Demystifying Compliance for the Research Administrator

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What We Will Cover

- The big three committees
  - IACUC
  - IBC
  - IRB
- PI Status
- Outside Activity Reporting (OAR)
- Required Trainings
- Export Controls
- Other Compliance Concerns

Institutional Animal Care & Use Committee (IACUC)

- Approval required for direct use of vertebrate animals
  - Research
    - Biomedical
    - Agricultural
    - Wildlife
  - Teaching
    - Courses involving animals
      - Animal & Dairy Sciences, Veterinary Medical Teaching Hospital, Medical Training
  - Outreach

IACUC – Protocols

- Required when using:
  - LIVE vertebrate animals
    - Mice, Rats, Fish, Birds, Cattle etc.
    - Wildlife - Capture, Radio Collars, Feeding etc.
- NOT required when using:
  - Deceased animals/tissue
    - Tissues obtained from a slaughterhouse, legal hunting
  - Invertebrates
    - Worms, fruit flies
  - Wildlife
    - Camera Traps, Vocalization Recordings, Passive Feces/Hair Collection etc.

Photo Credit: Jeff Miller
http://uwurbancanidproject.weebly.com/data-collection.html

IACUC – Protocol Review

- Veterinary Prereview
- Full Committee Review
  - Assigned to monthly meeting for review by all members
- Designated Member Review
  - Two committee members and an Animal Research Safety representative
- Veterinary Verification & Consultation (VVC)
  - Administrative review of certain changes preapproved by IACUC and verified by veterinarian
  - Speeds up some protocol amendments
- Updates required annually and renewal required every 3 years

Grant-Protocol Congruence Reviews

- Required by
  - DHHS, Public Health Service (PHS)
    - NIH, CDC, FDA, Agency for Healthcare Research, etc.
  - National Science Foundation (NSF)
  - Other sponsors upon request (Rare)
- Required for
  - New awards
  - Competing continuations

Congruence Reviews continued

- Conducted by Research Animal Resources & Compliance (RARC)
  - Principal Investigators (PIs) & Protocol Writers request review in ARROW protocol workspace
    - Grant must have been added to the funding page first!

- RARC issues a congruence letter to be sent with 2nd Just In Time (JIT) Request

Institutional Biosafety Committee (IBC)
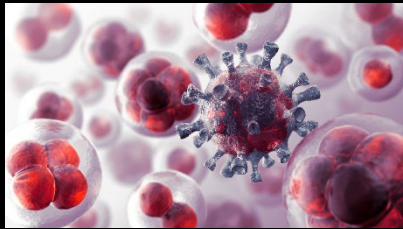
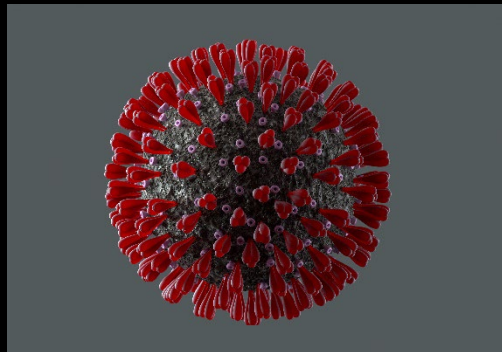Bloodborne Pathogens

Transgenic Animals
Photo: International Society for Transgenic Technologies
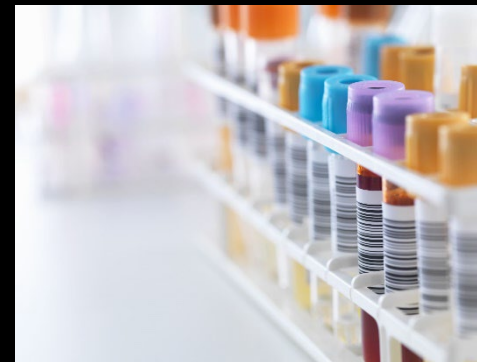
Recombinant DNA

Large-scale Propagation

Disease-causing agents

Transgenic Plants
Photo Credit: WCIC

Biological Samples

Biological Toxins

https://ehs.wisc.edu/labs-research/biological-safety/biosafety-protocol-arrow/

IBC Protocols

- Required when using
  - Human blood, cell lines, and other potentially infectious material
  - Gene editing of plants, animals, bacteria etc.
    - CRISPR, *Agrobacterium, Lentivirus*
  - Pathogens
    - Bacterial
    - Viral
    - Fungal
    - Prions & Parasites
  - Biological Toxins
- Reviewed by 2 committee members & a biosafety specialist
  - Then goes to full committee for a vote at the monthly meeting

Institutional Review Board (IRB)

- **Human Subjects Research**
  - Develops or contributes to generalizable knowledge and
  - Involves a living individual about whom an investigator
    - Obtains and uses <u>information or biospecimens through intervention or interaction</u> with the individual
    - Obtains, uses, studies, analyzes, or generates <u>identifiable private information or identifiable biospecimens</u>

IRB

- Two on campus
  - Health Sciences & Minimal Risk Research IRBs
- Must review all research involving human subjects
- Research cannot begin until a determination is reached
  - Approval, Exemption, Not Human Subjects Research, etc.
- Application Types
  - Non-Protocol Based (nPBA)
  - Protocol Based (PBA)
  - sIRB
  - Ceded

IRB Application Types

- Regular IRB Application
  - For minimal risk research
  - Protocol Development Activity (PDA)
    - Used for funding purposes when human subjects work will not begin for ≥ 6 months
    - Full approval or exemption must be obtained prior to start of human subjects work
- PBA
  - For more than minimal risk studies
- RSP will require IRB approval letter for award setup

IRB - Protocols

- Required for (examples)
  - Clinical trials and trials investigating
    Vaccines, medications, medical devices, surgical procedures etc.
  - Surveys & Questionnaires
    - Include identifiable personal information (name, birth date, financial info etc.)
  - Health care records reviews & data analysis
  - Research involving identifiable biospecimens
    - Blood, tissues, cells etc.
  - Sensory Panels

Other Clearances

- Stem Cell Research Oversight (SCRO)
  - Approval for human embryos or embryonic stem cells, or human pluripotent stem cells **in animals**
  - All other approvals (IBC, IRB, IACUC) must be in place first
- Human Fetal Tissue research
  - Requires IRB approval
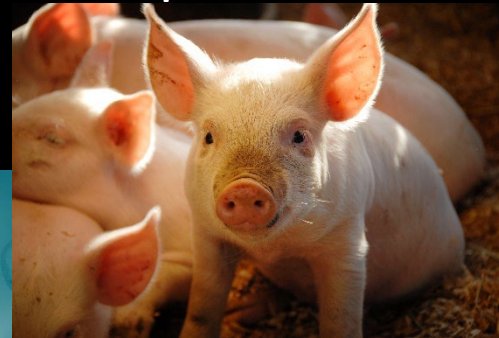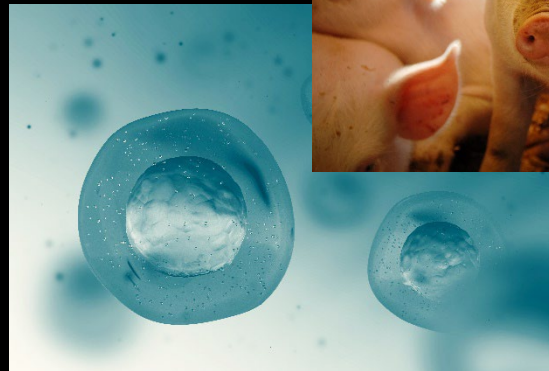
PI Status for Sponsored Projects

- PI Status for Grants
  - Tenured or tenure-track faculty
  - Employees with Research Professor track titles or Permanent PI status
  - Other academic staff may serve as PI on proposals and awards by requesting Limited PI Status on a project-by-project basis or by requesting Permanent PI Status
    - Instructions & Information - research.wisc.edu/compliance-policy/principal-investigator-status

PI Status Other

- IACUC - policy.wisc.edu/library/UW-4114
  - University PI Status, Morgridge Institute for Research (MIR) Approved PIs, those granted approval by IACUC by filing request form

- IBC - policy.wisc.edu/library/UW-6081
  - UW–Madison tenure track faculty, Research Professors (all levels), or academic staff that have been granted Permanent PI Status
  - Other as approved by IBC by filing request form

- IRB - https://policy.wisc.edu/library/UW-4063
  - Appropriate appointment and performing relevant research within the scope
  - Others as approved by IRB by filing request form

Adding Sponsored Projects to Protocols

- For New Grants, Competing Continuations and other agreements with new funding associated
  - PI must add the project to the funding page of protocol(s)
- For non-funded agreements (e.g., In-MTAs)
  - Approved protocols required but **do not** need project added
- Fee for Service
  - Add to approved protocol(s) in a generic manner
    - Leave Award # Blank
    - Add generic title to describe the work
    - Add a project ID set-up to encompass the work
    - List Sponsor as "Multiple Donors"

Adding Protocol Information - WISPER

- Under Required Clearances in
  - Projects page or
  - General page
- Compliance Specialist, PI, Research Administrator etc.
  - Adds protocol information for each required clearance

Adding Information – WISPER *continued*

- Compliance Specialist, PI, Research Administrator etc. will upload in Attachments
  - Protocol approval verification
  - Congruence Verification *(when applicable)*
- Approval Dates
  - Protocols and trainings must be in date at time of award setup

ARQ - Protocol Lookup System (PLuS)

- Find at: https://apps.research.wisc.edu/ARQ/Plus/
- Contact your department administrator to request access

Outside Activities Reporting (OAR)

- Method for reporting relationships having potential for conflict of interest
- Required for anyone listed on a sponsored project
  - Annually by April 30th
    - And Within 30 days of
      - acquiring a new financial interest
      - a change to an existing financial interest
    - At time of application for federally funded research

OARs & Foreign Entity Relationships

For NIH

- New Submissions, RPPRs, & JIT Requests require updates to Biographical Sketch and Other Support
  - Include Supporting Documentation for foreign
    - Appointments, employment, activities reported in "Other Support"
      - Copies of contracts, grants, other agreements specific to senior/key personnel
        - Translate to English *(if applicable)*
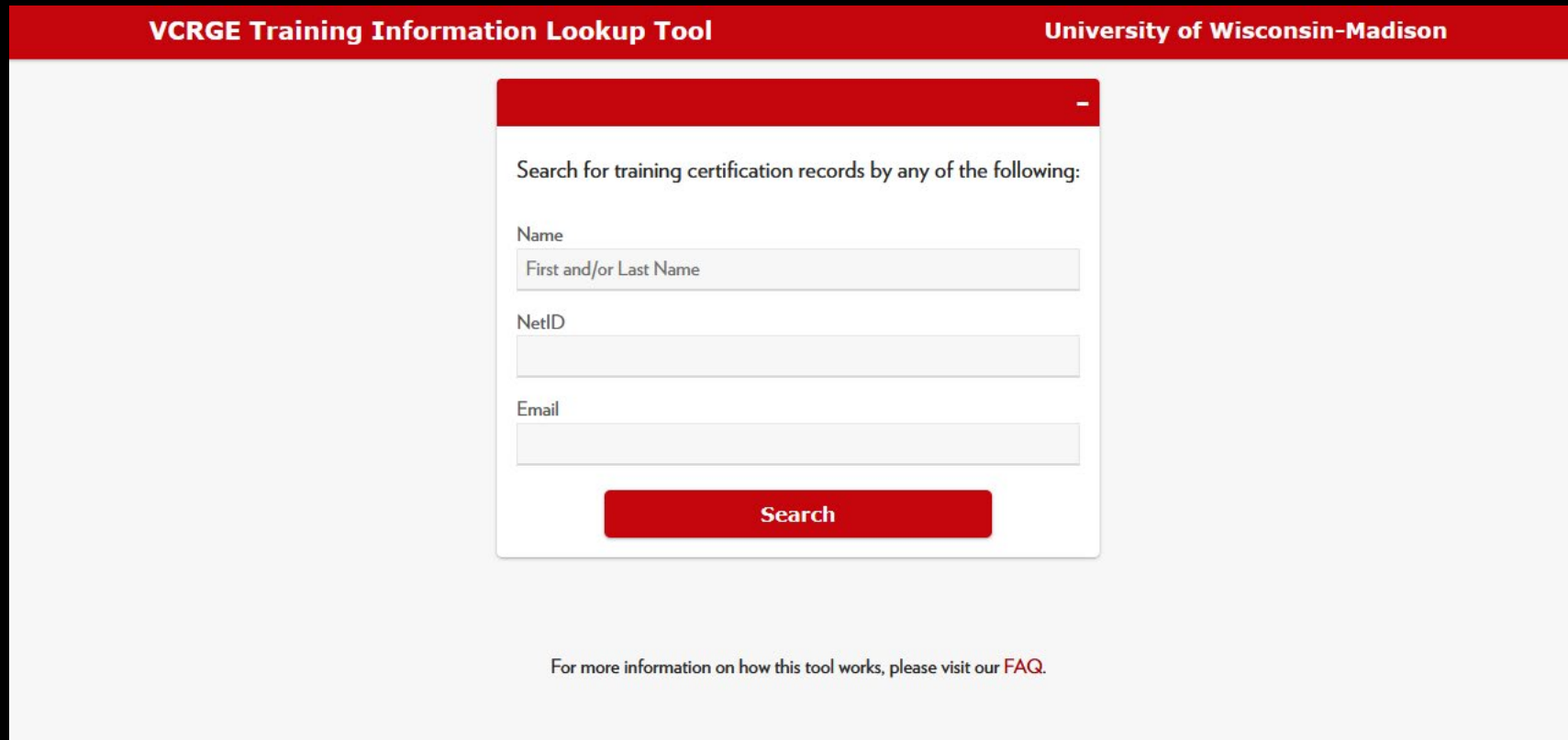 - Provide immediate notification of undisclosed Other Support

Required Trainings

- Conflict of Interest (COI)
  - Required for anyone listed on a federally sponsored research project or human subjects (IRB) protocol
    - canvas.wisc.edu/enroll/D9DRHR

- Responsible Conduct of Research (RCR)
  - Required for
    - NSF (students & post-docs)
    - USDA-NIFA
    - USDA-NIFA Capacity (142) Awards
    - NIH (Requirement included in grant application)

canvas.wisc.edu/enroll/EET6NH

VCRGE Training Information Lookup Tool

- https://apps.research.wisc.edu/TILT

Export Controls

- Federal laws & regulations control distribution of certain commodities, technologies, information and data to foreign persons or organizations
  - For national security
    - Military and dual use products, technology
  - For economic purposes
    - Sanctions, Restricted Parties and Specially Designated Nationals Lists

Export Controls

- Examples
  - Computer technology/Hardware & Software
    - Laptops, electronics, encryption software
  - Sensors & Lasers
  - Information & Data
  - Biological & Select Agents
    - Pathogens & Toxins
  - Chemicals
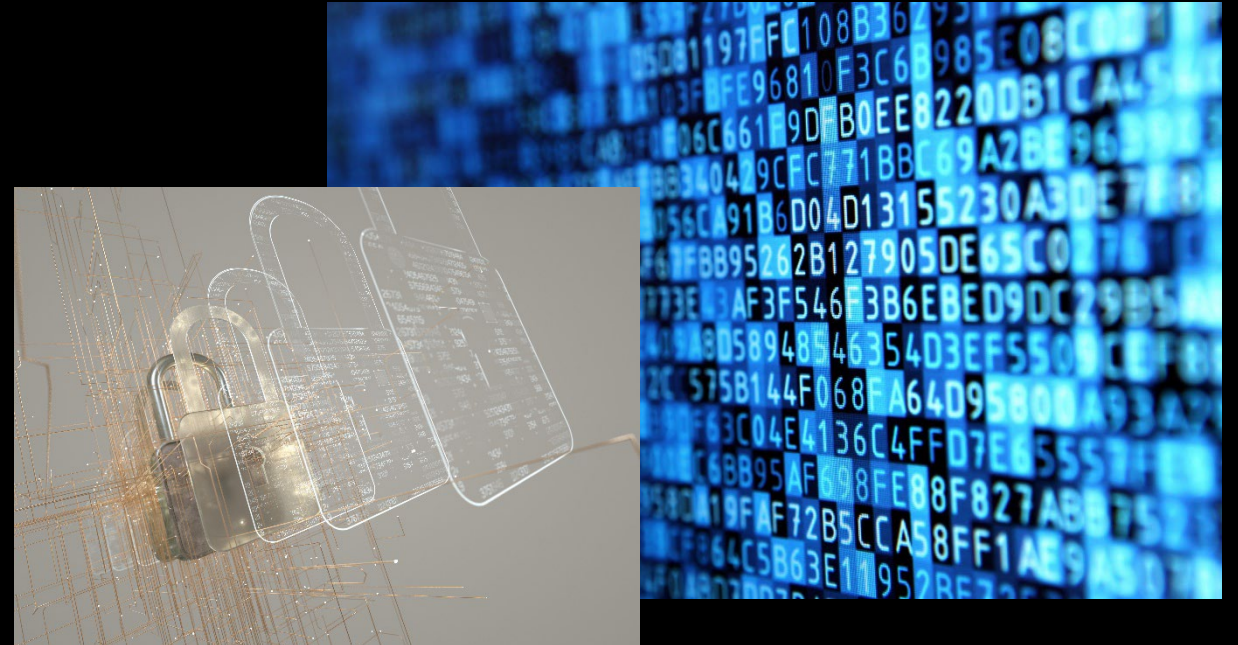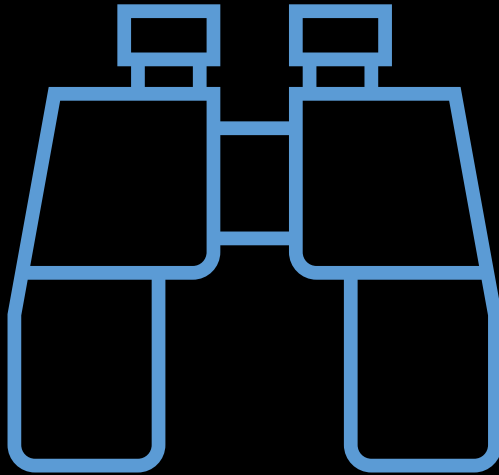
Export Controls - Exemptions

- Universities are exempt for information considered
  - Fundamental Research – published broadly
  - Public Domain – generally available publicly
  - Education – commonly taught in schools or colleges
- License may be required if exemptions do not apply.

Export Controls – What to look for

- Contract clauses – may remove the research exemptions
  - Publication restrictions
  - Personnel restrictions
  - Export control paragraph
  - NDAs for technical information
  - Controlled Unclassified Information (CUI)

Export Controls

- What to look for:
  - Some DoD funding
    - If *developmental* rather than *fundamental* research, it is subject to export controls.
  - International shipping & travel
  - Purchases from a foreign supplier
  - Service work not considered research
    - Unknown substance analysis
    - Manufacture for commercial devices
    - Providing materials for research outside UW

Export Controls

- Find export questions in Project Details

- Activities with potential implications
  - Traveling, Shipping, Collaborating Abroad
  - Working with
    - Controlled items
    - Restricted countries

- Export Control Office training research.wisc.edu/integrity-and-other-requirements/export-control

Other Compliance Concerns

- Bayh-Dole Act
- Effort reporting
- Research Vehicles Safety Oversight (RVSO)
- Dual Use Research of Concern (DURC)
- DEA Controlled Substances in Research
  - State Licensure and Federal DEA Registration Required
- Hemp Research

Compliance Hold-Ups

- There is no approved protocol to cover the work
  - New protocols and some major amendments can take 30 days or more for approval
- The protocol is in the amendment, renewal, or submission phase in ARROW
  - Projects cannot be added to the funding page
- Missing OAR
- Missing or expired COI training

Contacts

- IACUC – iacuc@rarc.wisc.edu
- IBC – Andrea Ladd andrea.ladd@wisc.edu
- IRB – asktheirb@wisc.edu
- COI/OAR
  - Your Department/Division: research.wisc.edu/kb-article/?id=32881
  - **COI Office:** coiprogram@research.wisc.edu
- Export Control Office
  - Tom Demke: tom.demke@ssec.wisc.edu, Bethany Nelson: bcnelson2@wisc.edu
- Your Department/Division Compliance Specialist
  - CALS – Sarah Johnson-Schlueter – Sarah.JohnsonSchlueter@wisc.edu

Resources

- WISPER – rsp.wisc.edu/WISPER
- ARROW – arrow.wisc.edu
- RARC – www.rarc.wisc.edu
- IRB – irb.wisc.edu
- OAR – oar.wisc.edu
- COI Training – research.wisc.edu/compliance-policy/outside-activities-reporting/training
- Export Control - https://research.wisc.edu/integrity-and-other-requirements/export-control/

Thank You!