Research Administration Series

*FCOI Process on Sponsored Projects and Compliance*

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Contact Info

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Today’s Agenda

• Animal Use Protocols – IACUC
• Biosafety Protocol – IBC
• Human Subjects Protocols – IRB
• Export Control

• Financial Conflict of Interest
  – What is COI and/or FCOI?
  – Outside Activities
  – Policies & Regulations
  – Management Plans
  – FCOI Process on Sponsored Projects
  – FCOI Award Set-up Tool (FAST)

Goals

• What is the function of an IACUC, IBC, & IRB?
• Who can I call for help with Protocol development?
• What trainings are mandatory?
• Where can researcher’s discover additional resource material?
• Why do requirements change?
Institutional Animal Care & Use Committee (IACUC)-function

• Regulatory Bodies:
  – NIH and Office of Laboratory Animal Welfare aka OLAW-reporting
    • The PHS Assurance on file with OLAW
  – USDA-APHIS-inspection

• AAALAC private accreditation option

Institutional Animal Care & Use Committee (IACUC)-function

• Local Over site
• 4 campus committees plus the All Campus Animal Planning and Advisory Committee aka ACAPAC
• SMPH, SVM, CALS, L&S & Graduate School
• Duties: inspection, program review, protect animal welfare
Institutional Animal Care & Use Committee (IACUC) - function

- Role of Research Animal Resource Center (RARC) and Institutional Official (IO)
  - Animal care and welfare
  - Protocol development and maintenance
  - Training and tracking
  - UW-Madison Animal Program oversight

Institutional Animal Care & Use Committee (IACUC) - protocol PI

- Policy #2000-013 Principle Investigator (PI)
- [https://www.rarc.wisc.edu/policies.html](https://www.rarc.wisc.edu/policies.html)
- Must have current UW-Madison appointment
- Eligible title:
  - Tenure track faculty
  - Others including emeritus, academic staff titles: Scientist, Lecturer, Program Manager, etc. need approval from department chair and college/school dean or designee
- IACUC has final authority
Institutional Animal Care & Use Committee (IACUC)-training

• Training Policy #1999-006
• Mandatory Animal Users Certification every 5 yrs. Complete prior to submission of protocol.
• Mandatory Occupational Health & Safety training every 5 yrs.
• Animal Contact Risk Questionnaire-annual update
• Other training

1/10/2017

Institutional Animal Care & Use Committee (IACUC)-resources

• Need Help?
• https://www.rarc.wisc.edu/
• IACUC Administrators Holly McEntee, Gayle Orner
• Animal-ARROW- on-line protocol process
• Trainers will visit labs and provide requested training

1/10/2017
IACUC Just in Time Processing

• For Verification of Required Clearances
  • Contact Investigator for the:
    – Protocol information
    Ask the Investigator or their designee to add:
    – Project title, sponsor, Agency Award #
    – Scope of work is covered
    – PHS & NSF funding/Protocol Congruence Check

Institutional Biosafety Committee (IBC)-function

• Application of regulations
  – NIH Guidelines for Research and CDC
• Biosafety Protocol; Risk assessment and mitigation plan for a research laboratory
• Use of recombinant DNA or Synthetic molecules, use of toxic, infectious or carcinogenic/mutagenic materials hazardous to Humans, Plants, or Animals.
Institutional Biosafety Committee (IBC)-function

• One campus wide committee
• Resource Biosafety in Microbiological and Biomedical Laboratories (BMBL)
• http://www.ehs.wisc.edu/biosafetyregulations.htm
• Duties: Reporting to NIH- exposures, non-compliance

Institutional Biosafety Committee (IBC)-protocol PI

• PI designation for protocol- tenure track Faculty
• Request for PI status
  – Academic staff – Scientist, Research Instructor, emeritus faculty
  – External agencies with formal agreement to provide IBC services
Institutional Biosafety Committee (IBC)-training

• Mandatory training for individuals listed on protocol
• 4 different online modules based upon research & funding source
• Self-registration at Learn@UW

Institutional Biosafety Committee (IBC)-resources

• Office of Biosafety- Andrea Ladd-Biological Safety Officer, Stephanie Kutz- Assistant BSO, Biosafety Protocol Advisors
• Role of Office of Biosafety
  – Assist with protocol development New Bio-Arrow
  – Review administrative amendments
  – Laboratory visits
• [http://www.ehs.wisc.edu/biosafetyprotocol.htm](http://www.ehs.wisc.edu/biosafetyprotocol.htm)
• [https://kb.wisc.edu/arrow/ibc/page.php?id=43188](https://kb.wisc.edu/arrow/ibc/page.php?id=43188)
IBC Just in Time Processing

• Verification of Required Clearances
Contact Investigator for the:
  – Protocol information
Ask the Investigator or their designee to add:
  – Project title, sponsor, Agency Award #
  – Scope of work must be included!
  – Send additions/changes to this email biosafety@fpm.wisc.edu paper version only

Institutional Review Board (IRB)- function

• Regulatory Bodies:
• Code of Federal Regulations (FDA)
• Office of Human Research Protections (NIH)
  – Belmont Report 1976-ethical principals and guidelines
  – Health and Human Services regulation oversight
  – Federal Policy: Common Rule, 3 subparts: protections for pregnant women/fetuses, protections for prisoners, protections for children
  – IRB Registration & Federal Wide Assurance
Institutional Review Board (IRB) - function

- 3 campus IRBs
- Health Sciences manages 2; Health Sciences-IRB and Minimal Risk IRB
- L&S manages Education/Social & Behavioral Science IRB
- Purview is determined by scope of research

Duties: exemption determination, UW-Madison policy; the IRB always determines the exemption category.
- Certify: Not Human Subjects Research
- Reporting obligations: non-compliance and adverse events
Institutional Review Board (IRB) - PI for protocol

- PI status Policy
  - [https://kb.wisc.edu/gsadminkb/page.php?id=29557](https://kb.wisc.edu/gsadminkb/page.php?id=29557)
- UW-Madison appointment
- Faculty with appointments @ 50% or more
- Unclassified staff with approval form signed by Chair/Director
- Exceptions granted with IRB Authorization agreement

Institutional Review Board (IRB)- training & resources

- Mandatory Training through CITI
- Training is dependent upon type of research Social & Behavioral or Health Sciences.
- Renewal needed every 3 years
- Education/consultation offered by the IRBs
  - [https://kb.wisc.edu/gsadminkb/page.php?id=34101](https://kb.wisc.edu/gsadminkb/page.php?id=34101)
  - [https://kb.wisc.edu/hsirbs/18837](https://kb.wisc.edu/hsirbs/18837)
Just-in-Time IRB

- PI will need to initiate protocol development as soon as notification of award.
- Collaborations and Multi-site research can lengthen the wait time between notice of award and acct set-ups.

Just in Time for the New Investigator

- Training must be completed prior to protocol submission:
  - Human Subjects-CITI training
  - Animal Users-RARC training
  - Biosafety-101-Basic, 104-Sharps, 201-NIH grants
- Additional Training may be required depending upon research
Need Help Developing a Protocol?

• Available Resources:
  – Review Board’s Websites
  – Protocol Office – General Questions
  – Ask for an appointment for help with on-line protocol submission

Export Compliance Security

• Export Control Program Office
  – Export Control Office: Tom Demke
  – Export Control Coordinator: Bethany Nelson

• Program Covers these regulations:
  – International Traffic in Arms Regulations
  – Export Administration Regulations
  – Foreign Asset Control Regulations
Export Compliance Security

- Project Assessments
- WISPER Screening Tool
- Export licenses
- Visa certifications
- Registrations with federal agencies
- Reporting Non-Compliance

https://research.wisc.edu/respolcomp/exportcontrol/

Other Campus Compliance

- Chemical Hygiene Plans
- Bloodborne pathogen plan/annual training
- Hazard Communications
- Outside Activity Reporting
PI Portal

- A dashboard of
- Personalized research administration
- Compliance
- Training information

- [https://research.wisc.edu/researchers/pi-portal/](https://research.wisc.edu/researchers/pi-portal/)

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Today’s Agenda

- Animal Use Protocols – IACUC
- Biosafety Protocol – IBC
- Human Subjects Protocols – IRB
- **Financial Conflict of Interest**
  - What is COI and/or FCOI?
  - Outside Activities
  - Policies & Regulations
  - OAR & Management Plans
  - FCOI Process on Sponsored Projects
  - FCOI Award Set-up Tool (FAST)
What is a Conflict of Interest?

What is a Financial Conflict of Interest?

- Exists when an investigator has a significant financial interest that could lead an independent observer to reasonable question whether the design, conduct or reporting of research might be influenced by the possibility of personal gain.

- It represents a state of affairs, not behavior.

- Frequently involve perceptions
What is a Financial Conflict of Interest?

UW Recognizes that Conflicts of Interests are...

• Common and frequently unavoidable
• Not necessarily “bad”
• Can often be appropriately managed
The importance of outside activities at UW is captured in the Wisconsin Idea
- Where knowledge gained from academic enterprise is shared to benefit society.

Faculty & Staff are encouraged to participate in outside activities, share expertise and transfer intellectual property to the private sector.

This participation in outside activities may generate conflicts between the needs of the institution and the outside entity.
- Financial
- Professional
- Others
Polices and Regulations

Federal and State Regulations
• Public Health Service (NIH, CDC, AHRQ...)
  – Grants: 42 CFR Part 50, Subpart F
  – Contracts: 45 CFR Part 94
• National Science Foundation, Grant Policy Manual 510
• State of Wisconsin, Admin Code, Section UWS 8

University Policies
• Faculty Policies and Procedures, Ch. 8
• Academic Staff Policies and Procedures, Ch. 12

Polices and Regulations – Why?

• Promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of sponsored research will be free from bias resulting from Investigator conflicts of interest.
Outside Activities Reporting

• Complete and submit an annual outside activities report (OAR)
  – Fulfills State of WI, UWS and Federal requirements
• Revise the annual report within 30 days whenever there is a significant change in:
  – New Relationship or changes to existing
  – Significant changes in research activities
  – If PHS funded, report any sponsored or reimbursed travel event

Outside Activities Reporting – Who?

• All Faculty
• Academic Staff appointment of 50% or greater
• Anyone listed as Key Personnel on a federal grant or human subject protocol (including some graduate students)
Outside Activities Reporting – What?

• Information for themselves, spouse and dependent children
• In a business or organization related to your institutional responsibilities
  – Ownership
  – Leadership
  – Compensation
  – Travel

Outside Activities Reporting – How?

• A OAR must be filled on an annual basis by April 30th & updated within 30 days of changes
• Online form located here: https://my.gradsch.wisc.edu/coi/index.html
• This form can be accessed anytime
UW COI Committee

- University-wide committee
  - Faculty reps (voting members)
  - Legal Counsel
  - Dean’s Office reps
  - Office of Research Policy
- Reviews outside activities for possible financial conflicts of interest
- If FCOI exists, a Management Plan is assigned

Management Plans

- Publication and presentation disclosure
- Disclosure to students, staff and co-investigators
- Disclose proposal research support to Dean’s Office
- Cannot have oversight of any purchases from outside entity
- Complete annual review of management plan with Chair
Management Plans and Human Subject Research

- For Human Subjects Research the following provision is applied to the Management Plan
  - Absent written approval from the COI committee, you cannot serve as principal investigator (PI), co-investigator (Co-I), or key personnel for a more than minimal risk human subjects protocol reviewed by a UW-Madison IRB if the outside entity:
    - sponsors the study, or
    - owns or licenses a technology tested in the study
    - ......

FCOI Process on Sponsored Projects

- Check in WISPER if OAR has been completed
- PHS funded projects require additional steps at the time of award
  - File an updated OAR (even if no change)
    - Has to be completed within 30 days
  - Complete online COI Training
  - FCOI Report filed with PHS, if necessary
University FCOI Compliance

• All PI/Co-I and Key Personnel required to have a valid annual OAR on file to receive RSP award set-up services
• Annual OAR submissions are due May 1st of each year
• This is indicated on the General tab of each WISPER record.

And Here:

And Here:

PHS FCOI Compliance

• Agencies Using the PHS FCOI Regulations: [http://sites.nationalacademies.org/PGA/fdp/PGA_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)
• This is also reflected in WISPER
• All PI/Co-I and Key Personnel on PHS Awards will need to complete FCOI training.
• All PI/Co-I and Key Personnel will need to update their OAR at time of Award Setup.
  *OAR updated within the last 30 days of record being added into FAST

**Process for PHS FCOI Screening:**
1. Key personnel are identified by RSP and loaded into the personnel section of the General tab in WISPER (If not listed already).
2. Record is then loaded to FAST by (FCOI Award Setup Tool)
3. Key personnel are notified via email and instructed to complete FCOI requirements. Department contact is also copied on this e-mail.
4. FAST tracks and logs FCOI items in compliance and emails RSP when items are completed
5. Only when all items are completed will RSP move forward.
FAST – FCOI Award Setup Tool

Once all boxes are green, all FCOI requirements have been completed.

RSP will continue to setup the award as usual.

https://my.gradsch.wisc.edu/coi-rsp/setupListView.pl
Questions??

"Yes, I am employee of the month again. And yes, I'm the one who chooses the employee of the month. And no, I don't see a conflict of interest."

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