University of Vermont

Research Protections Office Annual Report January 2025

University of Vermont

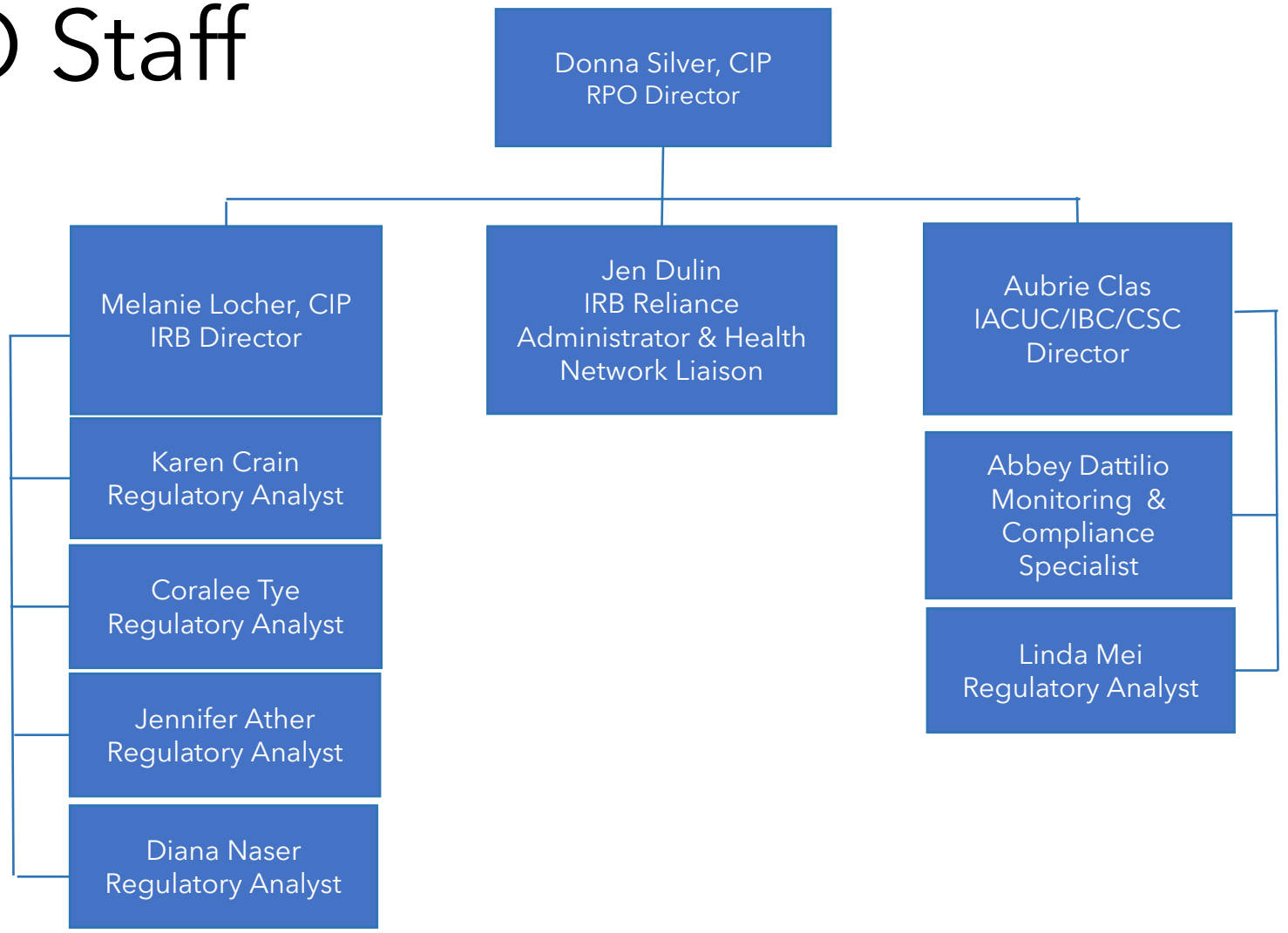
RPO Mission, Vision & Purpose

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. We strive to be recognized for outstanding review and oversight programs that support UVM's research vision and are trusted and respected secondary to our expertise, responsiveness, and collaborative disposition.

Please see the new RPO Charter outlining our mission, vision, purpose, authority and responsibilities.

University of Vermont

RPO Staff



University of Vermont

RPO Activities over the last 12 months

- Committee Membership
- New type of human subject research allowed at UVM
- Process Advances
- Technical Advances
- Quality Assurance Reviews
- Training & Outreach
- Single IRB
- AAALAC Accreditation
- Annual Numbers

University of Vermont

Committee Membership

- Dr. Borzoo Farhang replaced Dr. Nataniel Lester-Coll as Associate Chair of the IRB as of July 22, 2024.
- Dr. Joshua Woolsey became the Chair of the Controlled Substances Committee as of September 23, 2024.
- An inaugural luncheon was held for all compliance Committee members in November. Dr. Dombrowski personally thanked everyone for their dedication and support of the research enterprise and member milestones were celebrated.

Exception from Informed Consent in Emergency Research- EFIC

- How are emergency research studies unique? Emergency research involves the most vulnerable population of study participants, i.e., a population with no capacity to control what happens to them and no capacity to consent, in a setting where the emergency circumstances require prompt action and generally provide insufficient time and opportunity to locate and obtain consent from each participant's legally authorized representative. To protect these vulnerable subjects, 21 CFR 50.24 places additional responsibilities on parties involved with such research, including sponsors, clinical investigators, and IRBs.
- This year UVM and UVMMC, in collaboration with the Emergency Department, approved the first EFIC trial for pain management in trauma patients in the field.
- As EFIC trials require public consultation, do not be surprised to see discussions about this trial in your area, perhaps through social media, the local library, or Church socials.

Process Advances

Retirees Conducting Research

- The RPO found a gap in the current institutional process that allows retirees to continue conducting research. The Committees were not being informed of retirements. Researchers are allowed to continue research whether as PI or key personnel with departmental support and institutional sign off. However, the Committees need to be in the loop to manage the retiring individual's protocols according to his/her wishes. To that end, we worked with the Provost's Office to identify a process for retirees to request to continue their research at the time of their retirement. There is now a form on UVM's retirement page that requires completion and submission to our office. Receipt of that form notifies the office of the researcher's intention. The RPO has included the institutional process for obtaining approval from the Provost's Office in its Policy and Procedure Manuals.

External Study Team Members

- If you have external study team members that you would like to add to your IRB key personnel list in Click, there is now a process which can be found in the Policy and Procedure Manual.

IRB Internal Clean Up

- The IRB identified approximately 1400 older exempt study records in the Click system. These studies were still assigned an active status in our system; however, we suspected most having been approved greater than 3 years ago without further IRB communications had been completed. The IRB staff worked with those researchers who wished to continue their exempt study and closed the remainder. A process to remind PIs to close exempt records in the Click system is now in place.

IRB Self-Determination Tool

- The Self-Determination Tool was updated this year to point researchers with federal funding to their IRB Analyst to discuss the project. This was done for a couple of reasons. If there is an error in answering a question and the project requires IRB review, a researcher's funding could be at risk. Additionally, the NIH has, in the past, required IRB review of these types of projects. This additional check-in with the IRB will assist in identifying those that may need to come to the IRB.

University of Vermont

Technical Advances

- We transitioned all four of our RPO websites to the new institutional web platform with resources from the VPR Office.
- All UVM Click protocol submission modules were upgraded to Version 10. This version provided some needed updates.
- After months of collaborative work with UVMMC and LCOM, clinical trials approval information in UVMClick IRB is now being pushed to the new Oncore Clinical Trials Management System. We anticipate further adjustments to ensure smooth transitions of information.

Quality Assurance Visits

We have identified a need for increased support of trainees (fellows, residents, post-doctoral fellows, pos-doctoral associates, post-doctoral trainees, and any students (graduate or undergraduate). LCOM has instituted an ancillary review by the department Chairs or Vice Research Chairs. Non-LCOM departments are collectively working on supportive measures for trainees in the nonclinical areas. The VPR's office has committed support to enlist external training and the RPO is looking into a PI training course specific to trainees for 2025.

IBC/CSC

- 21 IBC lab visits, 23 CSC visits

IACUC

- 14 post approval monitoring visits, 365 semiannual lab inspections

IRB

- 12 visits, 8 UVM IRB of record and 4 SIRB.

University of Vermont

IRB Training & Outreach

- **Committee Members** – Topic sheets were distributed and discussed at convened meetings including Key Information Section of the Consent Form, Use of an Impartial Witness during Consent, Child Assent and Consent for those Reaching Legal Age While Enrolled, Secure Electronic Data Storage in the DMSP, Exceptions from Informed Consent, Federal Regulations for Non-English-Speaking Participants. CHRMS Committee Chair attended the national Public Responsibility in Medicine & Research meeting. New member orientation training was completed for 6 new members.
- **Staff Continuing Education** – Three staff were able to attend the national Public Responsibility in Medicine & Research annual meeting, one staff attended an Office for Human Subjects Protections event and multiple webinars were attended including topics on Exploring the Ethical and Practical Considerations of Psychedelics in Research, Single IRB and Artificial intelligence in human participant research.
- **Researchers** – RPO conducted and/or made available educational sessions regarding Roles and Responsibilities of Research Investigators and Faculty Sponsors, IRB and the PRMC – What is the Difference,? Ask the IRB, Quality Assurance Monitoring Program, Evolving Landscape of Human Research with AI, Single IRB Mini-Bootcamp for PIs and Research Teams, and UVMHN Compliance & Privacy Offices reviewed the current HIPAA forms and reporting requirements.

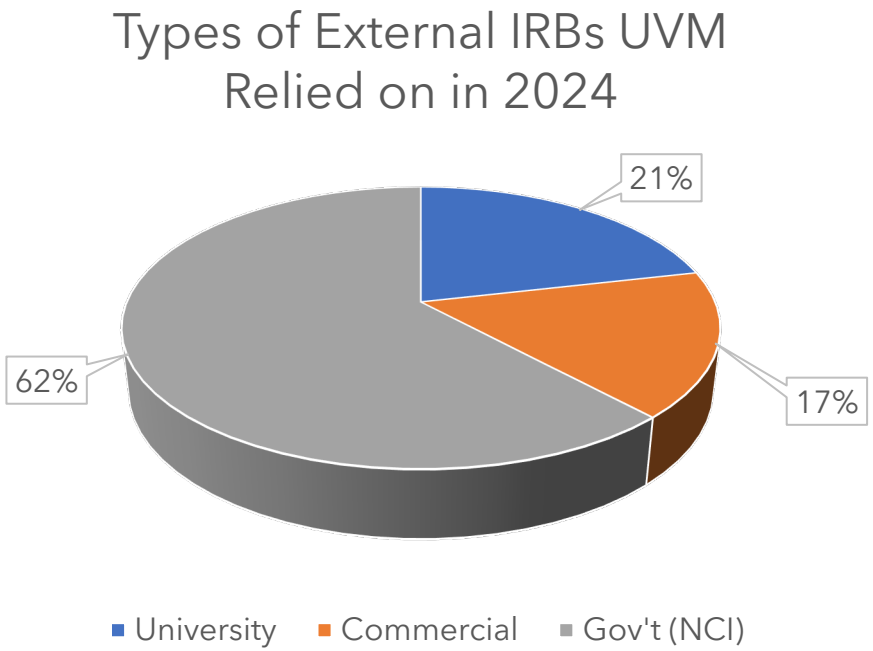
University of Vermont

IACUC/IRB/CSC Training & Outreach

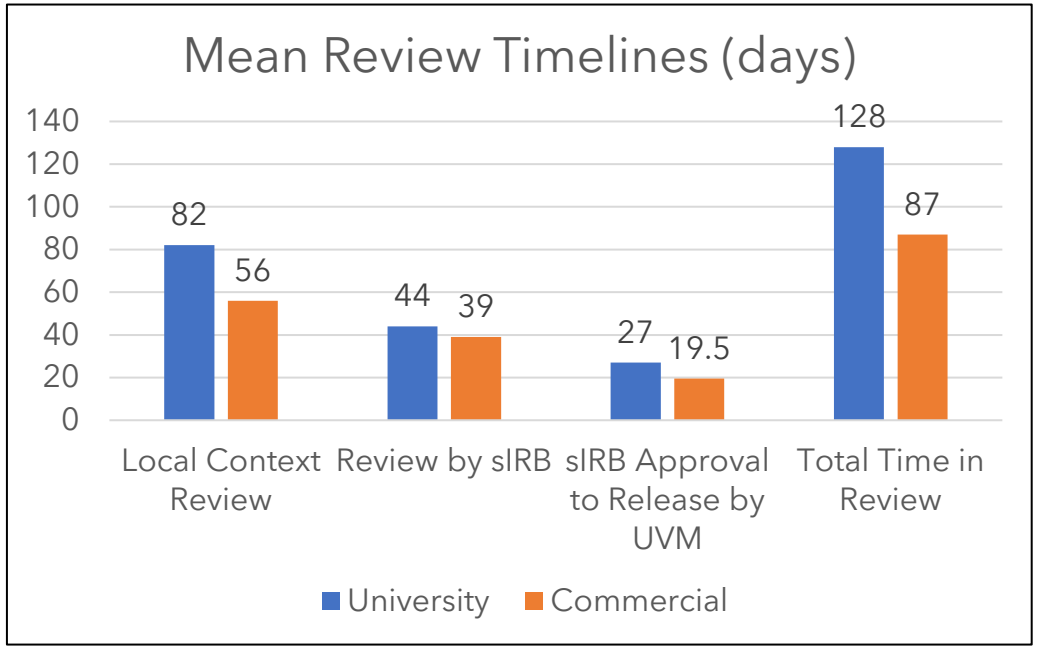
- **Committee Members** – Topic sheets were distributed and discussed at convened meetings including importance of Member Participation in IACUC Semiannual Inspections, USDA Covered Species, AAALAC's Position Statement on Cage or Pen Space. New member orientation training was completed for 4 members.
- **Staff Continuing Education** – One staff person was able to attend the national Public Responsibility in Medicine & Research annual meeting, Biosafety Program Compliance, UVM Inclusive Excellence Symposium, FDA/NIH Dos and Don'ts
- **Researchers** – RPO participated in the OACM Administration of Compounds to Rodents, newsletter op ed about the Post Approval Monitoring program, held Open QA hour, and multiple one-on-one Click support meetings and researcher training during lab site visits.

Single IRB Reliance Numbers

- In 2024 UVM
  - Executed12 reliance agreements to cede review to another IRB
  - Approved local activation for 27 new External IRB protocols
  - Completed an additional 15 UVM IRB Local Context Reviews, which now await Billing Compliance (10), DoD OHRO review (2), External IRB review (2), and EFIC Community Consultation & Disclosure Plan results (1)
- Despite increased standardization of reliance procedures, variances continue in institutional policy and regulatory interpretation, which result in delays (examples below.)
  - Requirement by a Reviewing IRB's institution to be added to UVM's institutional insurance,
  - Two External IRBs required HIPAA language in a consent when it was not applicable,
  - Disagreement on risk level resulting in difference of opinion regarding consent language.



Single IRB Is it Better?



*NCI CIRB timeline data not readily available, but Local Context review tends to be much shorter, there is no review of local documents by sIRB, and the biggest contribution to total time in review is waiting for local ancillary review completion.
**The 82-day local context review number was an outlier and was associated with UVM's first Exception from Informed Consent for Emergency Research (EFIC) trial which required review by UVMMC's EFIC Advisory Committee.

Conclusions Based on UVM's Data

- Single IRB is not necessarily more efficient. At least not the initial review and activation. Anecdotally there seems to be a reduction in burden post initial approval.
- Reliance requires negotiation because application of regulatory requirements and institutional policies differ, which affects review timelines.
- Commercial IRBs have a faster turn around time than University-based External IRBs. This is not unexpected given commercial IRBs have many resources.
- While we are unable to control response times from External IRBs, UVM will continue to search for ways to effectively streamline our local processes.
- To that end, in 2025 the IRB will create a single IRB list serve to provide much needed information, education and transparency around single IRB activities.

UVM as the Single IRB

- The process to establish an income/expense account has begun, and we have developed a weighted IRB charge rate as suggested by NIH and other institutions. We have created a researcher worksheet to assist with establishing the IRB direct costs for proposal budgets. Prior to publishing our rate and this worksheet, it will be tested with a few researchers in early 2025. Once vetted, the final income/expense proposal will be sent to UVM Financial Analysis and Billing Office for review.
- Other items that require completion are the development of an on-line request process for UVM to be the IRB of record, criteria for UVM to become the IRB of record (i.e., number of sites vs resources, level of risk, etc.), other tools to assist with streamlining the ongoing oversight of a multi-site grant-funded protocol.

UVM Health Network Affiliates

UVM's IRB is officially the IRB of record for Champlain Valley Physicians Hospital (CVPH) through a reliance agreement executed this past September.

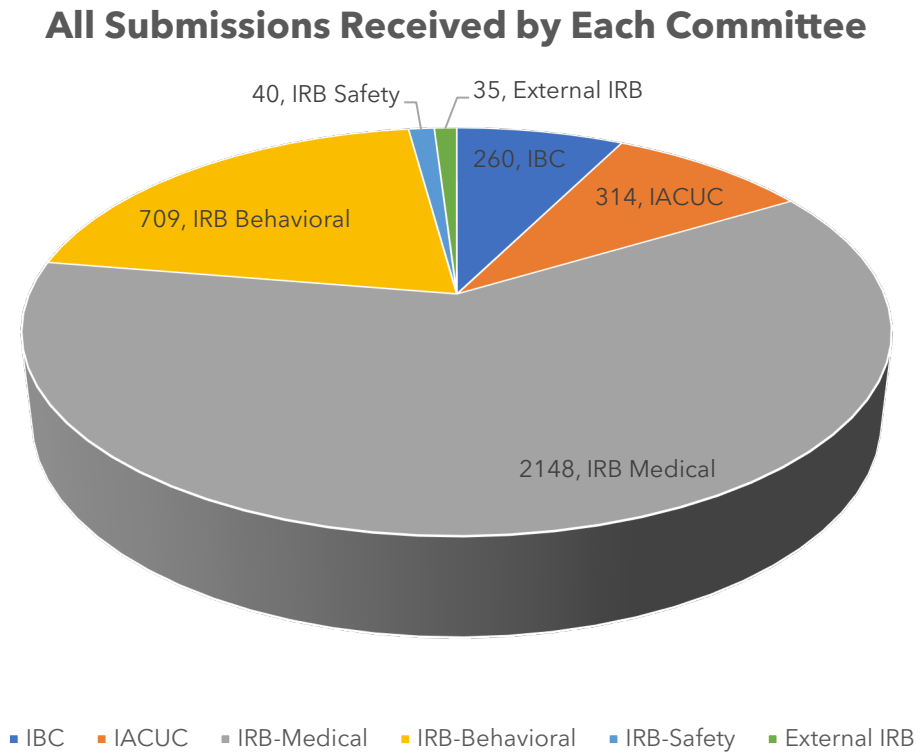
We await the hire of a UVM HN Human Subject Protections Administrator prior to reviewing new CVPH protocols or engaging with other sites.

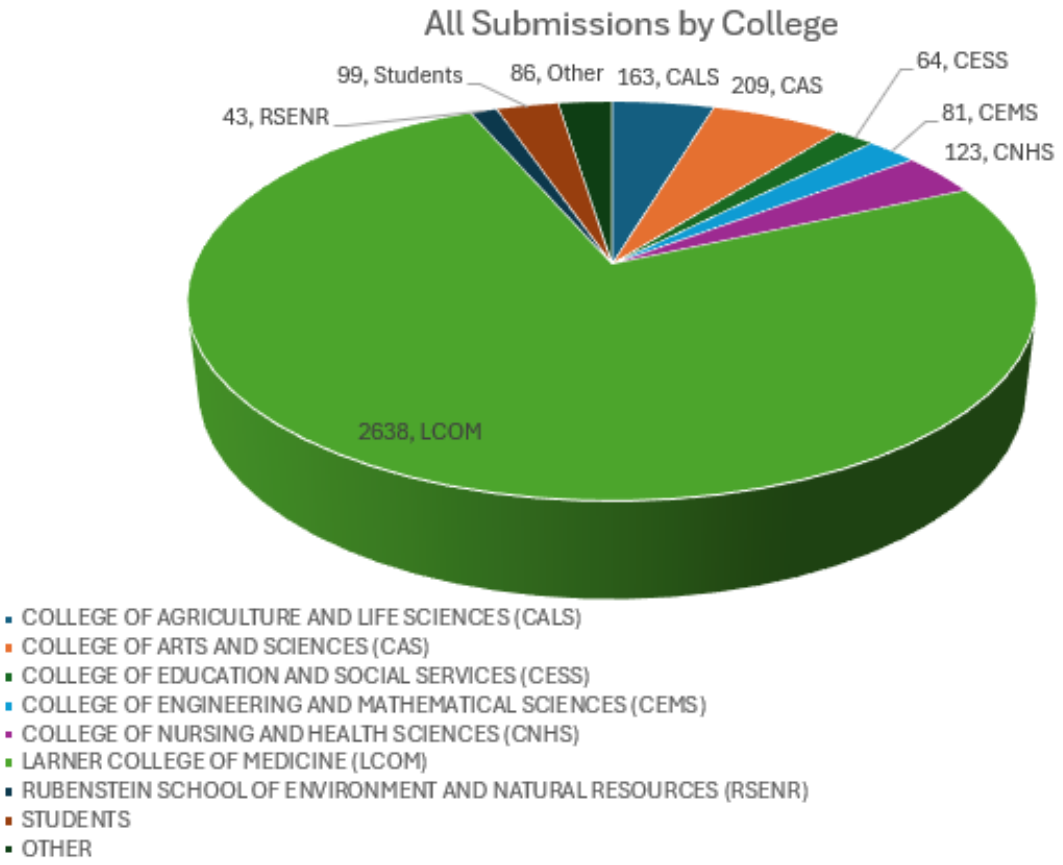
University of Vermont

AAALAC Accreditation

- AAALAC International is a private, nonprofit organization that promotes the humane treatment of animal in science through a voluntary accreditation program.
- UVM has been accredited by AAALAC since 1989.
- Accreditation requires annual reports, and a full written program description followed by a site visit to UVM every three years.
- This year the IACUC staff coordinated completion of the program description (approximately 230 pages) in anticipation of a site visit scheduled for the third week in March.
- Site inspectors will visit spaces where animals are held, they will ask questions of IACUC members and researchers, and they will review protocols.
- The IACUC Compliance Specialist is available to support you with your preparations and an informational meeting about the site visit and expectations will be held in February. Notice of this educational opportunity will be sent via the IACUC list serve. All are welcome.

Number of Submissions





Colleges with 1% or less have been combined under "other."

Ongoing Projects and New Initiatives in 2025

IRB for UVM Health Network sites continues

UVM's IRB becoming an IRB of record for grant funded protocols

New IBC regulatory requirement regarding DURC and PEPP effective May 2025

Artificial Intelligence in Human Subject Research – Ensuring Protections

AAALAC Accreditation – Triennial Site Visit

University of Vermont

For questions or feed back about this report contact:

Donna Silver, CIP, Director
Research Protections Office
University of Vermont
213 Waterman Building
85 South Prospect Street
Burlington, VT 05405
Donna.Silver@uvm.edu

Office Contact List
https://www.uvm.edu/rpo/contact-us