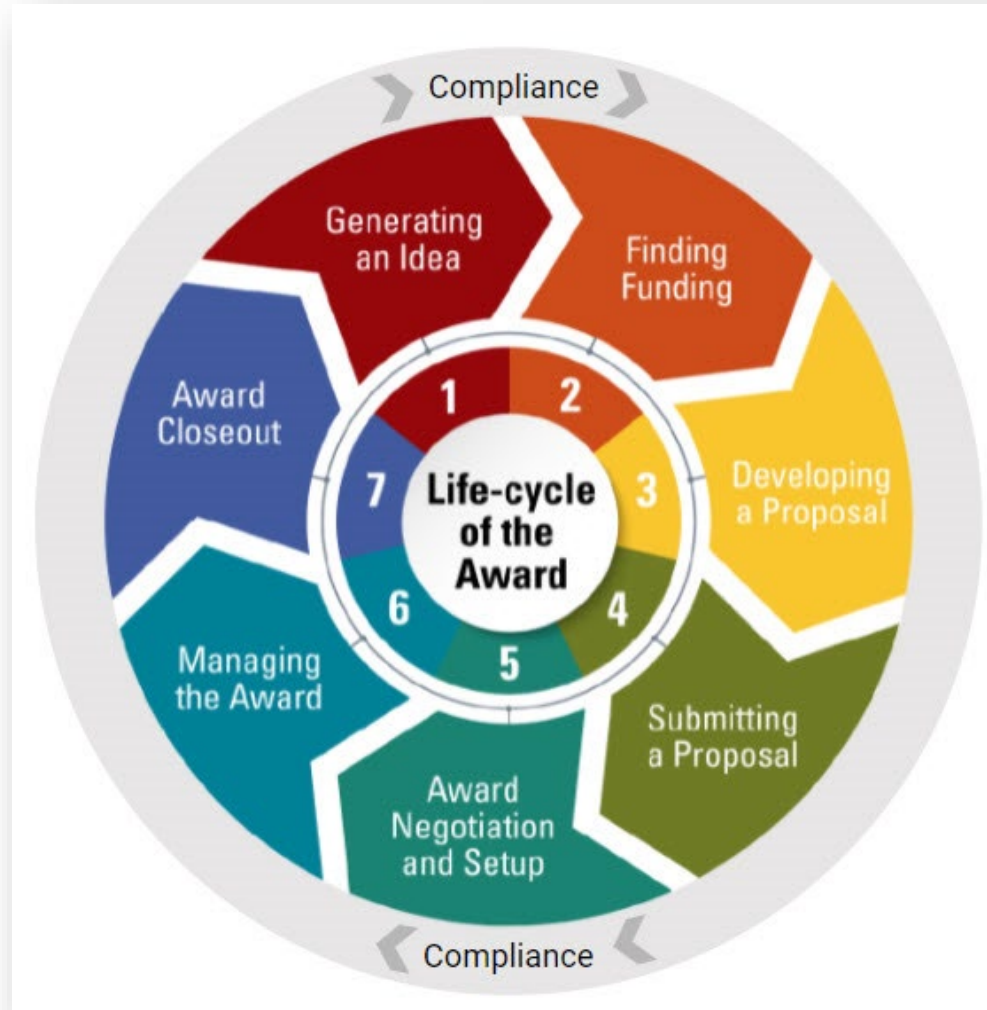


Compliance for the Research Administrator – An Overview –

University of Wisconsin-Madison

Sarah Johnson-Schlueter – Compliance Manager – College of Agricultural & Life Sciences

Compliance is Important



What We Will Cover



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

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
- Directions can be found at https://www.rarc.wisc.edu/protocols/request_grant_congruence.html

4/26/2022

To Whom It May Concern:

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

Title of Grant Application: _____

Grant number: _____

Name of Principal Investigator: _____

Protocol Number	Principal Investigator	Original Committee Approval Date	Approval Date of Version Reviewed	Protocol Expiration Date
_____	_____	10/23/2019	3/23/2022	10/21/2022

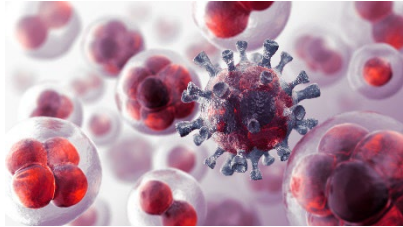
Protocol Congruence Specialist: Derrick Duchesneau

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 E-mail: congruence@rarc.wisc.edu www.rarc.wisc.edu

Institutional Biosafety Committee (IBC)



Bloodborne Pathogens



Transgenic Animals

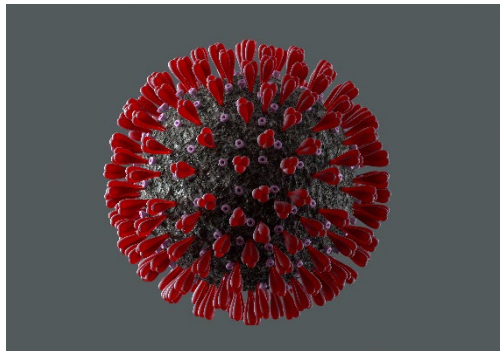
Photo: International Society for Transgenic Technologies



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 information or biospecimens through intervention or interaction with the individual
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens



Institutional Review Board (IRB)

- Health Sciences IRB & 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
 - Protocol Based (PBA)
 - Non-Protocol Based (nPBA)
 - sIRB
 - Ceded



IRB Application Types

- PBA
 - For more than minimal risk studies
- nPBA
 - For minimal risk research
 - Protocol Development Activity (PDA)
 - Used for funding purposes only.
 - Full approval or exemption must be obtained prior to start of human subjects work
- RSP will require IRB approval letter for award setup when:
 - 1) IRB review has been ceded
 - 2) Approval status is “Certified”

IRB – Protocol Examples

- Required for
 - 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

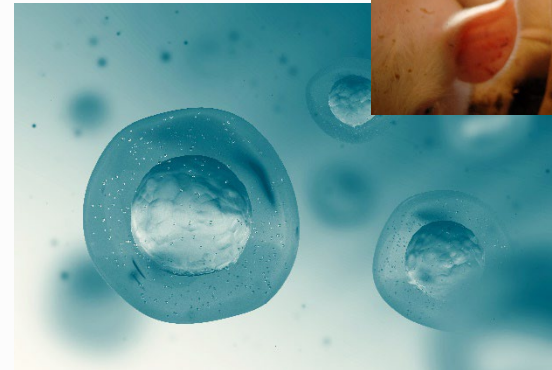


IRB – Tools

- To help determine when an IRB protocol is needed use
 - IRB worksheet #310- Human Research Determination
<https://uwmadison.app.box.com/s/y3oe7jenjvzff84bf7d6rja7st81j0y2>
 - Found at <https://irb.wisc.edu/toolkit-library/worksheets/>
 - IRB QI/Program Evaluation Self-Certification Tool
 - https://uwmadison.co1.qualtrics.com/jfe/form/SV_0uBiyxHZA7ygW9L?QJFE=qdg%22
 - This tool allows study teams to make the decision about whether their project constitutes the definition of research under the Common Rule (45 CFR 46) independent of the IRB. The tool is designed to help determine whether the project constitutes research or whether it is quality improvement or program evaluation, such that IRB review isn't required.

Other Compliance Review Questions

- Stem Cell Research Oversight (SCRO)
 - Approval for human embryos or embryonic stem cells, or human pluripotent stem cells in animals
- Human Fetal Tissue research
 - Requires IRB approval
- Dual Use Research of Concern (DURC)
 - Within the Biosafety question (3.b.)



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

- PI must add the project to the funding page of protocol(s)
 - For New Grants, Competing Continuations
- 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 in RAMP

- After the PI has added the RAMP record to their protocol, the information automatically populates into the Compliance Review smartform.
- Associated question(s) must be answered 'Yes'

The screenshot shows the RAMP Compliance Review smartform interface. At the top left is the University of Wisconsin-Madison logo and the text "WISCONSIN UNIVERSITY OF WISCONSIN-MADISON". Below this, the date and time are "Date: Friday, September 8, 2023 1:37:57 PM" and the protocol ID is "NIH_F31_Predoc_Dec_2022". On the right side, there are "Print" and "Close" buttons, and the text "Compliance Review". The main heading is "Compliance Review".

1. * Does this project include research with human subjects or use of identifiable human specimens or data?
 Yes No

2. * Does this project include activities using live vertebrate animals?
 Yes No

a. * Have you submitted or do you have an approved IACUC protocol application?
 Yes No

Related IACUC Protocols:

Protocol Number	Protocol Title	Status	PI Name	Approval Date	Expiration Date	Congruence
A00 R02	Diabetes research in mice	Active		2023-05-25	2026-05-24	

3. * Does the project include any of:

- Recombinant (transgenic) or synthetic DNA/RNA materials, including human gene therapy
- Microbes and disease-causing agents including bacteria, viruses, fungi, prions, protozoa, and parasites
- Large scale propagation consisting of a volume greater than 10L or more in one vessel
- Human cells and cell culture, organs or tissues, or biological samples

Adding Information in RAMP *continued*

- Compliance Specialist, PI, Research Administrator etc. will upload to attachments.
 - Congruence Verification (*when applicable*)
 - IRB Letter (*when applicable*)
- Approval Dates
 - Required protocol approvals, trainings, and reports must be in date at time of award setup.

Protocol Lookup System (PLuS)

- <https://apps.research.wisc.edu/ARQ/Plus/>

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:** 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 row of 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 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 grey 'Clear Form' button with a circular arrow icon.

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

- NIH

- As of January 2022 - New Submissions, RPPRs, & JIT Requests require updates to Biographical Sketch and Other Support

- Supporting documentation:

- Copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support; translated into English if written in another language.

- Immediate notification of undisclosed Other Support

Required Trainings

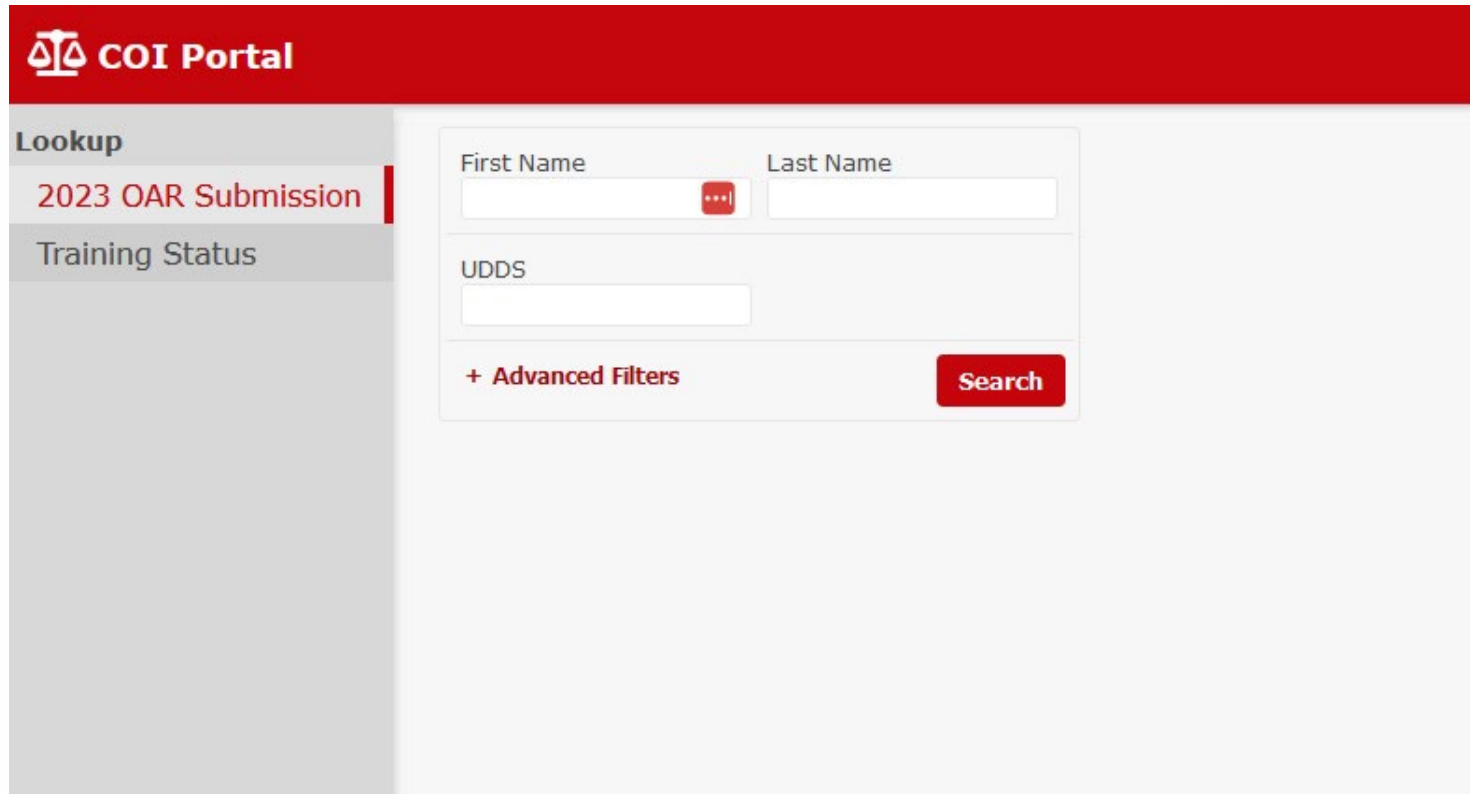
- Conflict of Interest (COI)
 - Required for anyone listed on a federally sponsored research project or human subjects (IRB) protocol
 - canvas.wisc.edu/enroll/D9DRHR
- Responsible Conduct of Research (RCR)
 - Required for
 - NSF
 - USDA-NIFA
 - USDA-NIFA Capacity (142) Awards
 - NIH (Requirement included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

canvas.wisc.edu/enroll/EET6NH

**New NSF
Requirements
Began in
August 2023!!**

COI Portal

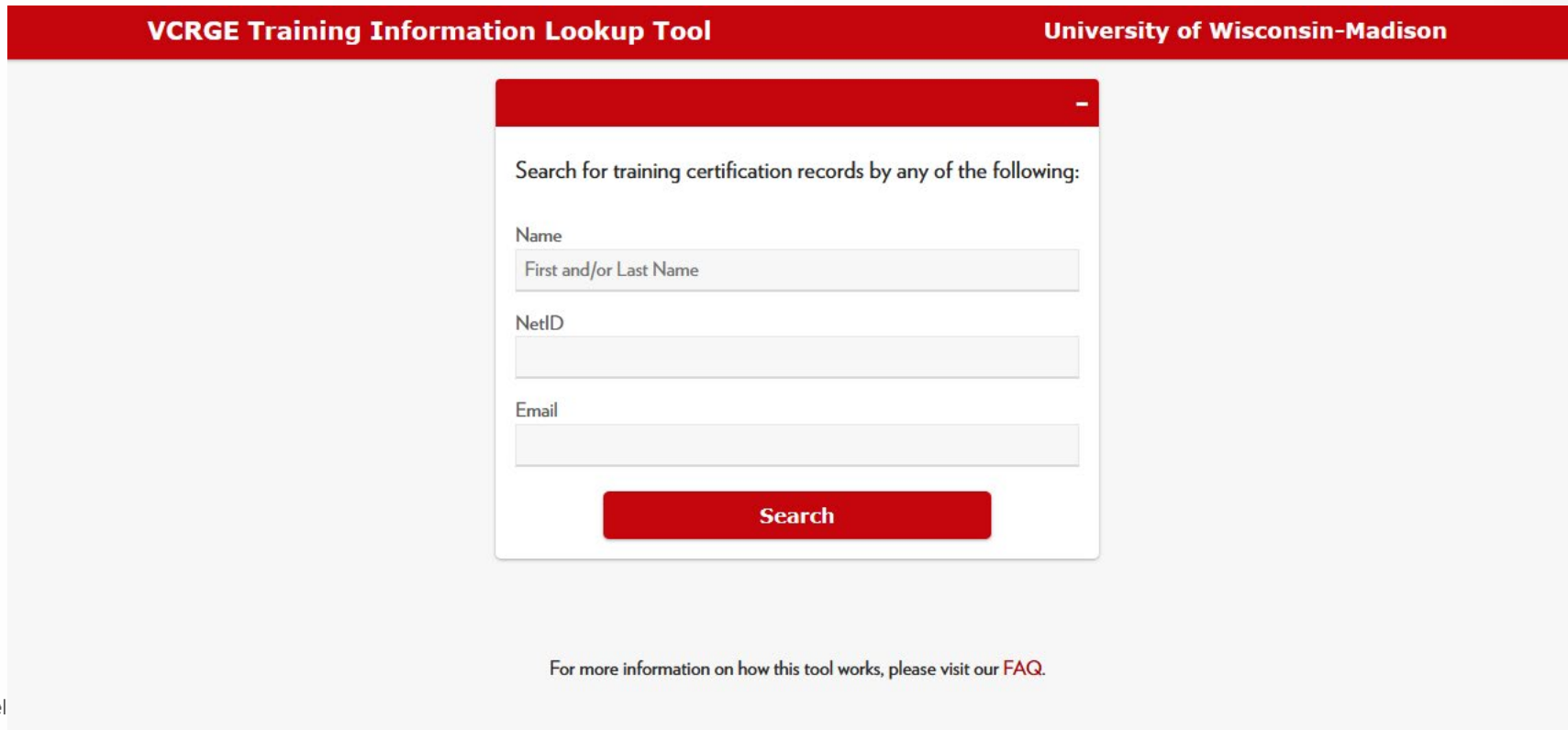
- Tool to determine OAR Status and COI Training
 - <https://apps.research.wisc.edu/COI/Lookups/OAR>



The screenshot shows the COI Portal search interface. It features a red header with the text "COI Portal" and a scale of justice icon. On the left, there is a sidebar with a "Lookup" section containing two options: "2023 OAR Submission" (highlighted with a red bar) and "Training Status". The main search area contains a form with the following fields: "First Name" and "Last Name" (each with a text input field and a red "x" icon), and "UDDS" (with a text input field). Below the form, there is a "+ Advanced Filters" link and a red "Search" button.

VCRGE Training Information Lookup Tool

- Search tool for: COI, RCR, and other Trainings
- <https://apps.research.wisc.edu/TILT>



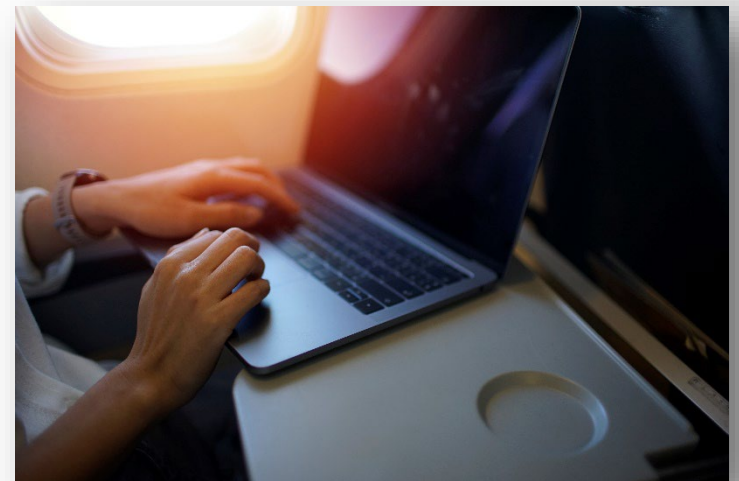
The screenshot displays the VCRGE Training Information Lookup Tool interface. At the top, a red banner contains the text "VCRGE Training Information Lookup Tool" on the left and "University of Wisconsin-Madison" on the right. Below this banner is a white search form with a red header bar. The form contains the following elements:

- A heading: "Search for training certification records by any of the following:"
- A "Name" section with a text input field labeled "First and/or Last Name".
- A "NetID" section with a text input field.
- An "Email" section with a text input field.
- A red "Search" button at the bottom of the form.

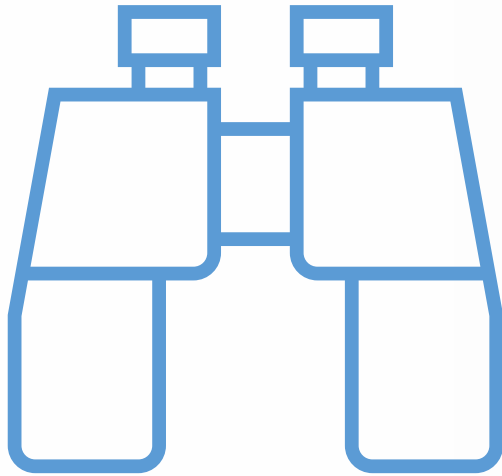
Below the search form, there is a link: "For more information on how this tool works, please visit our [FAQ](#)."

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 – 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 – RAMP

- PI answers questions 8, 9, & 10 on the Compliance Review smartform in RAMP
- Activities with potential implications
 - Traveling, Shipping, Collaborating Abroad
 - Working with
 - Controlled items
 - Restricted countries
- Export Control Office

8. * Controlled Technology - Does this project include any of the following:

- a. The project is sponsored by the U.S. Department of Defense (DOD) or a defense contractor AND has a potential military application, or
- b. The project includes hardware, software, substances, information or data controlled under the International Traffic in Arms Regulations (ITAR) or Export Administration Regulations (EAR), or
- c. 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).

Yes No

9. * Foreign Participation – Does this project include any of the following:

- a. A foreign organization or person sponsors the project.
- b. Foreign persons will participate in this project as collaborators or staff, where staff includes faculty, academic staff and students.
- c. You plan to ship hardware, software, materials, information, or data for this project out of the U.S. or transfer any of these items to a foreign person within the U.S.

Yes No

10. * Export Control Activities:
International Travel – e.g. Presenting data, conference attendance, investigator meetings, etc.
None of the above

a. Identify all countries:

Country
Canada

b. Provide additional details about the foreign activity:
Conference to present results

research.wisc.edu/integrity-and-other-requirements/export-control

Export Controls – Foreign Person

- Definition:
 - Someone who is not:
 - A U.S. citizen or national of the U.S.,
 - A permanent resident (green card holder) of the U.S.,
or
 - Lawfully admitted to the U.S. for refugee, asylum or amnesty reasons



Other Compliance Items



- Research Vehicles Safety Oversight (RVSO)
 - For autonomous vehicles: drones etc.
 - Pilot and Flight applications must be submitted in ARROW
- Hemp Research
 - USDA Licensure Required – College Specific
- DEA Controlled Substances in Research
 - State Licensure and Federal DEA Registration Required – PI contacts RARC
- Bayh-Dole Act:
<https://research.wisc.edu/bayhdole/>
- Effort Reporting

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
- OAR or COI trainings out of date or incomplete

Contacts

- IACUC – iacuc@rarc.wisc.edu
- IBC – Andrea Ladd andrea.ladd@wisc.edu
- IRB – asktheirb@wisc.edu
- COI
 - Your Department/Division: research.wisc.edu/kb-article/?id=32881
 - **COI Office:** coiprogram@research.wisc.edu
- Your Department/Division Compliance Manager or Specialist
 - CALS – Sarah Johnson-Schlueter – Sarah.JohnsonSchlueter@wisc.edu

Resources

- 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
- UW Conflict of Interest Policy – policy.wisc.edu/library/UW-4001
- Export Control - <https://research.wisc.edu/integrity-and-other-requirements/export-control/>

Thank You!

