



New UVM Faculty Orientation

An Introduction to the Research Protections Office

Melanie Locher, IRB Director



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)
- Controlled Substances Committee (CRC)

REQUIRED TRAINING THROUGH CITI

IRB – Human Subjects

- Medical researchers should take Biomedical Research
- Social or Behavioral researchers should take Social Behavioral Education Sciences
- College of Medicine faculty – Good Clinical Practice

IACUC – Lab Animals

- General Lab Animal Training course *in addition* to any Animal-Specific Courses (Amphibians, Cattle, Fish, etc.)
- Occupational Health and Safety Program for Employees Working with Animals:
- All personnel working with animals are required to complete a baseline risk assessment form prior to working with animals. Subsequent health reviews are required every three years.

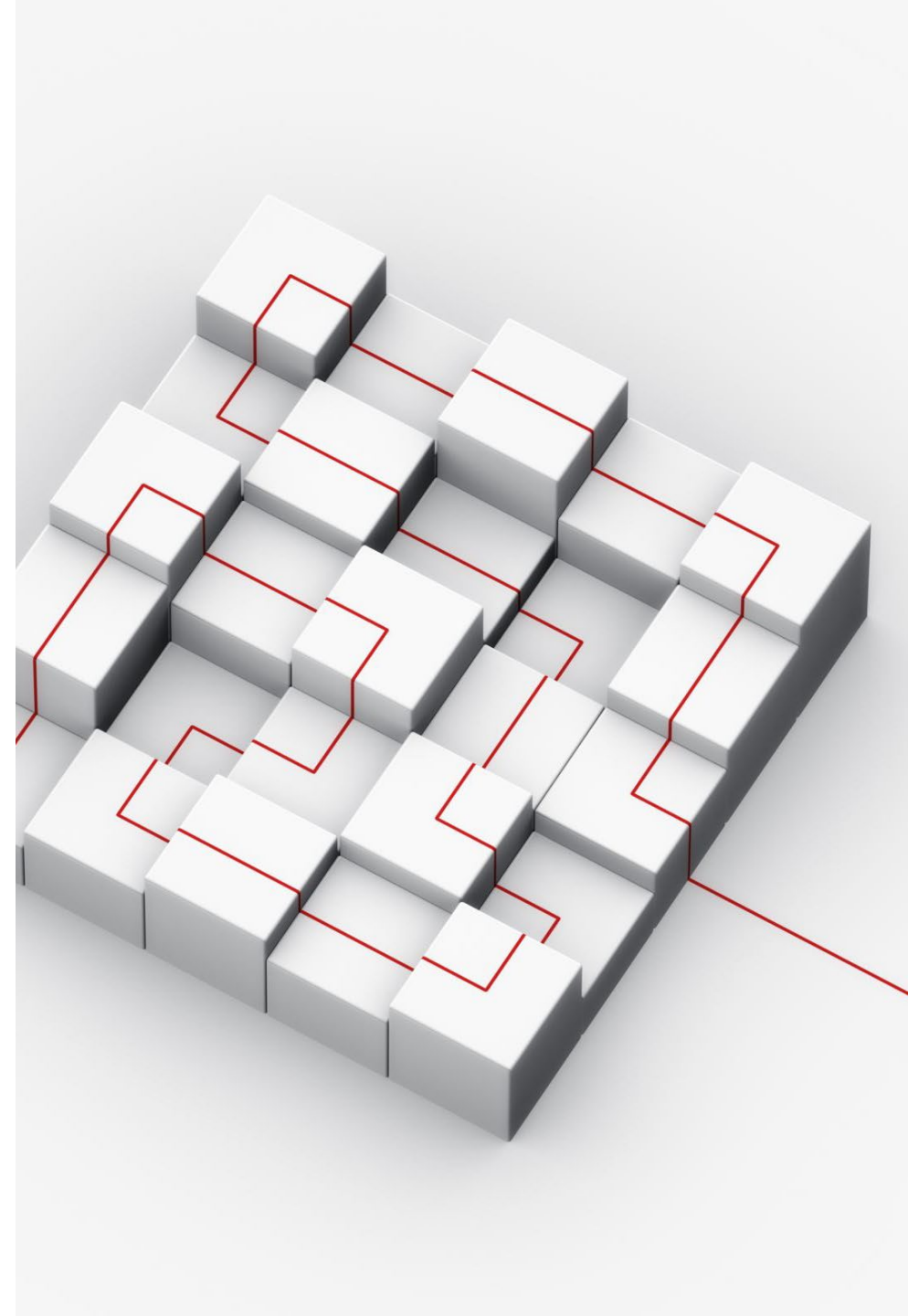
IBC

- 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: (nanotech, animal biosafety)
- OSHA Bloodborne Pathogens

Submission of Research Protocols and Lab Registrations through UVM Click

- UVMClick is a paperless, electronic method to submit new protocols, modifications, continuing reviews and reportable new information.
- Investigators should visit our committee specific "User Guides" to prepare a submission. Step by step directions along with screenshots of the database are located here.
- Tip Sheets have been created to help researchers troubleshoot the online system
- FAQ's have been created to answer PI's most frequently asked questions

<https://www.uvm.edu/ovpr/uvmclick>



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



IRB Committee Mission

The University of Vermont and UVM Medical Center are responsible for safeguarding the rights and welfare of human subjects involved in any research activity.

All 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.

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

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

Post Approval Process

Institutional Animal Care and Use Committee (IACUC)

Vertebrate Animals

IACUC Committee Mission

- The University of Vermont 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 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.

Determine if the Project requires IACUC review



- Does the proposed activity involve vertebrate animals in research or teaching? If yes, it must be reviewed by the IACUC
- We recommend that new investigators review the requirements on our webpage prior to submitting to the IACUC.

Protocol Submission Process

Initial Veterinary Review

A protocol, complete with grant application (if applicable), is sent to the University Veterinarian for review through the Click system.

Return to Investigator for modifications

Requests for changes or clarifications will be sent back to the Investigator through UVMClick. The system allows for direct communication back and forth between the investigator and veterinarian until all clarifications have been addressed.

Final Submission to IACUC

Once revisions are made and approved by the Veterinarian, the final version is submitted to the IACUC for review.

Assigned a review or placed on agenda

A pre-review by a research analyst is conducted and the protocol package is 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

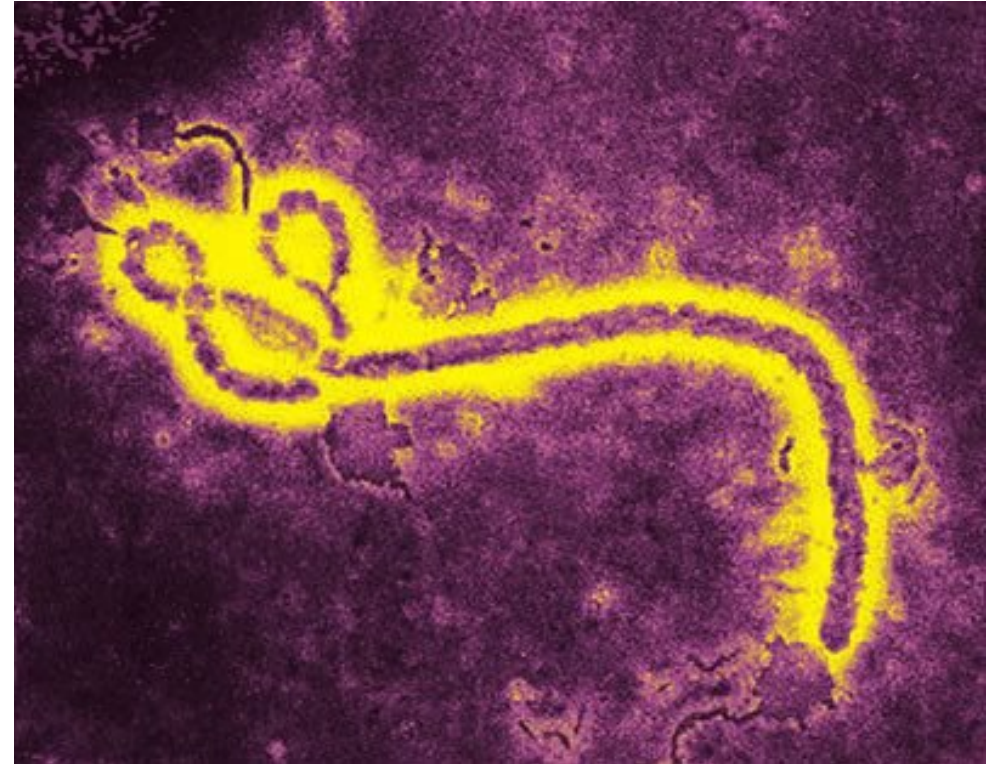
IBC Mission

- 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



What Forms are Needed for IBC approval

- A [Standard Operating Procedure](#) may be requested, at the discretion of the Committee, for hazardous substances listed in the 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.

Controlled Substances Committee

Controlled Substances Committee Mission

Due to their potential for misuse and abuse, items listed by the U.S. Department of Justice, Drug Enforcement Administration (DEA), scheduled drugs (controlled substances) are subject to special procurement, storage, use and disposal requirements.

The University takes this responsibility seriously and has developed the Controlled Substances in Research Operating Procedure. It is the responsibility of individual researchers and other staff using these materials to obtain appropriate registrations and licenses.

Controlled Substances Committee

- Establish and review policies and procedures on all matters relating to the purchase, storage, usage, and disposal of controlled substances by members of the University Research community;
- Review and authorize UVM researchers to purchase and use controlled substances;
- Develop standards for monitoring compliance and responding to non-compliance with regulations and/or institutional procedures; and
- If necessary, terminate a user's authority to use controlled substances at UVM.



Each investigator who orders, handles, or stores controlled substances must be registered with the DEA and approved by the UVM CSC

Maintain accurate inventories and records of controlled substances for a minimum of 2 years;

Designate Authorized Users: who have completed appropriate training, and is approved to handle controlled substances in the lab;

Supervise use of controlled substances in the lab and ensure that they are stored and disposed in a manner that prevents theft or misuse.

Comply with DEA and UVM reporting requirements;

Renew registrations annually

Administer the "Questionnaire for Access to Controlled Substances for Research Purposes" to all Authorized Users

CSC: Investigator Responsibilities



We're here to help

Research Protections Office
University of Vermont
213 Waterman Building
85 South Prospect Street
Burlington, Vermont 05405

[CONTACT STAFF](#)