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?
  - Policies & Regulations
  - Outside Activities Reporting (OAR)
  - Management Plans
  - How COI impacts sponsored projects

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?
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, LSVC
- Meetings are monthly

Institutional Animal Care & Use Committee (IACUC)-function

- Role of the Research Animal Resource & Compliance (RARC) and Institutional Official (IO)
  - Animal care and welfare
  - Pre-veterinary review of all protocols
  - 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.
- Mandatory Animal Contact Risk Questionnaire-annual update
- Other training

Institutional Animal Care & Use Committee (IACUC)-resources

- Need Help?
- [https://www.rarc.wisc.edu/](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
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
- Dual Use Research of Concern
- Occupational Health & Safety
  - Duties: protocol review, reporting to NIH-exposures, non-compliance
Institutional Biosafety Committee (IBC) - protocol PI

- PI designation for protocol - tenure track Faculty
- Request for PI status for protocol
  - Academic staff - Scientist, Research Instructor, emeritus faculty
  - External agencies with formal agreement to be provided IBC services

Institutional Biosafety Committee (IBC) - training

- Mandatory training for individuals listed on protocol
- Biosafety Required Training course
  - 6 modules covering risk assessment & mitigation, NIH Guidelines, protocol process, exposure response & reporting, disinfection/decontamination & disposal
- Learn@UW online course

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
- https://ehs.wisc.edu/biosafety-protocol-arrow/
- 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!

Institutional Review Board (IRB) - function

• Regulatory Responsibilities:
• Common Rule
  – Based on the 1976 Belmont Report- ethical principles and guidelines (federally funded research) policy for protection of human subjects
• Code of Federal Regulations (FDA)
  – Applied when research involved novel drugs or devices
• HIPAA Privacy Requirements
• UW Human Research Protection
  – IRB Registration & Federal Wide Assurance

Institutional Review Board (IRB) - function

• 3 campus IRBs
• Health Sciences manages 2; Health Sciences-IRB and Minimal Risk IRB
• VCRGE manages Education/Social & Behavioral Science IRB
• Purview is determined by scope of research
Institutional Review Board (IRB) - function

- Human subject research is defined as research involving living individual to obtain data, interactions/intervention, or collection of private information
- Research is defined as, a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Institutional Review Board (IRB) - function

- Protocol review/approval:
  - Risks are reasonable/potential harm is minimized
  - Selection of subjects is equitable
  - Informed consent is sought
  - Protect privacy
  - Protection of vulnerable populations
  - Maintain confidentiality of data
  - Mitigation of conflicts of interest
- 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
- Collaborative Research – condition of federally supported research grant
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/gradminkb/page.php?id=34101
  - 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 Training
  - 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

Other Campus Compliance

- Chemical Hygiene Plans
- Bloodborn pathogen plan/annual training
- Export Controls
- Outside Activity Reporting

Questions??
Research Administration Training Series: Compliance - Financial Conflict of Interest

November 29th, 2018
Presenters

Tammy Kuhn Martin
Assistant Dean for Research Administration
College of Engineering
tamara.kuhnmartin@wisc.edu.
(608) 265-0504

Sharon Vetter
Assistant Dean for Research Administration
School of Pharmacy
sharon.vetter@wisc.edu
(608) 262-0396
Agenda

• Financial Conflict of Interest (FCOI)
  – What is a Conflict of Interest
  – Policies & Regulations
  – FCOI Policies and Regulations – Why?
  – What's Required?
• Outside Activities
  – Outside Activities Reporting
  – Institutional Responsibilities
• FCOI on Sponsored Projects
• Case Studies
What is a Conflict of Interest?

“So, I’m the only one who sees a conflict of interest here?”
What is a Financial Conflict of Interest?

- Exists when an investigator has a significant financial interest that could lead an independent observer to reasonably 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
• **Federal Regulations**
  o Public Health Service (NIH, CDC, etc...)
    ▪ Grants: 42 CFR Part 50, Subpart F
    ▪ Contracts: 45 CFR Part 94

• **Sponsor Policies/Requirements**
  o Section 4.1.10 of the NIH GPS

• **State of Wisconsin Statutes**
  o Admin Code, Section UWS 8.025

• **UW Board of Regent Policy**
  o Regent Policy Document 20-7

• **UW-Madison FCOI Policy**
FCOI Policies 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.

• Ensure the public’s trust that federally-supported research is conducted with the highest scientific and ethical standards.
What's Required?

• Investigators are informed (i.e. training).

• Investigators engaging in, or proposing to engage in, federally funded research are required to report all significant financial interests held by themselves or their immediate families.

• Institutions must review disclosures and manage potential conflicts.

• Institutions must report to funding agencies when a conflict does exist.

• Institutions should monitor investigators with federal funding at least annually.
Outside Activities

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

• Importance of such outside activities is captured in the ‘Wisconsin Idea’. Where knowledge gained from academic enterprise is shared to benefit society

• Participation in outside activities may generate the perception of a conflict between the needs of the institution and the outside entity.
  - Financial
  - Professional
  - Others
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

• All Faculty and Academic Staff with appointment of 50% or greater
Institutional Responsibilities

• COI Committee reviews outside activities for possible financial conflicts of interest

• If FCOI exists, a Management Plan is assigned

• RSP will report the necessary FCOI information to the PHS agency at the time of award set-up and annually thereafter.
FCOI on Sponsored Projects

• Check in WISPER if annual OAR has been submitted

• PHS funded projects require additional steps at the time of award
  – File an updated OAR
  – Complete online COI Training
  – FCOI Report filed with PHS, if necessary (completed by RSP)
Open Discussion

• Retrospective Review

• Best Practices

• Real Life Examples
Questions? & Thank you for coming!

Tammy Kuhn Martin
Assistant Dean for Research Administration
College of Engineering
tamara.kuhnmartin@wisc.edu.
(608) 265-0504

Sharon Vetter
Assistant Dean for Research Administration
School of Pharmacy
sharon.vetter@wisc.edu
(608) 262-0396
Export control consists of a group of federal laws / regulations that control certain commodities, technologies, information and data.

- Limits what can be shipped out of the country and to whom it can be shipped
- Can limit access to information for certain foreign nationals and/or organizations
- Determines when a license is required to ship items or information abroad
**Definitions**

- **Physical Export**: Sending or taking anything out of the United States in any manner, except mere travel outside of the U.S. by a person whose personal knowledge includes technical data; including:
  - Shipping – commercial shippers or hand-carry
  - Verbal transfer of technical data (i.e., phone, Skype)
  - Electronic transfer of technical data (i.e., e-mail, fax, text, social media)
  - Items: computers, equipment, biological agents, materials, substances, etc.

- **Deemed Export**: Transfer (oral or visual disclosure) of technology, information or data to a foreign person within the U.S. is deemed to be an export to that person's home country
  - Deemed exports are treated in the same manner as a physical export to a foreign country
  - Examples of deemed export:
    - Foreign collaborators @ UW working on controlled technology
    - Phone calls regarding controlled technology w/ foreign collaborators working @ another U.S. university
    - Taking foreign visitors on a tour of a lab where they can view design details of controlled technology
    - Discussions regarding controlled technology w/ foreign persons at a conference w/in the U.S.
Researcher Training

Foreign Persons/Organizations

A Foreign Person or Organization is anyone who is NOT a U.S. Person. A U.S. Person is:

- U.S. citizen or national
- Permanent resident (green card holder) of the U.S.
- A refugee, someone granted political asylum or someone granted amnesty
- U.S. government agency and any state or local governments therein
- U.S. company, business, LLC or partnership
- U.S. university

Regulations

<table>
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<th>Parameter</th>
<th>ITAR</th>
<th>EAR</th>
<th>FACR</th>
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<tbody>
<tr>
<td>Name of Regulation</td>
<td>International Traffic in Arms Regulations</td>
<td>Export Administration Regulations</td>
<td>Foreign Asset Control Regulations</td>
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<tr>
<td>Agency</td>
<td>Department of State</td>
<td>Department of Commerce</td>
<td>Department of Treasury</td>
</tr>
<tr>
<td>What does it control?</td>
<td>Military equipment &amp; information</td>
<td>Dual use items &amp; information</td>
<td>Foreign assets</td>
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<td>Control Listing</td>
<td>USML (United States Munitions List)</td>
<td>CCL (Commerce Control List)</td>
<td>Specially Designated Nationals List</td>
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Please note that other government agencies maintain their own export regulations, but they have less effect on UW-Madison.

Examples on Campus: AERI cryocooler, StarTracker, select agents, lasers, integrated circuits
Exemptions for Universities

- **Fundamental Research Exemption (ITAR, EAR)**
  - No license is required for fundamental research – basic or applied research in science or engineering – at an accredited institution of higher learning in the U.S. and resulting in information that is ordinarily published and shared broadly in the scientific community.

- **Public Domain Exemption (ITAR, EAR)**
  - No license is required to export information or research that are generally available in the public domain. This does not apply to physical equipment, materials, substances, etc.

- **Education Exemption (ITAR, EAR)**
  - No license is required to transfer information to students, including foreign nationals, concerning general scientific, mathematical or engineering principles commonly taught in schools, colleges or universities.

Non-Compliances

- Civil & criminal penalties levied against individuals & organizations
- Disciplinary action by university toward responsible individual
- Bad press and loss of research funding

You can be held personally liable for non-compliance

Case of J. Bruce Roth - U of Tenn (Sept 2008):
- Retired professor in plasma physics
- Convicted on 18 counts of conspiracy, fraud & violating ITAR
- Gave 2 grad students from China & Iran access to sensitive info
- Sentence - 48 months in prison
- Worst case - 175 yrs in prison; $15.5M
Finding export control issues is much like looking for a golf ball in a haystack.

Discovering Issues

The Export Control Office reviews a number of processes to unearth issues, including:

- **Project Screening** – Using the WISPER screening tool
- **Visa Certification** – For H-1B and O-1 visas
- **Visa Screenings** – For J-1 visas from restricted countries
- **Outgoing International Material Transfer Agreements (MTAs)**
- **International Travel** – Weekly review of Concur bookings
- **Vendor Screenings**
- **Project Reviews** – Questions from staff regarding projects, staffing, shipping, etc.
Red Flags

1) The contract contains one or more of the following:
   - Publication restrictions
   - Personnel restrictions
   - Export control paragraph
     - Ask for ITAR or EAR classification
2) Technical information received under a NDA
3) Shipping items or information overseas
4) Working with foreign collaborators here or abroad

International Shipping

Who?
   - To whom are you shipping? Is the recipient a restricted party?
   - Do you know who the end user is?

What?
   - Some items require an export license (i.e., military equipment, spaceflight H/W or S/W;
     sat/phys agents; some lasers, high-speed cameras; night vision goggles)

Where?
   - E1 Countries: Crimea, Cuba, Iran, North Korea, Sudan, Syria – Major restrictions
   - OFAC & US Embargo List:
     - Balkans (western), Belarus, Burundi, Central African Republic, Cuba, Congo,
       Iran, Iraq, Lebanon, Libya, N. Korea, Sudan, South Sudan (revised), Sudan and Darfur, Syria, Ukraine/Russia-related,
     - Itar Prohibited Countries (22CFR 126.1): Afghanistan, Belarus, Belarus, Central African Republic,
       China, Congo, Cuba, Cyprus, Eritrea, Eritrea, Haiti, Iran, Iraq, Lebanon, Libya, N. Korea, Sudan, Sudan, Syria, Venezuela,
       Zimbabwe

For additional information & examples, see the Shipping Training @
https://kb.wisc.edu/images/group156/shared/ExportControl/shippingtraining.150105.pdf
International Travel

- **Where?**
  - Similar destination concerns as shipping
- **Why?**
  - Conferences, meetings – What do you plan to discuss?
  - Research – Is this fundamental research?
- **Who?**
  - Are you meeting with specific persons?
  - Some foreign universities are subject to restrictions by the federal govt
- **What?**
  - An export license may be required when traveling and taking something on a plane either in checked or hand-carried luggage
  - Hand-carry to a foreign country = ship to a foreign country

What Do You Do When You Find An Issue?

Technology Control Plan (TCP)

- Written plan describing what items are controlled, where they are located and who can have access
- Developed in collaboration between PI and Export Control Office

Export Licenses

- Not the "end of the world"
  - Typically takes 1-2 months to submit and receive approval
  - Export Control Office submits about 6 license applications a year (average 2010-2017)
- Notify Export Control Office if an export license may be needed
  - Develop license strategy
  - Can we manage information to prevent the need for a license?
  - Is there an exception we can use?
For Additional Information, Contact:

- Tom Demke, UW-Madison Export Control Officer
tom.demke@ssec.wisc.edu  262-8659
- Bethany Nelson, UW-Madison Export Control Coordinator
bnelson2@wisc.edu  261-1128
- Ben Griffiths, UW Senior Legal Counsel
  ben.griffiths@wisc.edu  263-7400
- Or e-mail: exportcontrol@grad.wisc.edu

UW Export Control Website:
https://research.wisc.edu/compliance-policy/export-control/