



## Research Protections Office Charter

### MISSION STATEMENT

The mission of the University of Vermont Research Protections Office (RPO) is to support the University research enterprise in understanding and complying with regulatory and local requirements to ensure safe, ethical and compliant conduct of research.

### RPO VISION

- Recognized for outstanding review and oversight programs that support UVM's research vision.
- Trusted and respected secondary to expertise, responsiveness, and collaborative disposition.

### PURPOSE

RPO facilitates the development and implementation of educational resources, policies and procedures, and compliance oversight necessary for the UVM academic and research enterprise to be successful.

RPO oversees four administrative units

- Institutional Review Boards (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Controlled Substances Committee (CSC)

Through active and close collaboration with these compliance committees and other research administrative partners, the RPO promotes the ethical and responsible conduct of research and ensures compliance with regulatory requirements related to human subject research, vertebrate animal research, and laboratory-based research.

### GOVERNING PRINCIPLES

Each of the Committees has governing principles to which each must adhere.

#### **IRB**

- DHHS, Code of Federal Regulations at 45 CFR 46
- FDA, 21 CFR 50 and 21 CFR 56
- HIPAA, 45 CFR 160, 162, & 164

#### **IACUC**

- Public Health Service, Animal Welfare Act
- US Dept. of Agriculture, Animal and Plant Health Inspection Service
- AAALAC International

#### **IBC**

- NIH Guidelines
- Biosafety in Microbiological and Biomedical Laboratories
- Centers for Disease Control and Prevention Select Agent Program

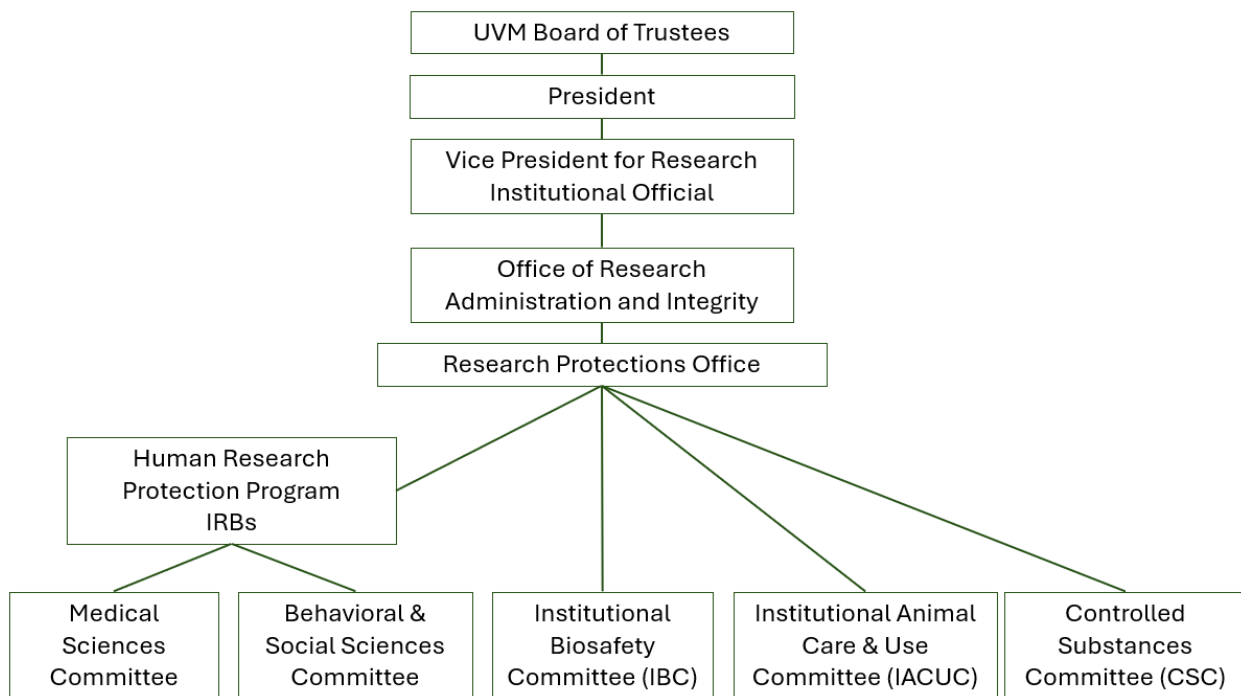
#### **CSC**

- US Dept. of Justice, Title 21, USC Controlled Substance Act
- Drug Enforcement Research Manual

## AUTHORITY AND REPORTING STRUCTURE

The University of Vermont has empowered the RPO with full authority to

- develop and implement policy
- perform quality assurance reviews to assess compliance with approved protocols and procedures and recommend improved controls, procedures, resources or stronger enforcement of regulatory requirements as needed
- obtain the essential assistance and cooperation of personnel in areas of the University where reviews and investigations are performed
- access records, data, personnel and physical property relevant to performing compliance reviews and investigations



## RESPONSIBILITIES

Unit-specific responsibilities based upon institutional and regulatory requirements can be found in Policy and Procedures manuals on each of the websites. Common responsibilities are

- Developing effective lines of communication with university partners.
  - Providing support, education, and outreach to researchers and research administrators.
  - Developing, maintaining, and revising policies and procedures.
  - Conducting research compliance monitoring, investigations, and reviews.
  - Responding promptly to detected and/or reported issues of concern and ensuring appropriate corrective actions are in place for resolution.
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- Promoting and enforcing standards through education, awareness, and training; and
  - Routinely evaluating research compliance program effectiveness.

## IMPACT DECISION CRITERIA

The RPO utilizes a set of decision criteria through which we make changes to policies and procedures.

**Integrity of the Review Process** - Work processes are grounded in regulatory and policy requirements.

**Welfare and Safety** - Safety and welfare for research participants, animals or lab personnel handling biohazards is never compromised.

**Researcher Burden** - Our decisions consider the impact on principal investigators and members of the research team.

**Efficiency and Accuracy** - We strive for simplicity, to do what is effective, and to reduce duplication/redundancy. Our processes are consistent and standardized appropriately.

**Ability to Perform Core Functions** - We focus on that which is central to the protocol life cycle.

**Staff Development** - We foster opportunities to advance and support new endeavors for our staff.

## COMMUNICATION

The RPO has developed a set of guiding principles for our methods of communication.

### Internal staff communications

- Commitment to broadly share information with all staff
- Emphasize respectful two-way communication with active listening
- Encourage questions and ideas
- Clearly communicate responsibilities and expectations
- Understanding context for effective communication

### External researcher communications

- Communications must be presented in a clear, concise and timely fashion
- Web presence should always be up-to-date and easy to navigate
- Seek to enhance working relationships and cooperation in our communications
- Utilization of different communication methods
- Understanding context for effective communication
- Encourage meetings to discuss complex issues

## RPO UVM PARTNERS

RPO strives to coordinate efforts with various UVM individuals/departments to ensure compliance and reduce administrative research burden.

- Principal Investigators and Research Coordinators
- Divisional, Departmental and School Leadership
- Office of Research and Integrity (Conflict of Interest Matters)
- Division of Inclusive Excellence
- Office of Risk Management
- UVM Compliance Office
- Enterprise Technology Service
- General Counsel Office

- Office of the Provost
- Sponsored Project Administration
- Division of Finance & Administration
- Office of Animal Care Management
- Environmental Health & Safety
- University Radiation Safety
- Student Faculty Sponsors/Mentors

Each of these offices is responsible for different academic and research compliance aspects but share the goals of serving the UVM community through the promotion of ethical and safe research. The offices collaborate but also work independently to achieve our shared goals.

### **Human Research Protections Program Components/Partners**

For research with human subjects this shared responsibility is referred to in the industry as the Human Research Protections Program (HRPP). The HRPP under RPO reaches across UVM, to our Academic Medical Center partner, and the UVM Health Network Affiliates. This requires partnerships from all institutions to ensure safe and compliant human subjects research activities. In addition to those listed above, the following are examples of other collaborating partners specific to human subjects research.

- Institutional Biosafety Committee
- Vermont Cancer Center
- Office for Clinical Trials Research
- Clinical Research Center
- Academic Medical Center Departments
  - Radiation Safety
  - Compliance and Privacy
  - Data Management Office
  - Investigational Drug Service
  - Infectious Disease Practice Committee
  - Billing Compliance Office