AURA Meeting Agenda  
Wednesday, July 25, 2012  
10:00 a.m. – 11:30 a.m.  
MSB 2.135

- Introductions  
  Jodi Ogden

- Financial Conflicts of Interest  
  Loretta Davis

- Cayuse Self –Submit  
  Krystal Toups

- Research Performance Progress Reports  
  Krystal Toups

- Just-In-Time  
  Tiffany Sagers

- Guarantee Accounts  
  Jodi Ogden

- OSP & PAF Websites  
  William Mitchell

- Hot Topics  
  Jodi Ogden

Next meeting:  September 26th
Introductions

Jodi Ogden, MBA, CRA

Executive Director, Sponsored Projects Administration
Research Conflicts of Interest Policy (HOOP 94)

Revised
August 23, 2012

Loretta Davis
Manager, Conflict of Interest Program

[UTHealth Logo]
To highlight revisions made to the Research Conflicts of Interest Policy (HOOP 94) resulting from:

🎉 Revised federal regulation ([42 CFR Part 50](https://www.cfr.gov)) entitled “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought” that will take effect on August 24, 2012.

🎉 New UT System Research COI Policy ([UTS175](https://www.utsystem.edu)) implemented and in effect for the UT academic health institutions.

To inform individuals covered by HOOP 94 (“Policy”) of their revised disclosure requirements and other responsibilities.
The Policy includes requirements that comply with the federal regulation, but is not limited to PHS-funded research. The Policy applies broadly to all research without regard to whether the research has external funding; and if externally funded, without regard to the funding source.

The Policy applies to research that might not go through the usual funding review by OSP, or through a research review by CPHS or AWC, such as:

- Research conducted through a gift designated to an employee.
- Research conducted using department startup funds or other internal funds.
“Neither the institution nor a Covered Individual may expend research funds unless the EVPARA has determined that no financial conflict of interest exists or that any financial conflict of interest is manageable in accordance with the terms of a management plan that has been adopted and implemented.”

(Policy section III. F)
An individual covered by the Research COI Policy is referred to as a “Covered Individual.”

“An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, co-investigator, project director, any other person identified as senior/key personnel in a grant application, research protocol, or report, and others who direct or can materially influence the research.

The principal investigator is responsible for determining if other research staff (e.g., research nurses, research coordinators, data managers) meet the definition of being responsible for the design, conduct, or reporting of the research.” (Policy section II.)
Disclosure Requirements

Covered Individuals must complete the following requirements:

1) Complete the required RCOI education.

2) Submit a Research COI Certification Form per research project.

2a) If there are related significant interests for a project, submit a Research COI Disclosure Form.

3) Submit an annual Financial Disclosure Statement.
Covered Individuals are required to complete training on the Policy, applicable policies/regulations/laws, and disclosure responsibilities prior to participation in research and then every two years.

The training is now completed upon employment and every two years as part of the UTHealth Mandatory Compliance Training for all employees.

Anyone designated by a principal investigator to be a Covered Individual but is not a UTHealth employee can fulfill this requirement by completing the UTHealth “Conflicts of Interest in Research Training” module located on the CITI site (Collaborative Institutional Training Initiative, University of Miami). CITI notifies UTHealth of the training completions.
(2) Research COI Certification Form

Covered Individuals submit a one-page Research COI Certification Form for each proposed research project.*

The Covered Individual certifies whether or not he/she (or a family member) has a significant financial interest related to the research by answering questions regarding:

- Personal outside activities with the research sponsor.
- Stock or business ownership in the research sponsor.
- Personally owned rights to the technology used or studied in the research.
- Interest in any entity that owns or licenses the technology used or studied.
- Any other interest or activity that might affect, or be affected by, the research.

*This requirement must be fulfilled at the time of the research application, protocol submission, or prior to other proposed research.
Covered Individuals submit a 3-page Research COI Disclosure Form ONLY if they have answered “yes” to any of the questions on the Certification Form.

The form provides an opportunity for the Covered Individual to describe his/her proposed role in the project and how their significant financial interests might affect, or be affected by, the proposed research.

“Covered Individuals initiating research not reviewed by the CPHS or the AWC, and not requiring the review and approval of OSP, should disclose any potential research conflicts of interest directly to the EVPARA using the Research COI Disclosure Form.” (Policy section III. C)
The Policy requires UTHealth’s review of significant financial interests to consider all the activities and interests that are related to the Covered Individual’s institutional responsibilities (i.e., the training and expertise utilized in their UTHealth position).

The Policy therefore requires all Covered Individuals to submit an annual Financial Disclosure Statement.* (Policy section III. B)

This is a new requirement for non-faculty employees who are designated as “Covered Individuals” on research projects.

Once this form is submitted, the requirement has been met for that year.

*Covered Individuals must file a Financial Disclosure each year by March 1.

*The web-based Financial Disclosure Statement must be on file with UTHealth at the time of the research application.
Financial Disclosure Questions

The Financial Disclosure Statement includes questions regarding the following types of relationships that might have the potential to create actual or perceived conflicts of interest if they are determined to be related to the employee’s UTHealth job responsibilities:

- Related outside activities (lectures, advising, board memberships, etc.).
- Related stocks, stock options, business ownership.
- Intellectual property related to research, clinical services, instructional media.
- Sponsored or reimbursed travel.
- Gifts of value greater than $250 that could appear to influence UTHealth job.
- Employment of close relatives at UTHealth.
When Covered Individuals inform UTHealth about their outside activities and financial interests, they must include the related activities and interests of “Covered Family Members.”

- Spouse;
- Dependent children or step children;
- Any person financially dependent upon the Covered Individual, regardless of a legal or biological family relationship; and
- Any other person with whom the Covered Individual has joint financial interests such that the relationship or the interest could affect their professional responsibilities.
Disclosure Requirements – Subrecipients

UTHealth research that is conducted through subrecipients is also covered by the Policy. (Policy section III. M)

If a subrecipient does not have its own conflict of interest policy that governs disclosures, reviews, management, and reporting of potential conflicts, the subrecipient must follow our UTHealth Policy and complete the standard requirements for Covered Individuals:

1) Required RCOI education
2) RCOI Certification Form
   2a) RCOI Disclosure Form (if related significant interests)
3) Financial Disclosure Statement

These requirements (verified by the subrecipient entity, or completed through UTHealth) must be fulfilled at the time of the research application.
Significant financial interests are specifically defined by the Policy:

- In a publicly-traded entity: compensation for services or other payments in the preceding 12 months and the value of stock, stock options, or ownership interests held on the date of disclosure that when aggregated exceeds $5,000. (Does not include stock held in mutual funds or retirement accounts.)
- In a non-publicly traded entity: compensation for services or other payments in the preceding 12 months that when aggregated exceeds $5,000.
- In a non-publicly traded entity: any amount of stock, stock options, or ownership interests held on the date of disclosure.
- Income from royalties, fees, and rights to such interests from an outside entity other than UTHealth.
- Service as an officer, director, or other fiduciary position for any entity from which the individual received remuneration or payment for expenses in the preceding 12 months.
- Gifts received from an outside entity in the preceding 12 months that in the aggregate exceed $250 in value.
- Reimbursed or sponsored travel in the preceding 12 months that represents a financial conflict of interest as determined by the EVPARA.
A significant financial interest has the potential to create a financial conflict of interest in the research if it is related to the research and could directly and significantly affect the design, conduct, or reporting of research. Here are some examples:

- A researcher serves on the scientific advisory board for a company and received a total of $6,000 in personal compensation for the work in the last 12 months. She now proposes to be an investigator on a new research project to be sponsored by the company.

- A research nurse has been participating in a research project at UTHealth sponsored by a company. With approval from his supervisor he began providing educational lectures for patients and their families that are sponsored by the company, and his personal compensation from the company for that work has now exceeded $5,000.

- A new faculty member personally owns the rights to intellectual property she created at a previous job. Her department plans to provide her with internal startup funds to perform research at UTHealth on the technology while she applies for external funding.
The Research Conflict of Interest Committee reviews disclosed significant financial interests, verifies if they are related to the proposed research, and determines if there is a financial conflict of interest in the research.

If a conflict is determined to be manageable, strategies are available to manage identified conflicts. The RCOI Committee would recommend implementation of a research management plan, with final approval by the EVPARA. Some plans require additional approval by the UT System.

UTHealth reports financial conflicts of interest on federally-sponsored research projects to the federal sponsor, prior to the expenditure of funds and annually throughout the life of the project.

UTHealth posts information about approved research conflict of interest management plans on its website available to the public.
For more information about the Research Conflicts of Interest Policy, disclosure responsibilities, or applicable forms and procedures, contact:

Sujatha Sridhar, M.B.B.S.
Executive Director
Research Compliance, Education, and Support Services
(713) 500-3622
Sujatha.Sridhar@uth.tmc.edu

Loretta Davis, MPA, CRA
Manager
Conflict of Interest Program
(713) 500-3239
Loretta.Davis@uth.tmc.edu
Self-Submit Update

Krystal Toups, CRA
Assistant Director, Grants
“Self-Submit” is a new process in which Principal Investigators (PIs)/Departments submit Cayuse424 proposals directly to the agency.

127 proposals submitted from the testing phase through 7/27/12.
## Testing Phase

### Participants

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<td>13</td>
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### Schools

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<td>School of Dentistry</td>
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<td>School of Nursing</td>
<td>Family Health</td>
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<td>Medical School</td>
<td>Neurobiology &amp; Anatomy</td>
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<td>Integrative Biology &amp; Pharmacology</td>
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<td>School of Public Health</td>
<td>Mgmt, Policy and Comm Health</td>
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<td>Biostatistics</td>
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<td>Epidemiology &amp; Disease Control</td>
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<td>Health Prom &amp; Behavioral Sci</td>
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<td>SW Ctr Occup &amp; Environ Health</td>
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Mid March 2012 through the end of May 2012
## Go Live – June 2012

### Participants

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<td>1-6/29/12</td>
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Out of 70:
1-AFOSR
1-DOD
1-DOE
67-NIH

### Schools

- School of Dentistry
- School of Bioinformatics
- School of Nursing
- CeTIR

### Departments

#### Medical School
- Biochem & molecular biology
- IM Rheumatology
- IMM
- Integrative bio & Pharmacology
- Internal Medicine, Infectious
- Microbiology & Mol. Genetics
- Neurobiology & Anatomy
- Neurology
- Pathology and Laboratory Medicine
- Pediatric Surgery
- Pediatrics-Nephrology
- Physical medicine & Rehabilitation
- PSY-Behavioral Sciences
- Radiology
- Surgery

#### School of Public Health
- Biostatistics
- Center for Health Promotion & Prevention
- Environ & Occup Health Science
- Epi, Human Genetics, & Environmental Sci.
- Health Promotion & Behavioral
Research Performance Progress Report (RPPR)

Krystal Toups, CRA
Assistant Director, Grants
What is the RPPR?

Research Performance Progress Report (RPPR)

The Office of Management and Budget (OMB) has mandated a uniform reporting format for interim research progress reporting for submission of required annual or other interim performance reporting on research grant and cooperative agreement awards to standardize recipient reporting on federally-funded research projects.

The uniform RPPR format will replace other performance reporting formats currently in use by agencies supporting research and research-related activities.
Timeline for Implementation

In order to implement the RPPR, each Federal research agency will post policy or an implementation plan on the NSF and RBM websites within nine months after issuance of the OMB “Memorandum to the Heads of Executive Departments and Agencies” on 4/21/10.

Agency RPPR Implementation Plans

DHHS/NIH (and Other PHS Agencies)
    January 2012 update
DHS
DOC
DOD
DOE
DoEd/Institute of Education Sciences
DOJ
EPA
NASA
NEH
NSF
USDA
Forest Services
NIFA

Office of Justice Programs
National Institute of Justice/Office of Justice Programs
NIH Implementation RPPR

- Electronic format only (eRA commons)
- Will eventually replace PHS 2590, including use of eSNAP module, and 416-9
- AHRQ, FDA and CDC partners will adopt

**Timeline:**

- **April 2012:** RPPR Pilot Opens to 7 CWG Institutions
- **June 2012:** All FDP institutions given early access to RPPR module
- **August 2012:** Use of RPPR is OPTIONAL
  - Progress Report Additional Materials (PRAM) functionality available
- **October 2012:** All NIH grantees given access to RPPR module
- **January 2013:** NIH mandates use of RPPR for all SNAP and F awards
- **March 2013:** RPPR for non SNAP awards TBD
Similarities

• Describe progress, study results, the significance of the findings, and any significant changes.

• Information is pre-populated from NIH systems for the grantee.

• Publications in PD/PI’s MyNCBI account.
Differences

- The RPPR will have separate screens for each of the following reporting components: Cover Page, Accomplishments, Products, Participants, Impact Changes, Special [agency specific] Reporting Requirements, Budget [applicable only for non-SNAP awards].

- Non-SNAP awards the Budget component will be a SF424(R&R) Budget.

- New format (checkbox, entering text or uploading a PDF, or selecting “Nothing to Report.”).

- New information to be provided by grantees through the RPPR includes: Foreign component information, Dollars spent in foreign country(ies) [through first-tier subawards], Organizational affiliation of personnel at foreign sites.

- Effort on All Personnel report will be rounded to nearest whole person month.
Questions
Just In Time

Tiffany Sagers
Sponsored Projects Assistant
New process for submitting JIT requests to the NIH requires all JIT’s to be submitted via eRA commons.

Revised JIT Process- NOT-OD-12-101

IRB/IACUC approval must be obtained prior to OSP submission.

Applies to standard JIT requests.
Example of Standard JIT

REQUEST FOR JUST-IN-TIME INFORMATION

era-notify@mail.nih.gov

Sent: Wed 7/4/2012 9:23 PM
To: Office of Sponsored Projects

*** This is an automated notification - Please do not reply to this message. ***

Principal Investigator:

Application entitled has completed the first phase of peer review.

This is NOT a Notice of Grant Award, nor should it be construed as an indicator of possible award. This notification requests Just-In-Time information.

Please follow the instructions contained on the following website: http://grants1.nih.gov/grants/peer/jit.pdf. The requested information must be submitted using the Just-In-Time submission feature of the NIH commons found in the Commons Status section. For information on the Commons, see: https://public-era.nih.gov:443/commons

If you have questions about this request, contact your assigned Grants Management Specialist or Program Official. Contact information for these individuals can be found in the Commons Status system.

This is a standard notice and request for information for all grant applications receiving an impact score of 40 or less.
Questions
Guarantee Accounts

Jodi Ogden, MBA, CRA
Executive Director, Sponsored Projects Administration
OSP & PAF Websites

William Mitchell, MPSA
Sponsored Projects Specialist
OSP Website

Office of Sponsored Projects

OSP Overview

Effective June 2012, all proposals built in Cayuse will be submitted by the PI or their delegate using the self-submit process. HOOP 64 requires OSP review of the Administrative & Financial (A&F) portion of the application. Once OSP reviews and approves this A&F portion, it will be routed back to the department. After the PI has completed the science, the PI or their delegate will submit the final application. For detailed instructions, click here.

Self-Submit Training Session

Training Presentation

The Office of Sponsored Projects (OSP) is the central office for managing proposal submissions, contract negotiations, award acceptance, and research compliance and ethics at UH-Health. OSP offers assurance to the potential sponsor that time and cost commitments are appropriate and all compliance issues (human subjects, animal use, export controls, and conflicts of interest) are adequately addressed. All grant proposals and contracts must be reviewed by OSP. This internal review process is necessary to ensure that contracts and proposals concur with the mission of the University, and adhere to all applicable federal, state, and institutional policies and guidelines.

OSP News

July 23, 2012  »  eRA Information: Like This Now Available to Signing Officials

July 23, 2012  »  New Human Embryonic Stem Cell Requirements for NIH applications

July 23, 2012  »  For an NIH Resubmission, May I Request a Different Study Section or IC?

July 20, 2012  »  NIH Announces Changes to the eRA Commons Financial Conflict of Interest (FCOI) Module to Accommodate Additional Reporting Requirements

July 20, 2012  »  For an NIH Resubmission, What is the Page Limit for the Intro?

Useful Links

Review & Approval Forms
Institutional Forms (budgets, etc.)
Contact your OSP Specialist
OSP Proposal Library
Relatev HOOP Policies
Financial Reporting

Page 1 of 3 Next Page
Older OSP News
Department News

 dances on the phone, watching the clock. She sent him a text message: "I'll be there in five minutes." The room was quiet except for the hum of the air conditioning and the occasional rustling of papers. She took a deep breath and squared her shoulders. She was always nervous before these events, but today was different. Today, she was determined. She fixed her jacket and walked out the door.
PAF Website

Post Award

PAF Overview

The Post-Award Finance team (PAF) is responsible for helping principal investigators and department administrators with the efficient and effective fiscal management of grants and contracts once awarded. PAF ensures grant and contract accounts are set-up correctly in the Financial Management System (FMS), are managed and administered accurately, and are closed out correctly and timely. PAF also serves as an institutional policy and compliance liaison. As part of this role, PAF works with and provides documentation for external audits and assists internal audit personnel in responding to audit findings with appropriate action.

Useful Links

Contact List
Presentations
Resource Links

Post Award News

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Hot Topics

Jodi Ogden, MBA, CRA
Executive Director, Sponsored Projects Administration