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)

REQUIRED TRAINING THROUGH CITI

- All faculty involved in the conduct of research with human subjects, or lab animals or infectious agents, regardless of funding source, must complete the Training through CITI.

https://www.uvm.edu/rpo/citi-program-training

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"

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 Approval Process

- The IRB Committee reviews and sends a clarification memo to PI through the CLICK system
- PI responds to any clarifications or concerns from the Committee via Click
- RPO office will verify researchers CITI training completion
- Receipt of final IRB assurance approval and stamped protocol & 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

IACUC Committee Mission

- 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.

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

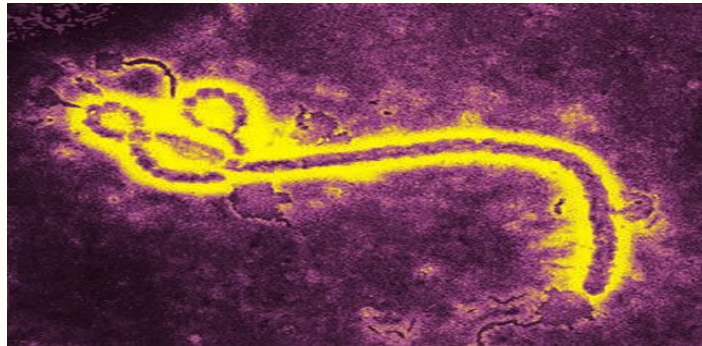
IBC Mission

- 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



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.

RPO STAFF

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Submission of Protocols throu...

Contact us with questions we're here to help

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