

# Demystifying Compliance for the Research Administrator

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Compliance Manager

UW-Madison, College of Agricultural & Life Sciences

# What We Will Cover

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- 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)

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- 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

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- 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

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- 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

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- 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

4/26/2022

To Whom It May Concern:

Grant-Protocol Congruence has been verified for the following grant application submitted [redacted] and its associated animal care and use protocol(s) listed below.

Title of Grant Application: [redacted]

Grant number: [redacted]

Name of Principal Investigator: [redacted]

Protocol Number	Principal Investigator	Original Committee Approval Date	Approval Date of Version Reviewed	Protocol Expiration Date
[redacted]	[redacted]	10/22/2019	3/22/2022	10/21/2022

Protocol Congruence Specialist: Derrick Duchesneau

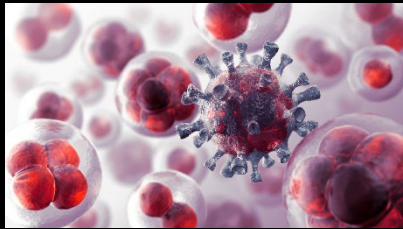
Congruence Verification Date: 4/26/2022

The University of Wisconsin-Madison has an animal welfare assurance on file with the Office of Laboratory Animal Welfare. The assurance number is D16-00239.

Research Animal Resources and Compliance  
University of Wisconsin-Madison Enzyme Institute 1710 University Avenue Madison, Wisconsin 53726-4087  
608/262-1238 Fax: 608/265-2698 Email: congruence@rarc.wisc.edu www.rarc.wisc.edu

# Institutional Biosafety Committee (IBC)

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Bloodborne Pathogens



Transgenic Animals

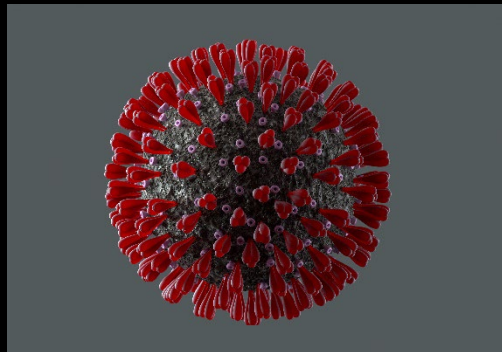
*Photo: International Society for Transgenic Technologies*



Recombinant DNA



Large-scale Propagation

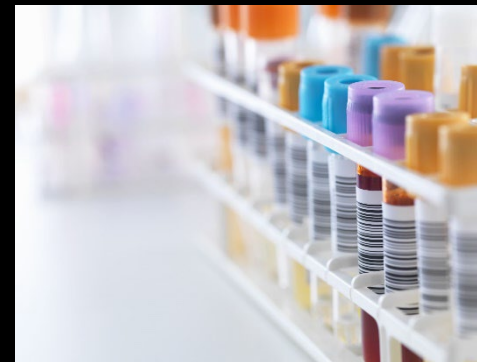


Disease-causing agents



Transgenic Plants

*Photo Credit: WCIC*



Biological Samples



Biological Toxins

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



# IBC Protocols

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- 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)

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



# IRB

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- 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

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- Regular IRB Application
  - For minimal risk research
  - Protocol Development Activity (PDA)
    - Used for funding purposes when human subjects work will not begin for  $\geq$  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

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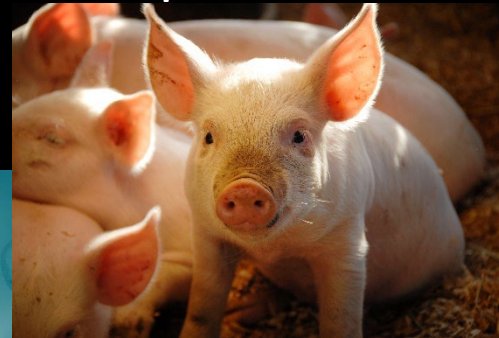
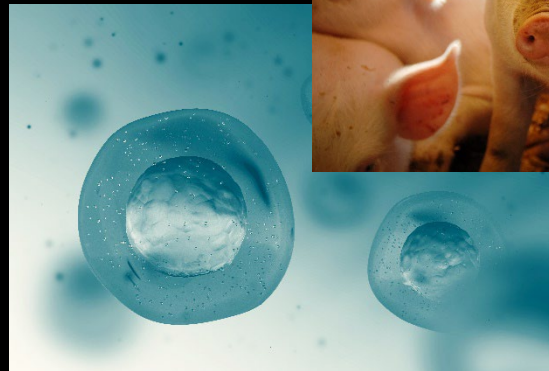
- Required for (examples)
  - Clinical trials and trials investigating  
Vaccines, medications, medical devices, surgical procedures etc.
  - Surveys & Questionnaires
    - Include identifiable personal information (name, birth date, financial info etc.)
  - Health care records reviews & data analysis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



# Other Clearances

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- 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

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- 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](https://research.wisc.edu/compliance-policy/principal-investigator-status)

# PI Status Other

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- IACUC - [policy.wisc.edu/library/UW-4114](https://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](https://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

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- 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

**Compliance**

Required Clearances - Does the project involve:

Yes  No Any of: a) microbes, prions or biological toxins with potential hazard to humans, other animals or plants; b) human or other animal cells, blood or tissues with potential hazard to humans or animals; c) recombinant or synthetic nucleic acid; d) transgenic or exotic animals or plants?

Yes  No use of human subjects or human tissue?

Yes  No Direct hands-on research, teaching, or outreach activities using live vertebrate animals in UW-Madison owned or managed facilities OR activities with wild, free-living vertebrate animals involving hands-on contact or alteration of natural behaviors?

Yes  No use of human embryos OR human embryonic stem cells OR transplantation of human pluripotent stem cells into animals with possible CNS integration or germline transmission?

Yes  No potential environmental impacts which require review under the Wisconsin Environmental Policy Act?

Yes  No action involving space, remodel, or construction?

Yes  No funding primarily dedicated to building, renovations, or equipment?

Yes  No research or services in a scientific, engineering or technology field?

[Enter Protocol Certification Details Here](#)

# Adding Information – WISPER *continued*

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- 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

The screenshot shows the ARQ Protocol Lookup System (PLuS) search interface. The header is red with 'ARQ' on the left and 'University of Wisconsin-Madison' on the right. Below the header is a dark grey bar with 'Protocol Lookup System'. The main content area is white and contains the following sections:

- Description:** A paragraph explaining the system's purpose: 'The Protocol Lookup System (PLUS) finds ARROW study statuses and funding information. To search, select at least one Project Type and any other filter criteria.'
- Project Type(s) - Required:** A section with five checkboxes: IRB, IACUC, Biosafety, SCRO, and RVSO.
- Protocol ID:** A text input field with a small icon on the right.
- Project Title:** A text input field.
- Principal Investigator:** A text input field with the placeholder text 'First and/or last name'.
- Funding Details:** A text input field with the placeholder text 'MSN Number, Project ID, Grant Title, or Sponsor'.
- Advanced Filters:** A section with a plus sign icon and the text 'Advanced Filters'.

At the bottom of the form are two buttons: a light grey 'Search' button with a magnifying glass icon, and a dark teal 'Clear Form' button with a circular arrow icon.

# Outside Activities Reporting (OAR)

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- Method for reporting relationships having potential for conflict of interest
- Required for anyone listed on a sponsored project
  - Annually by April 30<sup>th</sup>
    - 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

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## 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

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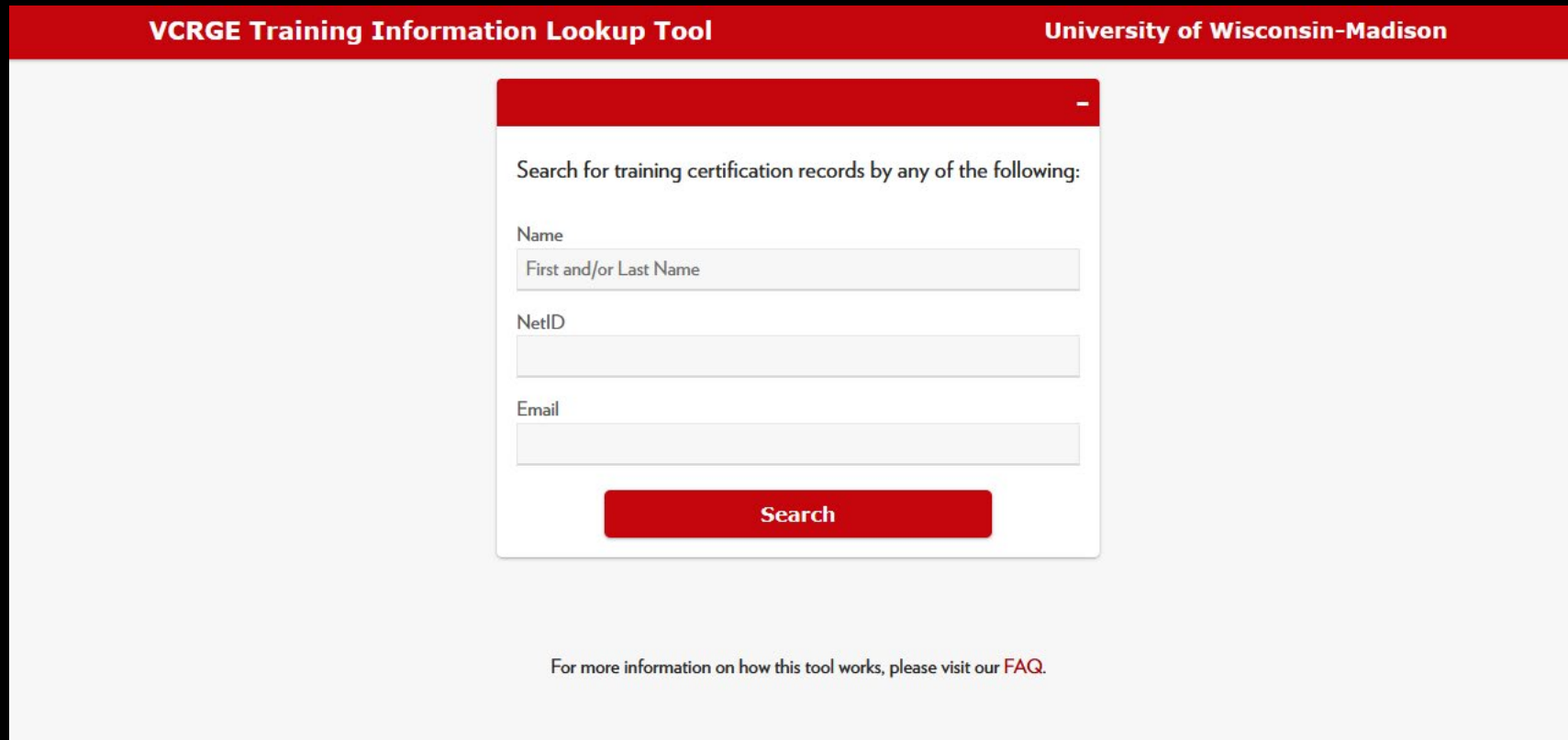
- Conflict of Interest (COI)
  - Required for anyone listed on a federally sponsored research project or human subjects (IRB) protocol
    - [canvas.wisc.edu/enroll/D9DRHR](https://canvas.wisc.edu/enroll/D9DRHR)
- Responsible Conduct of Research (RCR)
  - Required for
    - NSF (students & post-docs)
    - USDA-NIFA
    - USDA-NIFA Capacity (142) Awards
    - NIH (Requirement included in grant application)

[canvas.wisc.edu/enroll/EET6NH](https://canvas.wisc.edu/enroll/EET6NH)

# VCRGE Training Information Lookup Tool

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



The screenshot displays the VCRGE Training Information Lookup Tool interface. At the top, a red header bar contains the text "VCRGE Training Information Lookup Tool" on the left and "University of Wisconsin-Madison" on the right. Below the header, a white search form is centered. The form has a red title bar with a minus sign. The main content of the form is white and contains the following elements: a heading "Search for training certification records by any of the following:", three input fields labeled "Name", "NetID", and "Email", and a red "Search" button. The "Name" field has a placeholder text "First and/or Last Name". Below the search form, there is a link to the FAQ: "For more information on how this tool works, please visit our [FAQ](#)."



# Export Controls

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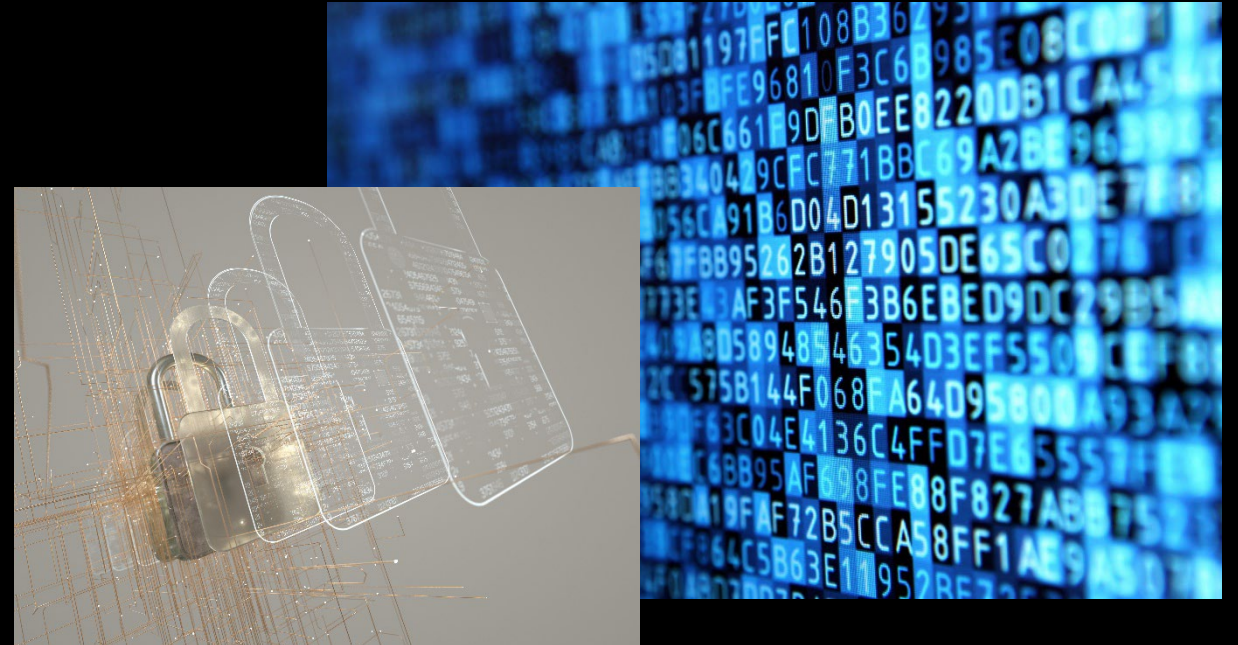
- Federal laws & regulations control distribution of certain commodities, technologies, information and data to foreign persons or organizations
  - For national security
    - Military and dual use products, technology
  - For economic purposes
    - Sanctions, Restricted Parties and Specially Designated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



# Export Controls

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



# Export Controls - Exemptions

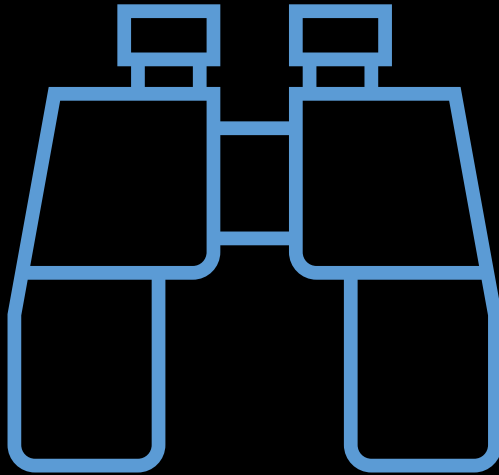
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- Universities are exempt for information considered
  - Fundamental Research – published broadly
  - Public Domain – generally available publicly
  - Education – commonly taught in schools or colleges
- License may be required if exemptions do not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



# Export Controls – What to look for

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

# Export Controls

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- 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](https://research.wisc.edu/integrity-and-other-requirements/export-control)

**Export Questions**

**Question 1:**

**Controlled Technology**

Click YES in the response field if any of the following apply to this award:

1. The project is sponsored by the U.S. Department of Defense (DOD) or a defense contractor AND has a potential military application, or
2. The project includes hardware, software, substances, information or data controlled under the International Traffic in Arms Regulations (ITAR) or Export Administration Regulations (EAR), or
3. The project uses or creates items, information or data of a technical nature that will NOT be made publicly available (such as subject to a publication restriction or non-disclosure agreement).

Help for Export Control Questions: <https://kb.wisc.edu/images/group156/shared/ExportControl/wisperhelpscreen.170209.pdf>

Response to Question 1

**Question 2:**

**Export/Deemed Export**

Click YES in the response field if any of the following apply to this award:

1. Foreign persons will participate in this project as sponsors, collaborators or staff, or
2. Hardware, software, substances, information or data for this project will be exported out of the U.S. or transferred to foreign persons within the U.S.

Help for Export Control Questions: <https://kb.wisc.edu/images/group156/shared/ExportControl/wisperhelpscreen.170209.pdf>

Response to Question 2

# Other Compliance Concerns

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- 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

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- 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

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

# Resources

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

# Thank You!

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