Navigating Required Clearances for Sponsored Projects

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Goals

- What is the function of an IACUC, IBC, & IRB?
- Who can be a PI for a Protocol?
- How many trainings are mandatory?
- Where can researcher's discover additional resource material?
- Why do requirements change?

Institutional Animal Care & Use Committee (IACUC)-function

- Application of Regulations
- NIH and Office of Laboratory Animal Welfare aka OLAW
- The PHS Assurance
- USDA-APHIS
- AAALAC private accreditation option
Institutional Animal Care & Use Committee (IACUC)-function

- Local Oversight
- 5 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
- Role of RARC and IO

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

- RARC PI Policy #2000-013
- https://www.rarc.wisc.edu/policies.html
- Must have current UW-Madison appointment
- Eligible titles: faculty including emeritus, academic staff titles: Scientist, Lecturer, Program Manager, etc.
- IACUC has final authority

Institutional Animal Care & Use Committee (IACUC)-training

- Training Policy #1999-006
- Mandatory Animal Users Certification every 5 yrs.
- Mandatory Occupational Health & Safety training
- Animal users Questionnaire
- Other training
Institutional Animal Care & Use Committee (IACUC) - resources

- Where to go for assistance
  - https://www.rarc.wisc.edu/
- IACUC Administrators Holly McEntee, Gayle Orner
- Role of RARC:
  - animal care and welfare
  - protocol development & maintenance
  - training development & tracking

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 listed
      - Scope of work
      - NIH Grant/Protocol Congruence Check
      - NEW, Online protocol submission

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](http://www.ehs.wisc.edu/biosafetyregulations.htm)
- Duties: Reporting to NIH- exposures, non-compliance

**Institutional Biosafety Committee (IBC) - protocol PI**
- Updated policy for PI designation for protocol- approved 12/4/13
- 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
- Self-registration at Learn@UW
Institutional Biosafety Committee (IBC) - resources

- Office of Biosafety - Jim Turk - Officer, Stephanie Kutz - Assistant BSO, Biosafety Protocol Advisors
- Role of Office of Biosafety
  - Assist with protocol development
  - Review administrative amendments
  - Laboratory visits
- http://www.ehs.wisc.edu/biosafetyprotocol.htm

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 biosafety@fpm.wisc.edu

Institutional Review Board (IRB) - function

- Application of Regulations:
- Code of Federal Regulations (FDA)
- Office of Human Research Protections
  - Common Rule
  - Health and Human Services oversight
  - Belmont Report - ethical principals and guidelines
  - 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

Institutional Review Board (IRB) - function

- Duties: exemption determination, UW-Madison policy; the IRB always determines the exemption category.
- Exemption: Not Human Subjects Research What ??
- Reporting obligations: non-compliance and adverse events

Institutional Review Board (IRB) - PI for protocol

- PI status Policy
- [http://my.gradsch.wisc.edu/hrpp/10237.htm](http://my.gradsch.wisc.edu/hrpp/10237.htm)
- 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/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.
- Resources policy and guidance documents: https://kb.wisc.edu/hsirbs/18837

Just in Time for the New Investigator

- Training must be completed prior to protocol submission: PLuS
- 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:
- Websites
- Protocol Office - General Questions
- Ask for an appointment

Other Campus Compliance
- Chemical Hygiene Plans
- Bloodborn pathogen plan/annual training
- Hazard Communications
- Outside Activity Reporting

Outside Activates & Conflict of Interest

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Outside Activities

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.

Outside Activities - Conflicts

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

UW Recognizes that Conflicts of Interests are...

- Common and frequently unavoidable
- Not necessarily “bad”
- Can often be appropriately managed
What does Conflict of Interest mean?

- 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

Regulations and Policies

Federal and State Regulations
- U.S. Public Health Service, 42 CFR 50(F)
- 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

Individual Obligations

- Complete and submit an annual outside activities report
  - 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
UW Outside Activity Report

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

Who has to complete an OAR

- 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)

What is Reported

- Information for themselves, spouse and dependent children
- In a business or organization related to your institutional responsibilities
- Ownership
- Leadership
- Compensation
- Travel
**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 Protocols**
- 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
What you need to know as Research Administrator

- Check in WISPER if OAR has been completed
- PHS funded grants require additional steps at award setup time
  - 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

FAST – FCOI Award Setup Tool

- RSP enters PHS award into FAST
- FAST checks to see if COI Training and OAR update is completed
- Automated email is sent informing Investigators of the requirements
- [https://my.gradsch.wisc.edu/coi-rsp/setupListView.pl](https://my.gradsch.wisc.edu/coi-rsp/setupListView.pl)

FAST

- Once all boxes are green, all FCOI requirements have been completed
- RSP will continue to setup the award as usual
Questions??