encourages reporting on the progress in the RPPR as soon as October 1, 2013.

This "encouraged" implementation responds to one of the recommendations made by the Biomedical Work Force Working Group of the NIH Director's Advisory Committee. The goal of the IDPs is to better prepare graduate students and post-doctoral researchers – scholars, trainees, fellows, etc. – to participate in a broad-based and evolving biomedical economy. The notice, NIH Encourages Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers (NOT-OD-13-093), can be read in its entirety at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-093.html

Though the IDPs are "encouraged" readers should be reminded that the NIH public access to publications policy was also implemented as voluntary until it became required.

Feedback on the consultation has been universally positive regarding the value of the service and the value of the specific meeting. The feedback has also provided an opportunity for researchers to comment on any other concerns they may have about other HRPP functions (e.g., the electronic system, turnaround time for protocol review).

In further support to the research community, a FAQ section on the HRPP website was launched in December 2012. Questions appearing on the site were derived from a survey of study coordinators and an HRPP staff review of call logs and emails identifying questions most frequently asked.

Overall, the HRPP is committed to providing as many venues and opportunities as possible to provide information to the research community.

Sharing Our Experience: HRPP Posters at the Annual PRIM&R conference

Each year Public Responsibility in Medicine and Research (PRIM&R) holds a national conference for HRPP and IRB professionals and volunteers. The conference includes an array of juried posters on issues pertinent to HRPP/IRB function and issues. This year Yale had seven posters accepted for presentation, they included:

- *Go Team:* A description of HRPP's organization of regulatory analysts into teams, which mirrors the Office of Grant and Contract Administration's (GCA) teams
- *Harmonization:* A description of HRPP's process of assessing common functions of the biomedical and social/behavioral/educational IRBs in order to develop more standard shared tools for protocol review.
- *Checklists:* A description of HRPP's process for creating regulatory analyst protocol review checklists that ensure review of all fundamental regulatory criteria as well as incorporation of criteria specific to various types of research, e.g., international research, clinical trials.
- *Streamlining Review of Social and Behavioral Science Protocols During Peak Submission Seasons:* A description of HRPP's initiative to educate social/behavioral/educational researchers regarding delays of protocol approval and how they can be avoided through early submission and thorough protocol application completion.
- *FAQs:* Describes the process and content of developing and assessing the effectiveness of the HRPP Frequently Asked Questions website.
- *Sustainability:* Describes the HRPP efforts to create a more environmentally responsible workplace through decreased use of paper, ink, electricity, and disposable bottles and utensils.
- *Infoshorts:* Describes the initiation of a program of brief educational presentations and discussions as part of each IRB Committee meeting.

Congratulations to the HRPP staff who worked to effect these changes, and who developed successful posters. Your hard work and dedication to the protection of human subjects research is appreciated.

New eShipGlobal Features for Improvements in Shipping and Export Control Compliance

Effective November, 2013, eShipGlobal will implement several new enhancements in order to improve compliance with shipping and export control regulations. Yale strongly encourages everyone to use eShipGlobal for all shipping needs. These enhancements include:

1. Intra-Campus Shipments of Research/Clinical Materials will now be delivered through Yale Traffic Receiving and Stores (TR&S).

It is imperative that research/clinical materials (e.g., biological, chemical and radioactive materials) be processed through eShipGlobal and packaged by trained research/clinical staff and compliantly transported by trained TR&S staff. Research/Clinical materials must not be transported in personal vehicles or on public transportation, including Yale Shuttles. Properly packaged research/clinical materials will be picked up and delivered door to door the same day if processed in eShipGlobal by 2:00 PM. Shipments processed after 2:00 pm will be picked up and delivered the next business day. This new door to door service will include all Yale Campus, including West Campus, Science Hill, Medical School and the West Haven Veterans Administration Hospital. As with other eShipGlobal shipments, the process will ask the preparer to specify the research

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materials being shipped and will verify that the person has the required training to make the shipment. At the present time, the cost of these shipments will be centrally funded. Users will not need to provide their own VIP Number or PTAEO.

2. New International Shipping Requirement

Other than for international shipments of research materials (biological materials, chemicals, etc.), international shipments section of the website will display a series of new prompts in order to classify the item being shipped (e.g., Documents, Software or Products). Users will be asked whether the contents meet any of a number of conditions that may warrant review to determine whether the materials are subject to Export Control regulations. If the user is preparing the shipment on behalf of someone, he or she must verify the contents with the Initiator prior to completing the transaction.

If the user answers "Yes" to any of the questions regarding the shipment, eShipGlobal will route the transaction to the Yale Export Controls team in the Office of Grant and Contract Administration (GCA), which will review/approve the international shipping request. International shipments of research materials will continue to be reviewed by Environmental Health and Safety.

International shipments with a Declared Value of more than $2,500 require an Internal Transaction Number (ITN) from the U.S. Census Bureau. The transaction will be automatically routed to EHS, which will apply for the ITN and once obtained will update/approve the shipment. The shipper will then be notified via email, usually within 2 hours.

3. Restricted Party Screening (RPS) Check for All Shipments, both Domestic and International

After users enter details about the sender, recipient, and item, eShipGlobal will perform checks on all shipments to confirm that the parties involved are not identified on any federal or international RPS database. If a RPS match is identified, the eShipGlobal shipping request will be routed for review/approval to Yale Environmental Health & Safety (EHS). If necessary, EHS will communicate with the Yale Export Controls team in GCA. Once all necessary reviews have been completed, the shipper will be notified via email, usually within 2 hours. In a few cases, additional information may be required to obtain approval.

To obtain more information and guidance regarding the implementation of the new features of eShipGlobal, please visit: *http://yalebiz.yale.edu/transactions/express-shipping*

For questions, please contact the ITS Help Desk at 432.9000.

Key Contacts:

- Environmental Health & Safety
  Kevin Charbonneau: 203.737.2139
  kevin.charbonneau@yale.edu
  Manager Safety Advisor Program, Assistant RSO
- Export Controls
  Donald Deyo: 203.785.3817
  donald.deyo@yale.edu
  Dir Corporate Contracts and Export Control Licensing

Affordable Care Act (Obamacare) Expands Coverage of Routine Costs Rendered under Approved Clinical Trials

Starting January 1, 2014, all third-party payers of health benefits or insurance claims are required to cover **routine patient costs** associated with participation in an **approved clinical trial** to a **qualified individual.** This new law (US code 42 U.S.C §300gg-8) may help researchers recruit subjects who decline from participating in a study because of fears their insurer will not cover certain routine costs not being paid for by the research sponsor.

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Routine patient costs include all items and services typically covered by the insurer for a qualified individual who is not enrolled in a clinical trial. They do not include:

(I) the investigational item, device or service itself;

(II) items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

(III) a service that is clearly inconsistent with widely accepted and established standard of care for a particular diagnosis.

Approved clinical trials are generally defined as Phase I, II, III and IV studies that are conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and have federal funding or are being conducted under an IND or considered exempt for the IND application requirements.

A **qualified individual** is one who is eligible to participate in an approved clinical trial according to the trial protocol; and either the participant's health care provider determined his/her is appropriate or the participant provides medical and scientific information establishing that they meet the protocol's eligibility criteria and his/her participation is appropriate.

The new federal law establishes the minimal national coverage requirements. Human subjects insured by Medicare are already entitled to the routine costs coverage benefits provided under the Affordable Care Act (ACA) provision. However, the clinical trial provisions under the ACA do not apply to human subjects insured with an insurance plan that is considered to have a 'grandfathered' status. (A 'grandfathered plan' is a plan in which the individual was enrolled on March 23, 2010 and did not provide coverage of routine costs associated with a clinical trial.) A 'grandfathered' status is lost when the plan either reduces benefits or increases costs to enrollees. Once the 'grandfathered' status is lost, individuals insured by that plan become entitled to all ACA provisions.

Researchers also should be aware that state statutes determine what costs associated with a clinical trial can be expected to be covered by the subject's insurer. The State of Connecticut has several statutes to protect research subjects from bearing the costs associated with participation in clinical trials. Information regarding these statutes can be found at *http://ycci.yale.edu/comply/insurance/ctlegislation.aspx*

The Importance of Understanding the Export Control Regulations

First, what is the definition of an "export" as defined by the Export Administration Regulations (EAR). An export according to the EAR is:

a. an actual shipment outside of the U.S. of controlled equipment or materials (actual items); or

b. any disclosure of information or technical data related to controlled equipment or materials by any means (verbal, email, fax, visual inspection, internet or training outside the U.S or inside the U.S.) Disclosure of information or technical data to a foreign national in the U.S. (at Yale) is defined as a "**deemed export**". For deemed exports, foreign nationals would be any person who is not a lawful permanent resident of the U.S., a group not organized to conduct business in the U.S. or a foreign government (or any branch of a foreign government).

The United States export control laws regulate the distribution of controlled technologies, services, and information (export) for reasons of national security and economic regulations to foreign nationals and foreign countries. There are several export control and/or sanctions related regulations. Those that impact Yale University most significantly are the Export Administration Regulations and the laws and regulations implemented by the Office of Foreign Assets Control (OFAC).

The Export Administration Regulations (EAR), under the purview of the U.S. Department of Commerce, regulate items, information, software and services that are dual use (i.e., predominantly civil applications but

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may also have military applications) or are strictly civil in nature. The list of EAR-controlled items (included in the Commerce Control List, or "CCL") is published at 15 CFR §774, Supplement 1. and identifies controlled items under the following 10 broad categories:

0) Nuclear Materials, Facilities and Equipment, and Miscellaneous
1) Materials, Chemicals, Microorganisms, and Toxins
2) Materials Processing
3) Electronics
4) Computers
5) Telecommunications and Information Security
6) Lasers and Sensors
7) Navigation and Avionics
8) Marine
9) Propulsion Systems, Space Vehicles, and Related Equipment

A complete alphabetical list of CCL items is accessible at: *http://www.access.gpo.gov/bis/ear/pdf/indexccl.pdf.*

For goods and technology listed on the CCL, a license may be required for export, depending on the destination country, receiving party, and end use, unless an exclusion or exemption applies.

The regulations administered by OFAC **implement the general rule that transactions of value** (payments, providing services, collaborations) **with certain countries and individuals are prohibited without a license from the U.S. government.** The United States maintains embargoes and comprehensive sanctions on six countries: Cuba, Iran, Myanmar (Burma), North Korea, Sudan and Syria. Many academic, clinical, and research activities involving these countries are *prohibited*, unless a U.S. Government license is obtained authorizing the specific activity. Even charitable or humanitarian activities conducted in these countries are likely to require a license.

It is important to emphasize that many of the most beneficent academic and clinical interactions may require licensure. Examples include but are not limited to the following:

- Advising local professionals on disease prevention
- Receiving de-identified tissue samples
- Providing clinical services on-site or through consults by phone or Internet
- Taking your computer or phone into the country, even if they contain no data
- 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

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 can require a license.

Upcoming Research Administration Training/Educational Events

Sponsored Projects Administration Information, Education, and Training Opportunities

For a complete listing of opportunities, visit: *http://researchadministration.yale.edu/calendar*

Faculty Web-based Opportunities:

Sponsored Projects Administration Training for Faculty (Required in order to be a PI)

Visit: *http://www.yale.edu/training/*

- On the left side of screen click "Browse Courses and Forms by Course Owner"
- Scroll down to and click on "Office of Research Administration"
- Select ORA "Courses"
- Select "Sponsored Projects Administration for Faculty"

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Fundamentals of Export Controls

Visit: *http://www.yale.edu/training/*

- On the left side of screen click "Browse Courses and Forms by Course Owner"
- Scroll down to and click on "Grant and Contract Training"
- Select GCA and GCFA Training "Courses"
- Select "Fundamentals of Export Controls"

CITI Responsible Conduct of Research (RCR)

Visit: *http://www.yale.edu/training/*

- On the left side of screen click "Browse Courses and Forms by Course Owner"
- Scroll down to and click on "Office of Research Administration"
- Select CITI – RCR "Courses"
- Select "The CITI RCR Course"

Faculty Instructor-lead Programs: Funding/Grantsmanship Training

Workshops to assist faculty and trainees identify funding opportunities for their research and prepare successful, well-targeted grant applications are offered on a regular basis. These courses include the following:

- *Developing A Funded Research Program*
- *Science Writing (for Grants and Scientific Manuscripts)*
- *How To Write A Compelling Grant Abstract: A Hands-On, Skill-Building Workshop*
- *All About Career Awards: Applications, Review, and Stepping Stones to Funding Your Future*
- *Show Me The Money: Using the Internet to Identify Funding Opportunities for Your Research*
- *Behind the Scenes at NSF, DOE, DOD and Other Funding Agencies: An Insider's Perspective on Grant Review*

To register for any of the above courses, click:
http://calendar.yale.edu/cal/funding/month/20131110/GrantsmanshipTraining_MonthlyTraining/

- On the left side bar click on "Funding/Grantsmanship Training" to view the calendar of events and/or actual presentations. Any questions regarding registering or the offering itself, please contact *melanie.smith@yale.edu.*

Administrator Education:

The following courses address sponsored projects related issues and are available to administrators.

- *Introduction to Sponsored Projects Administration (SPA)*
- *Allocating Allowable Costs*
- *Cost Transfer Principles*
- *Direct Charging of F&A Type Costs to Sponsored Awards*
- *Effort Reporting System (ERS) Training*
- *Effort Reporting Principles*
- *Financial Reporting and Closeout*
- *Fly America Act and Open Skies Agreements*
- *Research Compliance Principles for Administrators*
- *Subrecipient Basics and Monitoring*
- *Understanding the F&A Rate Calculation*
- *Understanding the PTAEO and How It Is Used for Sponsored Projects*
- *What Research Staff Need to Know About Sponsored Spending Sponsored Project Funds*

To register for any of the above offerings, go to *http://www.yale.edu/training/*

- Click on "Browse Courses and Forms by Course Owner".
- Scroll down and click on "Grant and Contract Training"
- Click on "Courses"
- Select the desired course title and click on "Register".

Questions regarding these courses can be directed to Ms. Eileen Joyce, at *eileen.joyce@yale.edu.*

On-line Primers:

PI Eligibility: *http://www.yale.edu/hrpp/coeus/PI%20Eligibility%20/story.html*

Happy Holidays!

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.