

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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Selling Mice or Cell Lines? Developing Educational Materials? Be Aware of Program Income!

What exactly is program income? Program income is any income that is directly generated by a federally funded activity, or earned as a result of the activity. It includes fees for services performed, such as guest fees for a conference you host, or fees received for use of federally acquired equipment, or the sale of anything made by using sponsored project funds.

The basic rule is that if you make any money from a federal award, those dollars are subject to the same terms and conditions as the federal award. For example, if you sell any biological materials you created using National Institutes of Health funds or if you created education materials under a Department of Education award, all the receipts for the sale of the biological materials or educational materials must be deposited into the sponsored project account, and appropriately spent to further the project or program objectives.

In general, the terms and conditions of a federally supported sponsored project require that program income be added to the federal award and must be used to further the project or program objectives, consistent with federal spending rules. Under certain circumstances, the federal sponsor may require that you reduce total grant funds by the amount you receive in program income, commonly referred to as “deductive alternative”. If you have program income, check the terms and conditions of the award or contact the Office of Grant and Contract Administration (GCA) for assistance. Unless otherwise stated in the award document, the default for all federal grants is that the program income is added to the award, commonly referred to as “additive alternative”.

Most importantly, if you are receiving program income, make sure you do not use it for other university activities. It must be deposited to the sponsored project.

There is one exception, however. The federal rules say that license fees and royalties from copyrights, patents, and inventions are not subject to these requirements. They are still program income, but they do not have to be returned to the sponsored project. To qualify for this exception, you must report the invention and commercialize it through the Office of Cooperative Research (<http://www.yale.edu/ocr/disclose.html>). OCR will report the invention and the royalties to the agency. Once that has occurred, any proceeds will be distributed according to Yale’s patent policy. Expenses on the sponsored project attributable to the creation of the material will be reimbursed to the sponsored project.

If you are just giving small amounts of material to another research institution, such as a few mice or a cell line, you can do that under a material transfer agreement through GCA, recover your costs, and reimburse the sponsored project for those costs. Following this guidance will keep you and Yale in compliance with the program income rules.

Did you know that...

GCA has established a new webpage dedicated to information on the American Reinvestment & Recovery Act ARRA funding opportunities and implementation details? Please visit the following site for the latest information regarding funding opportunities, reporting requirements and proposal submission requirements: http://www.yale.edu/grants/funding_info/ARRA.html

UPCOMING RE-ACCREDITATION OF THE ANIMAL PROGRAM AT YALE

Animal research is a critical component of Yale's research portfolio. Approximately 37% of sponsored research projects at Yale (43% of direct costs) involve the use of live vertebrate animals. Yale must demonstrate that its program meets the requirements set forth by federal laws and policies governing the care and use of laboratory animals prior to receiving the funds. The "gold standard" for demonstrating compliance with animal care and use regulations is accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. The accreditation process requires research programs to demonstrate that they meet the standards required by law, and are also going the extra step to achieve excellence in animal care and use.

The School of Medicine has been continuously accredited by AAALAC since 1967, University-wide since 1994. The process for re-accreditation by AAALAC will begin this summer after the submission of Yale's program description, a 200 page document describing Yale's animal care and use program. Submission of the program description is followed by a multi-day site visit during the fall. The site visit includes a team of highly qualified professionals who provide a confidential, onsite evaluation of the institution's animal care and use program. The independent review assures management that a research program is applying the standards it promised. The site visitors will inspect animal facilities and laboratories (animal use areas). They also will review IACUC processes (e.g., appropriate membership, minutes, and Facility and Program Evaluation reports), animal protocols, animal use records, standard operating procedures, and applicable policies and practices associated with animal care and use, training, and occupational health during their evaluation. They also may question laboratory personnel about the use of animals or may observe animal procedures.

As part of Yale's ongoing post approval monitoring program, Regulatory & Safety Services staff, on behalf of the IACUC, will be visiting laboratories to ensure policies and practices are in accordance with Institutional requirements. This is a timely opportunity, before the site visit, to confirm that our high standards of animal use are being maintained. It is also important to ensure all laboratory personnel are aware of the applicable IACUC/University Policies (please visit www.iacuc.yale.edu), that animal use records are complete, and drugs are in-date and inventories are complete.

Retaining Yale University's AAALAC accreditation shows that Yale is serious about setting, achieving, and maintaining high standards for animal care and use in research. More than 770 institutions in 29 countries have earned AAALAC accreditation, making it a symbol of quality recognized world wide.

If you have any questions about preparing your laboratory for AAALAC accreditation please contact Randi Palmisano at randina.palmisano@yale.edu.

Did you know that...

The Office of Cooperative Research has available on its website advice to Yale faculty concerning external consulting activities? The website provides guidance for faculty to help avoid any conflicts with consulting agreements and the University's general objectives and policies. To read the entire article please visit the following link: <http://www.yale.edu/ocr/pfg/index.html>

Did you know that...

The National Cancer Institute (NCI) announced a change in allowable levels of salary support for their early career (K) awards? Effective for competing applications for these awards submitted after January 1, 2009, the salary cap will be set at \$100,000 per year. To view the full announcement visit the following link: <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-09-013.html>

NIH POLICY CONCERNING CAREER DEVELOPMENT (K) AWARDS: NEW POLICY ON PART-TIME INSTITUTIONAL APPOINTMENTS

Until recently, all K award candidates were subject to the full-time appointment requirement as well as to a minimum 75% effort requirement. The new National Institutes of Health (NIH) policy announced that K awardees may request a reduction of their appointment to less than full-time (but not less than three-quarter time) for a period not to exceed 12 continuous months during the K award project period. Awardees cannot concurrently request a reduction in appointment status from full-time to part-time and reduce percent effort to less than 75%. However, both of these options are available after a K award has been issued. At the time of application and initial award, all candidates must meet the full-time appointment requirement as well as the minimum 75% effort requirement. The K awardee must continue to commit at least 75% effort (of the part-time appointment) to research and career development activities. *(continued on next page)*

Did you know that...

Extra compensation is generally not an allowable charge to a federal sponsored project? Intra-university consulting is assumed to be undertaken as a University obligation requiring no compensation in addition to full-time base salary – this principle also applies to Yale faculty members who function as consultants or otherwise contribute to a sponsored project conducted by another Yale faculty member. OMB Circular A-21, the NIH Grants Policy Statement and the NSF Proposal and Award Policies and Procedures Guide each consider extra compensation unallowable unless certain criteria are met and the sponsor has approved the arrangement for extra compensation in writing.

In order for extra compensation to be allowable on a federal sponsored project, the arrangement

must be specifically provided for in the agreement or approved in writing by the sponsoring agency. Sponsors will generally not approve such arrangements unless it involves an unusual situation in which the consultation is across departmental lines or involves a separate or remote operation and the work performed is in addition to the faculty member's regular departmental load.

In addition to federal restrictions, Yale policy prohibits intra-university consulting and faculty extra compensation payments using sponsored project funds except in certain specific circumstances with documented prior approval. Post-doctoral fellows and associates can receive extra compensation only in certain circumstances and with documented prior approval.

Resources:

- Yale University Faculty Handbook:
http://www.yale.edu/provost/handbook/handbook_viii_faculty_compensation_ben.html#T8
- Provost Letter regarding Teaching by PDAs and PDFs:
http://www.yale.edu/provost/html/provost_ltr_pdateaching.html
- A-21 Section J 8 (a):
<http://www.whitehouse.gov/omb/circulars/a021/a021.html>
- NIH Grants Policy Statement Part II Subpart A Select Items of Cost (consultant services):
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm#_Toc54600125
- NSF Proposal and Award Policies and Procedures Guide Chapter V Part B section 6 (b):
http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_29/aag_5.jsp

NIH POLICY CONCERNING CAREER DEVELOPMENT (K) AWARDS: NEW POLICY ON PART-TIME INSTITUTIONAL APPOINTMENTS (continued from previous page)

All requests submitted to the NIH for a reduced faculty appointment require Yale to provide supporting documentation describing the need for a reduced faculty appointment or percent effort and assuring Yale's continuing commitment to the scientific and research career development of the awardee. The K awardee should justify the request to reduce either his/her appointment to less than full-time status or to less than 75% effort and must describe the anticipated impact of the requested change on his/her career progress during the remainder of the K award period. The awardee should also submit assurance of his/her intention to return to a full-time faculty appointment or to at least 75% effort as soon as possible. The mentor must provide a revised mentoring plan and specifically describe updated milestones for the awardee's progression to independence. Lastly, a revised statement of Yale's commitment to the awardee must ensure continued "protected time" and describe additional support that will assist the K awardee to continue to make progress toward his/her goals during the requested period of reduced time/effort devoted to the K award. During the period of reduced appointment or percent effort, salary and other costs supported by the award will be reduced accordingly. Requests will be considered on a case-by-case basis.

For information on specific K awards (**K22, K99/R00, K07, K24, K12 and KL2 awardees**) please visit the full announcement at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html>

Did you know that...

The National Science Foundation (NSF) has published a revised version of the NSF Proposal and Award Policies and Procedures Guide? Part I of the Guide now includes the NSF's mentoring requirements for postdoctoral researchers. The Guide, with its new additions, will become effective for proposals received on or after April 6, 2009. To read more, please visit the following link to the Guide: http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf0929

MATERIAL TRANSFER AGREEMENTS

MTA Basics

Material Transfer Agreements (MTAs) are legal contracts that document the transfer of physical material between Yale University and academic and non-profit institutions, governmental agencies, and commercial entities. MTAs may be used to document the transfer of biological materials (plasmids, cell lines, mouse strains, etc.) or non-biological materials including pharmaceutical compounds. Yale faculty members at the level of Associate Research Scientist or higher may receive material, but must first ensure that the provider's *incoming MTA* has been signed by both the provider and Yale's authorized signatory in the Office of Grant and Contract Administration (GCA). Yale faculty who wish to send materials to colleagues first must ensure that the appropriate Yale *outgoing MTA* is in place before any material is sent.

Roles and Responsibilities

GCA: All *incoming* MTAs (materials coming *in* to Yale from academic, governmental, non-profit institutions, and for-profit companies) and *outgoing*

academic MTAs (Yale materials sent *out* to academic, governmental, and non-profit institutions) are processed by the GCA MTA Team.

OCR: *Outgoing* MTAs to a commercial entity (Yale materials sent *out* to for-profit entities) are processed by Yale's Office of Cooperative Research (OCR) as they often contain commercial terms related to providing the requested material.

Yale faculty member: For *incoming* MTAs from non-profit institutions, the faculty member must contact the institution sending the material and request that they send a MTA. When the MTA is received the faculty member must send the MTA to the GCA MTA Team along with a completed MTA questionnaire located at: <http://www.yale.edu/grants/mta/incoming.html>

For *incoming* MTAs from for-profit entities, the faculty member must contact GCA or OCR to discuss their proposed research plan first or mark their research plan CONFIDENTIAL when contacting that entity to request materials. When the MTA is received

the faculty member must send the MTA to the GCA MTA Team along with a completed MTA questionnaire located at: <http://www.yale.edu/grants/mta/incoming.html>

For *outgoing* MTAs to non-profit institutions the faculty member must complete an Outgoing MTA form located at:

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

For *outgoing* MTAs to for-profit organizations, the faculty member should contact OCR at ext. 436-8096.

Terms and Conditions

The terms and conditions for each MTA are reviewed and often negotiated by the GCA MTA Team. Terms often include the reason and length of time for use of the material, confidentiality of information provided with the material, obligations related to publication of results, ownership and licensing of intellectual property, and warranty and liability related to the use of the material. Terms unfavorable to Yale are removed through a negotiation process between GCA and the provider.

The GCA MTA Team often coordinates efforts with OCR and the Office of General Counsel (OGC) because it is important, especially for material received from industry, to ensure that the provider does not include terms and conditions that may restrict the researcher's academic freedom, assert undue rights of ownership of discoveries, or use indemnification language that may put Yale at risk. MTAs protect both the researcher's and Yale's interests and the ability to conduct future research related to the material.

Compliance Considerations

If required and necessary, the GCA MTA Team coordinates with other Yale research compliance units:

- **Human Investigation Committee (HIC):** If the MTA involves human material, or the material involved requires HIC approval, faculty members must provide the GCA MTA Team with the HIC approved protocol number or a copy of the HIC letter of exemption by fax or email.
- **Institutional Animal Care and Use Committee (IACUC):** If the MTA involves live vertebrate animals, or the material will be used in live ver-

tebrate animals, faculty members must provide the GCA MTA Team with the IACUC approved protocol number.

- **Office of Environmental Health & Safety (OEHS):** All outgoing MTAs to other academic institutions are reviewed by OEHS to ensure compliance both with shipping procedures and export control issues. This review is coordinated by the GCA MTA Team, based on the Yale faculty member's submission of an outgoing MTA questionnaire. OEHS reviews the material to be transferred and the recipient institution/investigators to ensure there are no restrictions on transferring the material. OEHS may contact the Yale faculty member directly to discuss the material to be transferred, or to ensure Yale laboratory personnel have appropriate training to ship the material.

Contact Information

Information related to the MTA process, MTA contacts, and links to related MTA information may be found on the GCA MTA web site at the following URL:

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

If you have questions regarding MTAs, please contact the GCA MTA Team and/or OCR as appropriate:

GCA MTA Team:

Christine Howe, Ph.D., MTA Manager
christine.howe@yale.edu; 203-785-6762

Don Wiggin, MTA Manager
donald.wiggin@yale.edu; 203-785-6313

Linda Clough, Sr. Administrative Assistant
linda.clough@yale.edu; 203-737-1551

OCR:

<http://www.yale.edu/ocr/>
OCR@yale.edu

Central Campus: 203-436-8096

Medical School: 203-785-6209

What is an “Export”?

An export can be the actual shipment of a commodity or item (equipment, biological materials for example) out of the country. In addition, the export control regulations also include in the definition of “export”, the transfer, release or disclosure to foreign persons **in the United States** of technical data about controlled commodities. This “deemed export” definition states that a transfer of “technology” (EAR term) or “technical data” (ITAR term) to a foreign national is “deemed” to be an export to the home country of the foreign person. Accordingly, for all controlled commodities, a license or license exception is required prior to the transfer of “technology” or “technical data” about the controlled commodity to foreign persons.

What does the phrase “public domain” mean?

Information is in the “public domain” (and therefore not subject to export controls) when such information becomes generally accessible to the interested public in any form, including: (1) publication in periodicals, books, print, electronic, or other media available for general distribution (including websites that provide free uncontrolled access); (2) readily available at libraries open to the public or at university libraries; (3) patents and published patent applications available at any patent office; and (4) release at an open conference, meeting, seminar, or trade show.

What is the “Fundamental Research” exclusion?

The export control regulations exempt from licensing requirements **information** (but not controlled items) resulting from “fundamental research”. Fundamental research is defined as *basic and applied* research in science and engineering conducted at an accredited U.S. institution of higher education where the resulting information is ordinarily published and shared broadly within the scientific community. Research conducted at Yale will normally be considered fundamental research. The fundamental research exclusion allows foreign nationals at Yale (students, faculty, and staff) to participate in research projects involving export-controlled technical information on campus in the U.S. without a deemed export license. In addition, information resulting from fundamental research may be shared with foreign colleagues abroad and shipped out of the United States without securing a license.

University based research is not considered “fundamental research” if the University or its researchers accept (at the request, for example of an industrial sponsor) restrictions on publication of scientific and technical information resulting from the project.

What terms and conditions in a grant or contract funded by the Federal Government would compromise the Fundamental Research exclusion?

If the Federal Government has terms and conditions in a grant or contract which are specific controls on the use and dissemination of information resulting from the research, then information resulting from the project will not be considered fundamental research. Examples of “specific controls” include requirements for prepublication review by the funding agency, with right to withhold permission for publication; restrictions on prepublication dissemination of information to non-U.S. citizens or other categories of persons; or restrictions on participation of non-U.S. citizens.

Did you know that...

In accordance with federal requirements, the University is obligated to have written agreements with its faculty requiring disclosure and assignment of inventions? In order to satisfy this requirement all personnel receiving federal funds must have a signed University Patent Policy Acknowledgement Agreement (PPAA) on file. Please visit the office of Cooperative Research at www.yale.edu/ocr to obtain a copy of the PPAA.

Did you know that...

Effective March 13, 2009 the Yale Proposal Summary and Certification Form (ProSum) was revised? The new form includes Proposal Types for the American Reinvestment & Recovery Act

to better track and monitor awards made under the Act. The revised form can be downloaded at: <http://www.yale.edu/grants/forms/index.html>

RESEARCH ADMINISTRATION TRAINING OPPORTUNITIES

UPCOMING TRAINING EVENTS

- Brown Bag Luncheon Series:
Yale Center for Clinical Investigation (YCCI): From the Bench to Bedside from Clinic to Community
Wednesday, April 22, 2009: NOON – 1:15 PM
The Anlyan Center, Congress Avenue,
N107 Auditorium
- Brown Bag Luncheon Series:
Proposal Summary and Certification Form “ProSum”: Demystifying How to Complete the Form
Tuesday, May 12, 2009: NOON – 1:15 PM
Harkness Auditorium, 333 Cedar Street,
Yale School of Medicine
- Fundamentals of Sponsored Projects Administration 2-day training program:
May 4-5, 2009, 9:00 AM
25 Science Park, Conference Room 125
- Fundamentals of Sponsored Projects Administration 2-day training program:
July 22-23, 2009, 9:00 AM
155 Whitney Avenue, Conference Room 222,
Second Floor

For details and to register for these events, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Training and click on Courses under GCA and GCFA Training.

ADDITIONAL TRAINING FOR FACULTY AND ADMINISTRATORS

(Some of the following offerings are web-based)

To learn more and to register for these sessions, visit <http://www.yale.edu/training/>, navigate to Grant and Contract Training, then click on Courses under GCA and GCFA Training.

Grant and Contract Financial Administration (GCFA)

- Effort Reporting Principles
- 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*

Office of Environmental Health & Safety (OEHS)

NEW Online Biosafety Regulatory Overview for Principal Investigators and Lab Managers.

- The following link is a web based training course to assist the community in better understanding the regulatory compliance requirements of Biological Safety:

<http://www.yale.edu/oehs/onlinetraining/Bio-safety/BioAdmin.htm>

This training opportunity will also provide a ‘snapshot’ view of biological research categories and their corresponding registration, training and inspection requirements prior to use of biological materials.

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.