



The University of Vermont

RESEARCH PROTECTIONS OFFICE

Single IRB

[RPO](#) | [Human Subjects Research](#) | [Single IRB](#)

Single IRB Definitions

- **Authorization Agreement/Reliance Agreement**
 - written agreement between two or more institutions that is used to document the delegation of IRB review responsibilities
- **Cede review**
 - the act of transferring IRB review and oversight
- **Reviewing IRB**
 - the IRB of record performing review on behalf of one or more institutions, also referred to as the single IRB and/or central IRB and/or external IRB in the case UVM cedes review
- **Relying Institution**
 - the entity that agrees to rely upon the reviewing IRB
- **Sponsors and funders**
 - generally refers to any entity that is supporting research and includes non-profit and for profit entities
- **Single IRB**
 - the Single IRB is the selected IRB of record that conducts the ethical review for participating sites of a multi-site study

What are the goals of the NIH Single IRB Policy? ^

The goal of the policy is to enhance and streamline the IRB review process in the context of multi-site research so that research can proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections.

What is the scope and applicability of the NIH Single IRB Policy? ^

This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.

Is use of a Single IRB required? ^

Yes. Use of a Single IRB for NIH-funded multi-site research is required as of January 25, 2018. The policy does not dictate to whom the Single IRB responsibilities have to fall. The Single IRB responsibilities can fall to the lead PI of the grant, to another participating site, or to a commercial IRB.

How is the decision made as to which IRB will be the reviewing IRB and which institution(s) will be the relying institution? ^

The sponsor or funder may identify the reviewing IRB; the applicant for funding may propose the reviewing IRB; or the group of researchers involved in the research may collectively decide which IRB they would prefer to serve as the reviewing IRB.

In all cases, consideration should be given to issues such as expertise in a particular area of research or familiarity with the patient population, or one IRB's capabilities for serving as the reviewing IRB.

If I am the lead principal investigator (PI) on a grant, is the UVM IRB required to be the single IRB for the protocol? ^

No, it is not required that the funded PI's institution be the single IRB of record. Consideration needs to be given to IRB experience and capacity, lead PI administrative support, and cost. Relying on another institution or a commercial IRB does not decrease your opportunities for future grant funding.

What are my responsibilities as the NIH grant applicant? ^

- Application must have description of the single IRB that will be selected to serve as the IRB of record for all study sites
- Statement confirming that all participating sites will adhere to the NIH single IRB policy
- Description of how sites and single IRB will communicate
- Application must include direct costs of establishment and review of the multi-site study by the single IRB

To whom and when should researchers submit a request for use of a Single IRB? ^

UVM will not be the IRB of record at this time. Requests to UVM to cede review to another institution must be submitted to the UVM IRB (form pending). UVM IRB can provide letters of support indicating our willingness to rely on another IRB.

Will I need to notify UVM when the protocol closes? ^

Yes, a protocol closure must be submitted to close out the file at UVM.

What is a Reliance Agreement? ^

A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site.

What is the purpose of a Reliance Agreement? ^

A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol. Once the agreement is executed, it can lessen the administrative burden and regulatory oversight of multiple institutions' IRBs.

Are reliance agreements accepted by all institutions? ^

Institutions vary as to whether they will utilize reliance agreements. Many institutions will decide if they will allow a reliance agreement based on the research protocol being reviewed. Some institutions have standing arrangements to utilize other IRBs for specific types of research. From a regulatory perspective, federal regulations allow for reliance agreements to be used for multi-site research.

Does the University of Vermont utilize reliance agreements? ^

UVM IRB will negotiate reliance agreements on a protocol-by-protocol basis. The UVM IRB has a standing arrangement with the National Cancer Institute Central IRB to rely on their review for adult and pediatric oncology trials. At this time, we will not engage in reliance agreements with international IRBs.

What is the SMART IRB? ^

The SMART IRB, Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform, is an initiative developed under an award from the National Center for Advancing Translational Sciences (“NCATS”) of the National Institutes of Health (“NIH”) to support single Institutional Review Board (“IRB”) review in facilitation of multi-site human subjects research.

The SMART IRB is not a single IRB that institutions can use. It is a clearinghouse for institutional reliance agreements. Institutions who participate have already been vetted with master agreements in place to enable institutions to more readily participate in collaborative multi-site research under a single IRB.

Is UVM a participant in the SMART IRB? ^

UVM is an approved institution. UVM will only consider reliance on other IRBs for NIH funded studies.

Can I request that UVM be the Single IRB of record? ^

At this time any NIH funded multi-site clinical study must use WIRB commercial IRB. Contact information for WIRB is forthcoming.

What would be my responsibilities as lead PI? ^

If you are the lead principal investigator, your responsibilities increase.

You are not only responsible to ensure IRB review/oversight/reporting of research activities at the University of Vermont but also those research activities occurring at the sites included in your protocol. It is important that before you consider assuming this responsibility, you have the resources and infrastructure to do so. This will likely depend on relationships with investigators at the other sites since you will need to depend on them to provide information about the research activities at their sites.

Once a reliance agreement has been executed for other sites to rely upon (cede review to) the commercial IRB, the UVM PI is considered the ‘overall PI’ for the multi-site research protocol and obtains overall responsibility for the protection of human subjects for all sites.

This includes ensuring external sites are complying with local state laws and regulations.

If UVM is the lead site, is an IRB application still required by the relying institutions IRB? ^

This will depend on the external institution’s policies. Relying researchers may need to submit through their local IRB system even if that IRB will rely upon the commercial IRB. Further information should be obtained from that institution’s IRB office.

As the lead PI, what do I need to consider at the time of continuing review? ^

As the 'overall PI' with other institutions relying on the commercial IRB, you need to collect all required information needed to complete the continuing review submission form. The continuing review conducted by the commercial IRB will apply to all sites. Therefore, all information such as enrollment numbers, reportable events, etc. must be collected from all relying sites and included in continuing review submission.

As the lead PI, do I need to report unanticipated problems to both the commercial IRB as well as the UVM IRB? ^

Yes. All unanticipated problems, deviations, suspensions and terminations, noncompliance, subject complaints, etc. from any relying site must be reported to the commercial IRB as well as the UVM IRB.

If UVM is using a commercial IRB and I am the lead PI, do the relying sites use a UVM consent form? ^

A template for the consent(s) must be developed and approved by the commercial IRB. Each relying site will need to use this template and include their required consent language. The commercial IRB will approve each of those consents.

Can I request that UVM rely on an external IRB? ^

Requests can be made to the UVM IRB to cede review to another IRB for NIH studies only. You will be requested to provide information about the study, the funding source, risk level, use of drugs and devices, and need for FDA exceptions from informed consent (form pending). The UVM IRB will use this information to determine if they are willing to rely.

If UVM cedes review to an external IRB, what responsibilities does the UVM PI and research staff have? ^

Once a reliance agreement has been executed for UVM to cede review to another IRB, the UVM PI is responsible for interacting and responding to human subjects protection issues with the new external IRB. UVM PI and research staff will need to learn the electronic system, IRB policies and processes of the external IRB.

You will no longer have daily interaction with the UVM IRB. However, you will be required to submit a minimal amount of paperwork to enable the UVM IRB to continue to oversee the conduct of the study locally.

While the UVM IRB has no human subjects review jurisdiction, the PI is still required to obtain all necessary internal reviews (billing compliance, pharmacy, radiation safety, IBC, etc) prior to registering with the UVM IRB. The UVM IRB is developing a list of these core areas for PIs and research staff to reference to ensure these ancillary review requirements have been met. This is a standard requirement outlined in the reliance agreements.

If review has been ceded to another IRB, is an initial application still needed with the UVM IRB? ^

No, however the protocol does need to be registered locally in InfoEd. The UVM IRB is developing a submission form for this purpose. This submission is not an IRB review process (since the IRB review will be ceded to another institution) but rather is a means to track ceded protocols, check that applicable ancillary reviews are complete, capture unanticipated problems or noncompliance and track overall research activities occurring at UVM/UVMMC.

If review has been ceded to another IRB, is Continuing Review (Renewal) still needed with the UVM IRB? ^

No, the continuing review occurs at the external IRB of record. You will need to provide all necessary information to the "overall PI" to include in the continuing review report to the external IRB. A continuing review will not occur at UVM.

If review has been ceded to another IRB, if an unanticipated problem (UAP) has occurred with one of my subjects, who do I report it to? ^

All UAPs, deviations, suspensions and terminations, noncompliance, subject complaints, etc. must be reported to the 'overall PI' at the external institution following the external IRB's reporting criteria and policies. You must submit any local UAPs, deviations or noncompliance that meet UVM IRB criteria through InfoEd. Any suspensions or terminations of research whether local or study-wide must be reported to the UVM IRB as well. Any local subject complaints must be submitted to the UVM IRB.

If review has been ceded to another IRB, do I still use a UVM consent form? ^

No, the consent forms to be used at UVM will be reviewed and approved by the external IRB of record. However, they must include UVM/UVMMC-specific information (leaderhead, HIPAA/privacy language, injury language, contact information, etc.). The UVM IRB is developing a consent template that can be used to ensure the required information is being included in the final document.

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