



THE UNIVERSITY OF ALABAMA

THE CAPSTONE OF HIGHER EDUCATION

Office for Research Compliance

Tanta Myles

Lunch n Learn

September 17, 2014

Office Overview



Who are you?



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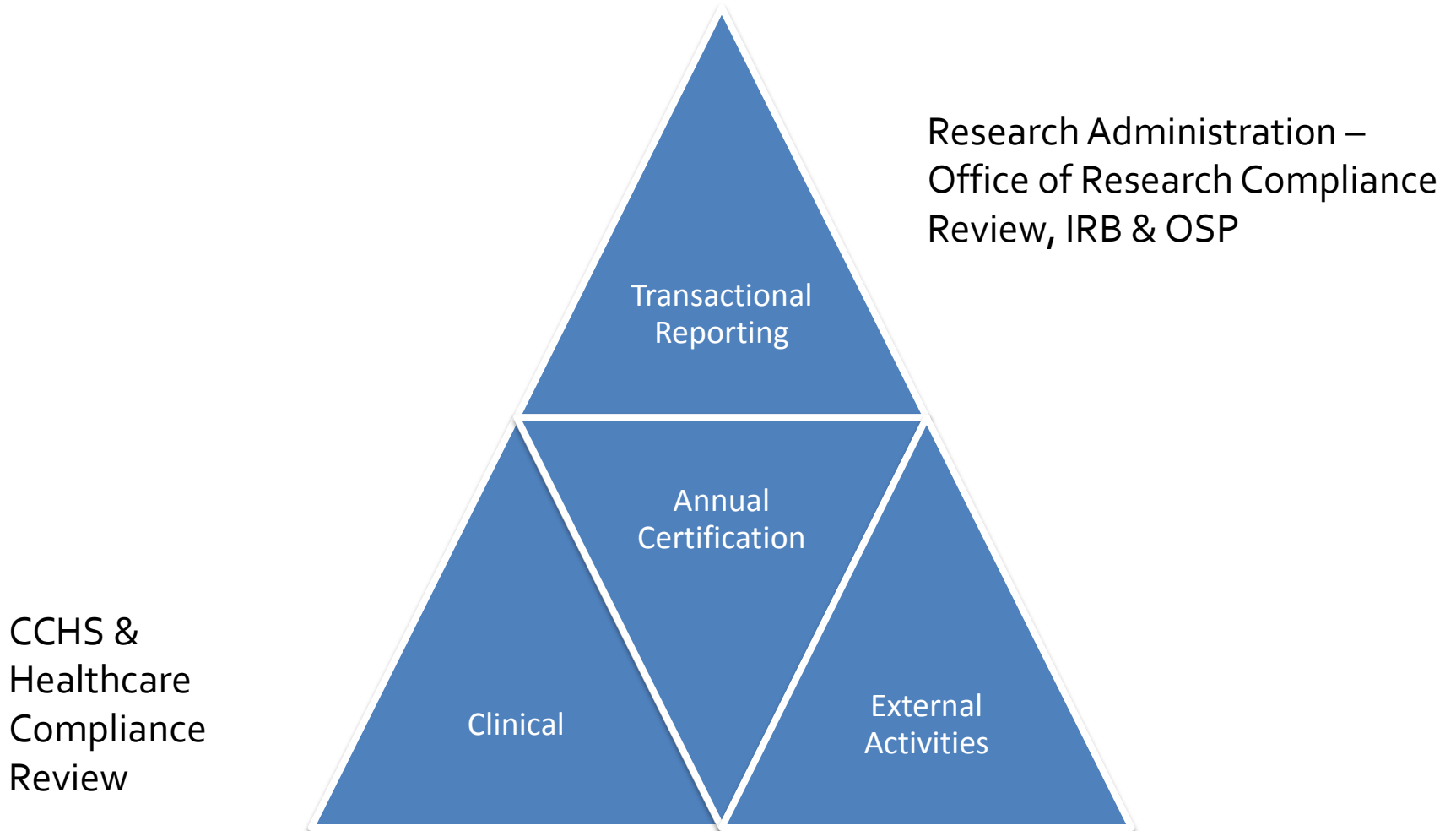
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Financial Conflict of Interest

- **Actual or potential conflicts of interest may occur in the normal course of research and other sponsored activities at a vibrant university.**
- **Do not necessarily represent any impropriety by employees if disclosed and properly managed.**
- **The key to identifying a conflict of interest is to evaluate whether there is a potential for improper personal gain or influence resulting from the dual roles the employee plays.**
- **Perceived conflicts of interest can be as harmful as real conflicts of interest. Therefore, it is UA's policy that all outside interests of an investigator should be reported.**

Overview of UA COI Review



FCOI

- **Annual Disclosure (Statement of Financial Interest)**
 - **Who Needs to Disclose?**
 - Anyone who is responsible for the design, conduct, or reporting of federally-funded research, regardless of his/her title or role on the project or the receipt of funding must submit a disclosure. This definition includes adjunct faculty, students, volunteers, subcontractors, consultants, collaborators, research coordinators, research assistants, and other research staff.
 - **When is a Disclosure?**
 - Any new researchers are required to submit an FCOI disclosure at the time of submission of proposals for any federal funding.
 - All existing researchers are required to renew their FCOI during the annual disclosure period, currently September 1st - 30th.
 - All researchers are required to submit an updated FCOI disclosure immediately as changes occur.
 - **What happens if an annual disclosure is not completed?**
 - Grant proposals and contracts may not be submitted if you are listed as personnel
 - Funds from grant or other sponsored program awards will not be distributed;
 - IRB and IACUC will not release the final letter of approval;
 - Other disciplinary action as required by federal regulation; and
 - The granting or sponsoring agency will be notified, if applicable.
- <http://osp.ua.edu/site/FAQs.pdf>
- **Training - Required every four years or when the UA FCOI policy changes.**
 - <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

FCOI

- DERM
 - Disclosure
 - Eliminate
 - Reduce
 - Management
- FCOI Management Plan
 - Role and duties of investigator, condition of the plan, plan monitoring details, review/ acceptance by UCIC and acceptance by the investigator.



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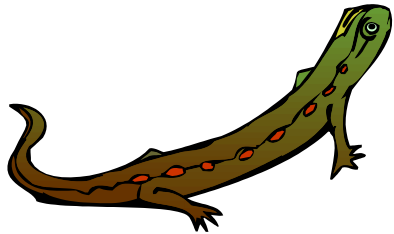
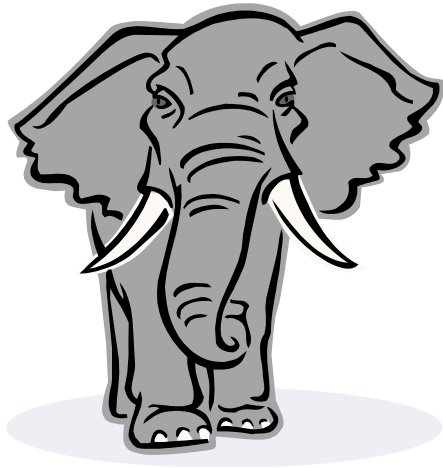
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Institutional Animal Care and Use Committee (IACUC)



<http://osp.ua.edu/site/iacuc.html>



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What Are Export Control Regulations?

- **Export Control Laws (ECLs) prohibit the unauthorized “export” of certain controlled ITEMS, INFORMATION OR SOFTWARE to foreign person or entities in the U.S. and abroad**
 - **ITEMS = Tangible things, equipment or hardware**
 - **INFORMATION = ‘Technical Data’ such as models, formulae, engineering designs or ‘Technical Assistance’ such as training or instruction**
 - **SOFTWARE = Computer programs or microprograms in either “source Code” (programming statements) or “Object Code” (machine-readable instructions)**

Who is a “Foreign Person”?

- **Anyone who is not a “U.S. person”**
- **A “U.S. person” is either:**
 - **A U.S. citizen, lawful permanent resident alien (“Green Card Holder”), refugee, protected political asylee or someone granted temporary residency under amnesty**
 - **Any juridical person (i.e. organization under the laws of the United States or any jurisdiction within the U.S., including foreign branches)**
 - **Examples of foreign person:**
 - **Individuals in the U.S. with Non-Immigrant Status (H-1B, F-1, J-1)**
 - **Any branch of a foreign government**
 - **Any foreign corporation or group that is not incorporated or organized to do business in the U.S.**

Export Control

<u>Governing Department</u>	<u>Mechanism</u>	<u>Areas Covered</u>
State	ITAR	Military items; space-related technology & research
Commerce	EAR	Dual-use goods, technology & software
Treasury	OFAC	Trade prohibitions with sanctioned countries/entities

http://osp.ua.edu/site/RC_ExC.html

International Travel

- **NSF**

- Expenses for transportation, lodging, subsistence and related items incurred by project personnel and by outside consultants employed on the project (GPM 614, "Travel Costs") who are on travel status on business related to an NSF-supported project are allowable as prescribed in the governing cost principles. The requirements for prior approval detailed in the governing cost principles are waived.

- **Some awards may:**

- Prohibit foreign travel
- Require pre-authorization for each trip
- Restrict the number of trips that can be taken
- Restrict the number of travelers on an authorized trip
- Set a maximum dollar value per trip
- Allow attendance to a conference to present research, but not just for the purpose of “staying current in the field”
- Limit travel to a specific destination or purpose
- Specify maximum meal, mileage or other cost rate

- **PHS/NIH**

- Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country.
- In all cases, travel costs are limited to that allowed by formal organizational travel policy and, in the case of air travel, less than first class accommodations must be used when available. Grantees are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets where travel schedules can be planned in advance (such as for national meetings and other scheduled events).

International Travel

- USA.gov
<http://www.usa.gov/Citizen/Topics/Travel/International.shtml>
- <https://step.state.gov/step/>
- UA Policy
 - <http://accountspayable.ua.edu/pages/travel-policies.html#International>College Requirement (example)
 - <http://www.ccom.ua.edu/pdf/InternationalTravelApprovalForm.pdf>



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Responsible Conduct of Research (RCR)

- NIH - In 1990, National Institutes of Health began requiring institutional training grant applications to describe formal and informal activities related to instruction on the Responsible Conduct of Research (RCR) which should provide instruction in scientific integrity and/or the responsible conduct of research.
- NSF -In August 2007, the America Competes Act was signed into law which mandates Responsible Conduct of Research training and a mentoring plan for Postdoctoral researchers for NSF funding.
- <https://www.citiprogram.org/> or <https://login.ua.edu/cas/login?service=https%3A%2F%2Fidp.ua.edu%2Fidp%2FAuthn%2FRemoteUser>



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What is the “IRB”

- “IRB” is short for “Institutional Review Board”
- The IRB is a University Committee that reviews, approves, and monitors human subjects research
- The existence of the IRB is required by the federal government because UA receives federal research money

Purposes of the IRB

- To protect the health, welfare and rights of HUMAN research participants
- To review and approve all UA research with human participants
- To monitor ethical conduct of research
- To educate the UA community as well as the outside community about ethical research and research rights

Ways to Submit the Application

- Our office receives protocol submissions via the following methods
 - Email
 - Traditional Mail
 - eProtocol Submission (online submission system)
<http://eprotocol.ua.edu:8080/hs/?sa=Online+Protocol+Submission>
- *Please note: In order to use the eProtocol system you will need to request a user ID and password from rscompliance@fa.ua.edu.*

The Review Process

- Applications for Human Subjects Research fall into three categories:
 - Exempt Review
 - Expedited Review
 - Full Board Review
- *Please note: The type of review that an application receives is determined within the Office for Research Compliance, but researchers may request a particular type of review.*



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Office Overview



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