

13.3 Procedures for Relying on External IRB for NIH Research (Sec ___ .114(b)(1))

At this time, the University of Vermont (UVM) will allow UVM researchers to rely on an External IRB for multicenter, domestic human subjects protocols where the project has NIH funding. Currently, UVM has the following master reliance agreements in place to meet the NIH requirement. Master reliance agreements allow UVM to rely on a single IRB repeatedly without having to resign an agreement for each individual project.

National Cancer Institute Central IRB (NCI CIRB) – adult and pediatric oncology protocols

SMART IRB

StrokeNet – StrokeNet protocols

Western IRB (WIRB) – when UVM Lead Investigator wishes to subcontract single IRB

Reliance agreements with other institutions for NIH funded research will be considered following the “Steps to Allow Reliance on an External IRB” later in this document.

Cooperative research protocols where there is no NIH funding, will continue to be reviewed by the UVM IRB.

RESPONSIBILITIES

The External IRB will be responsible for Committee review and ensuring that the protocol meets the regulatory requirements for protecting human subjects. The University of Vermont and the University of Vermont Medical Center (UVMMMC) are responsible for oversight of human subject

protections. Each of the following roles play an important part in protecting human subjects.

ROLES

Institutions

UVM and UVMMC are responsible for the following, regardless of which IRB reviews the research:

- Education and training of our local investigators & research staff

- Monitoring the conduct of local research activities

- Conflict of Interest review

- Execution of institutional reliance agreements

IRB

The role of an IRB is to review protocols to ensure that adequate human subject protections are in place.

UVM/UVMMC Principal Investigator

UVM PIs have the overall responsibility for the conduct of the protocol and must adhere to the policies and procedures of both the External IRB and the UVM IRB when there is reliance on another IRB.

Designated Contact Person

The UVM/UVMMC PI needs to identify one person on their research staff as their designated contact for all interactions and communications with the External IRB. This person will work as the liaison between the other institutional point of contact or directly with the External IRB and the local PI as well as the intermediary between the External IRB and UVM's IRB.

Others

UVM PIs who will conduct protocols utilizing UVMMC resources will work with the UVMMC Compliance Office to create a billing plan.

UVM Office of General Counsel will be involved with reliance agreement negotiations as necessary.

HIPAA issues may arise which would involve the UVMMC Privacy Specialist.

Institutional Committees

Other departments or individuals may need to be consulted.

STEPS TO ALLOW RELIANCE ON AN EXTERNAL IRB

1. Request to Allow Reliance on an External IRB

For NIH Research: PIs must complete and submit electronically to UVM IRB a *Request to Rely on an External IRB* form (UVM PI may need to contact the external IRB for answers to questions 2 – 5 on the form). Submission of this form and its required attachments begins a record in UVM's electronic system. To help us determine the level of local oversight that may be required for this protocol, the UVM IRB requires that you submit the following additional materials for review:

a copy of the human subject protocol;

the sponsor provided consent template(s);

roster of key personnel working on the protocol;

any reliance agreements that require institutional signature;

and a Data Management and Security Plan form.

The latter is a UVM-specific form and addresses data collection, storage and sharing. This information helps to determine if data use agreements are necessary.

Note: It is very important that you receive approval from your department chair, required applicable institutional committees as well as be in contact with any ancillary departments that are included or impacted by your participation in the research project. (e.g., *Radiation Safety Committee, Institutional Biosafety Committee, Scientific Advisory Committee, Investigational Pharmacy*).

Research projects that utilize any UVMMC resources are required to have a coverage analysis and billing plan conducted by UVMMC Billing Compliance, so you should contact that office early in the process.

2. Meeting with UVM IRB Staff

Before submitting protocol/consent materials to an External IRB for review the PI and his/her designated contact are required to meet with IRB staff. This meeting is to review:

- the Single IRB process;
- your responsibilities as the UVM PI;
- your responsibilities to the external IRB;
- an appropriate consent/HIPAA document;
- our expectations for continued submissions and communications; and
- the status of the agreement.

We will review an exit interview document together and the PI will be provided with a signed copy to document UVM IRB's approval to move forward with reliance on an external

IRB. Completion of this step does not mean that you may begin protocol activities. Allowance to begin protocol activities at UVM/UVMMC will not occur until you have reached step 5 in this process.

3. Develop Materials for External IRB Submission

UVM designated contact is responsible for communicating with the External IRB to determine what documents are needed for review and the procedures for submission.

UVM designated contact will develop the local consent to include the local UVM required consent and HIPAA language. Contact the IRB for more information.

4. Once UVM PI Obtains External IRB Approval

Prior to the start of any research activities at UVM, the UVM PI must complete and submit electronically, the *Notification of Approval from the External Single IRB form* to the UVM IRB.

Include the following materials in the submission:

- External IRB approval letter;

- Final approved protocol;

- Final approved local consent form;

- Additionally, if there have been any changes to your key personnel roster or the original Data Management and Security Plan submit those changes.

The PI may not begin protocol activities until he/she receives notification from the UVM IRB that they have met the local requirements and are allowed to begin the protocol.

5. Allowance to Begin Research Activities Locally

The UVM IRB will review the materials, as listed above, to ensure that all local requirements are met, for example, UVMMC has completed a Coverage Analysis and Billing Plan

if applicable, the final consent includes the required language, agreements are in place, etc. Once it has been determined that all issues are addressed, an *Allowance to Begin Research Activities Reviewed by an External IRB* memo will be forwarded to the UVM PI.

UVM IRB ONGOING SUBMISSION REQUIREMENTS

Changes in PI or Key Personnel

UVM PI or designated contact must submit any changes to the protocol PI or key personnel. UVM is required to know who is assigned as the PI, as well as to ensure key personnel have completed required human subjects training prior to working on the protocol. Use electronic form to update personnel.

Unanticipated Problems

UVM PI or designated contact must submit local adverse events or unanticipated problems meeting the UVM IRB reporting criteria. Complete the UVM IRB Unanticipated Problem ... form and submit through the electronic system.

Closure of Protocol

UVM PI or designated contact must submit a notice of protocol closure. Submit sponsor closure correspondence through the electronic system.

Non-Compliance Issues

UVM PI or designated contact must submit allegations of non-compliance meeting the UVM reporting criteria. Complete the UVM IRB Unanticipated Problem ... form and submit through the electronic system.

Protocol changes which affect required consent language

Protocol changes that affect our required consent language must be submitted to the UVM IRB for review, prior to implementation. Submit electronically the sponsor correspondence regarding the protocol change along with revised local consent form for review and prior UVM IRB approval.

ONGOING MONITORING

Dependent upon the complexity and risk level of the protocol, the UVM IRB may develop a formal monitoring plan. This will be determined at Steps 2 and 5 above and communicated through the *Allowance to Begin Research Activities Reviewed by an External IRB* memo.

The External IRB may request that the UVM IRB conduct an investigation of any compliance-related issues that they discover. If so, we will follow the current monitoring policy located in the policy and procedures manual.

SERIOUS/CONTINUING NONCOMPLIANCE REVIEW PROCESS

UVM IRB will investigate issues of serious or continuing non-compliance independent of the External IRB, following the Noncompliance Policy and Procedures guidance. It is possible that the External IRB may investigate separately or the investigative process may be shared between the two IRBs.

The External IRB is responsible for reporting to applicable regulators and sponsors. The UVM IRB will report to the Institutional Officials and Department Chair.