New UVM Faculty Orientation

An Introduction to the Research Protections Office
Research Safety, Ethics & Compliance Issues

UVM's Research Protections Office (RPO) is responsible for the review/oversight programs that support the institution’s conduct of safe and ethically sound scientific research involving human participants, vertebrate animals and biohazards.

– Institutional Review Board (IRB)
– Institutional Animal Care and Use Committee (IACUC)
– Institutional Biosafety Committee (IBC)
Institutional Review Board (IRB)

Human Subject Research
Institutional Review Board (IRB)

University of Vermont (UVM) and UVM Medical Center are involved in important behavioral and biomedical research and are committed to assuring that all research activities are conducted in a manner that promotes the rights and welfare of the participants. UVM currently has two IRB’s:

- CHRMS - Committees on Human Research in the Medical Sciences

- CHRBSS – Committee on Human Research in the Behavioral & Social Sciences
The University of Vermont and UVM Medical Center are responsible for safeguarding the rights and welfare of human subjects involved in any research activity.

According to institutional policy, all such research, funded or unfunded, conducted by University and/or UVM Medical Center personnel, including students, or done under the auspices or sponsorship of either institution must be reviewed by either the Medical or Behavioral Institutional Review Boards.

Approval must be obtained BEFORE the research activity starts and more than minimal risk protocols must be reviewed at least annually for as long as it is active.
REQUIRED TRAINING THROUGH CITI

- All faculty involved in the conduct of research with human subjects, regardless of funding source, must complete the Human Subjects Training through CITI. In addition, principal investigators or key personnel working on a clinical trial involving human subjects and all personnel affiliated with the UVM Larner College of Medicine will need to complete the Good Clinical Practice Training. Every three years, all personnel still listed on an active protocol are required to retake the training.

https://www.uvm.edu/rpo/citi-program-training
Determine if the Project Requires IRB Review

– Researchers can start here and determine if their project requires submission to the Research Protections Office for approval.

– If it is research and it involves human subjects, it must be submitted for review
Submission of Protocols through UVM Click

- UVMClick is a paperless, electronic method to submit new protocols, modifications, continuing reviews and reportable new information.

- Investigators should visit our Forms Library and the "User Guides" to prepare a submission. Protocol, consent and informational sheet templates can be found here and will be helpful in developing your submission.

- Forms Library
- UVMClick "User Guides"
IRB Approval Process

- The Committee reviews and sends memo to PI through the CLICK system
- PI responds to any clarifications or concerns from the Committee
- Verification of applicable CITI training completion
- Receipt of final IRB assurance approval and stamped consent forms (if applicable)
- PI is ready to begin human subject research
Post Approval Process

Ongoing IRB review

- Yearly continuing review reports for more than minimal risk protocols
- Modifications to the protocol, consent form, recruitment material, updates to the drug brochures etc.
- Key personnel changes
- Reporting of adverse events /unanticipated problems
- Quality Assurance Visits by RPO staff
Institutional Animal Care and Use Committee (IACUC)

Vertebrate Animals
The University of Vermont (UVM) is committed to the humane care and use of animals in activities related to research, testing and teaching. There are two separate organizational components at UVM designated to ensure appropriate implementation of all aspects of the animal care and use program:

- The Institutional Animal Care and Use Committee (IACUC) is UVM’s central review body for matters relating to the care, use and treatment of animals in these areas and is located in the Research Protections Office.

- The Office of Animal Care Management (OACM) with the University Veterinarian as its director, is responsible for the oversight of all animal care and use and for ensuring compliance with federal, state and local regulations.
REQUIRED TRAINING THROUGH CITI

– All faculty involved in the conduct of research with vertebrate animals, regardless of funding source, must complete
  – IACUC - Lab Animals
  – General Lab Animal Training
  – Animal-Specific Courses (e.g. mouse, rat, guinea pig, etc...)
  – https://www.uvm.edu/rpo/citi-program-training

– OCCUPATIONAL HEALTH AND SAFETY

All personnel working with animals are required to complete a baseline risk assessment form prior to working (opens in a new window).
Determine if the Project requires IACUC review

- Does the proposed activity involves vertebrate animals in research or teaching? If yes, it must be reviewed by the IACUC.

- We recommend that new investigators review the requirements here prior to submitting to the IACUC.
Submission of Protocols through UVM Click

- UVMClick is a paperless, electronic method to submit new protocols, amendments, continuing reviews and reportable new information.
- New Investigators should visit our "User Guides" to prepare a submission.
- UVMClick "User Guides"
Protocol Submission Process

Initial Veterinary Review

A protocol is sent to the University Veterinarian for review and approval through the CLICK system.

Return to Investigator for modifications

The draft protocol is returned to the investigator with a written review and a copy of the protocol with tracked changes. The veterinarian must sign the protocol.

Final Submission to IACUC

After revisions are made, a final document is submitted to the IACUC for review. A grant, if applicable, must be submitted as well.

Assigned a review or placed on agenda

A pre-review by a research analyst is conducted and the protocol and supporting documents are assigned to committee reviewers and added to the next available agenda if applicable.
Protocol Maintenance

- IACUC protocols that include USDA species require a basic annual review. All other protocols complete the triennial review.
- Any change to the protocol/experiments/procedures must be submitted through UVMClick to the IACUC for approval before those changes are implemented.
- Key personnel rosters must be kept up to date. Personnel additions to the roster must be submitted and approved by the Committee before those individuals can work in the lab.
Institutional Biosafety Committee (IBC)

Infectious agents and recombinant DNA
IBC Mission

– The University of Vermont (UVM) Institutional Biosafety Committee (IBC) is a standing committee that ensures that all research and teaching activities involving biohazardous materials are conducted in a safe and informed manner.

– The IBC is responsible for ensuring full compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) and for monitoring all other research and teaching activities involving the use of infectious or potentially infectious biological materials and biotoxins.
Biosafety Oversight

The IBC reviews all research and teaching protocols that involve the following materials without regard to the source of funding:

- Recombinant or synthetic nucleic acid molecules as specified in the NIH Guidelines
- Human, animal, and plant pathogens (bacteria, fungi, viruses, parasites, prions)
- Plasmid vectors
- Viral vectors
- Human-derived materials (blood, blood products, cells, tissues, and clinical specimens) when used in conjunction with recombinant or synthetic nucleic acid molecules
- Biotoxins
- Select Agents and Toxins
REQUIRED TRAINING THROUGH CITI

Active PIs and key personnel as listed on an IBC registration will be required to complete the CITI Program Training.

Depending on the level of containment, you will need to complete either the BSL-1 or BSL-2 Basic Course. The BSL-2 Basic Course meets all requirements for BSL-1 related work.

AND other CITI course(s) if applicable:

- OSHA Blood borne Pathogens (check with EHS at safety@uvm.edu to see if this is required)
- Animal Biosafety
- Select Agents/DURC
- Nanotechnology

https://www.uvm.edu/rpo/citi-program-training
Submission of Protocols through UVMClick

- You will need to initiate a new Master Protocol Registration (MPR) through the [UVMClick – IBC](#) module. This will require that you complete SMART Forms and attach Standard Operating Procedures (SOPs) or Biohazardous Agent Reference Documents (BARDs) as needed.
- The Biosafety Officer review will be initiated by IBC staff once the MPR has been submitted.
What Forms are Needed for IBC approval

- A [Standard Operating Procedure](#) must be submitted for each biohazardous agent listed in the Master Protocol Registration.
- The Biohazardous Agent Reference Document ([BARD](#)) is a general guidance resource that reviews and summarizes the nature of a pathogen or bio toxin, and offers safety requirements for work with the agent in the laboratory. During the Risk Assessment, the Biosafety Officer may recommend the use of a BARD, however, additional SOP documentation may be required as determined by the risk assessment.
Post Approval Monitoring

- The primary focus of the monitoring process is to assess PPE use and management, educate and advise on biosafety and IBC compliance matters, and address any questions or concerns brought forth by principal investigators.
- This process is intended to be collegial and interactive, not punitive. If a biosafety or IBC compliance issue is discovered during a visit, the IBC will assist the investigators in addressing the issue.
Post Approval Monitoring

– Assessment frequency will depend upon the level of risk associated with the laboratory work and the principal investigators history of compliance/non-compliance with IBC policies. In the absence of any IBC related noncompliance, the UVM IBC will adhere to the following assessment schedule:

This schedule includes teaching laboratories.

– BSL-1 laboratories – every 3 years
– BSL-2 laboratories – every 2 years
– BSL-3 laboratories – annually
Contact us with questions we’re here to help

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CONTACT STAFF