At this time, the University of Vermont (UVM) will allow engaged UVM and UVMHN researchers to rely on an External IRB for multicenter, domestic, non-Exempt, human subjects research protocols **where the project has federal funding or single IRB is otherwise required**. Other requests may be considered on a case-by-case basis. This request is to be submitted as a new protocol through the [UVMClick- IRB System](https://irb.connect.uvm.edu/irb). Click instructions may be found [here](https://www.uvm.edu/ovpr/uvmclick-irb). In addition to this Request to Rely form, the submission must include:

* A Protocol approved by the External IRB
* External IRB-approved Consent (and HIPAA Authorization if applicable) template document(s) edited to include UVM required language (["Consent/HIPAA checklist for required language"](https://www.uvm.edu/rpo/uvmclick-irb-forms-library))
* [Data Management and Security Plan](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) (UVM-specific form)
* Any required reliance agreements, if not using an [approved Master Agreement](https://www.uvm.edu/rpo/single-irb)
* Any local context/site info forms required by the External IRB to be completed by the UVM IRB
* The initial, study-wide approval memo from the External IRB

|  |  |  |
| --- | --- | --- |
| **UVM PI** | | |
| Click or tap here to enter text. | | |
| **UVM Click Study Number and Title** | | |
| Click or tap here to enter text. | | |
| **Designated Contact Person for UVMHN/UVM research team** | | |
| *Who on your research team will manage matters related to UVM’s reliance on an external IRB?*  Click or tap here to enter text. | | |
| **Does the Principal Investigator have a significant financial interest related to this research?** | | |
| [University of Vermont Policy - Disclosing your significant financial Interest (SFI)](https://www.uvm.edu/sites/default/files/Sponsored-Project-Administration/What_is_a_Significant_Financial_Interest.pdf)  Yes  No | | |
| **External IRB Name** | | |
| Click or tap here to enter text. | | |
| **External IRB Federal wide Assurance (FWA). If no FWA put in N/A.** | | |
| Click or tap here to enter text. | | |
| **Does the External IRB request that UVM use the SMART IRB Master Reliance Agreement?** | | |
| Yes  No | | |
| **If using the SMART Agreement, does the External IRB request UVM use the Online Reliance System?** | | |
| *If the Online Reliance System will not be used to document reliance using the SMART Agreement, include the SMART IRB Letter of Acknowledgement in the UVMClick submission for UVM signature.*  Yes  No  N/A | | |
| **Will the External IRB also act as the HIPAA Privacy Board? (will they be making the determination as to whether written authorization or a waiver/alteration of authorization is appropriate)** | | |
| Yes  No | | |
| **Please provide a link to (or attach) the External IRB’s policies and procedures/SOPs.** | | |
| Click or tap here to enter text. | | |
| **Protocol-Specific Questions** | | |
| Date of initial, study-wide approval at lead site: Choose an item: | | |
| Identify overall level of study risk as determined by the External IRB. Choose an item: | | |
| What is the phase of the study (if it is a Clinical Trial)? Choose an item: | | |
| Subpart Determinations: Identify category or level of risk as approved by the External IRB for:   * Child Risk: Choose an item: * Prisoner Research: Choose an item: * Protections for Pregnant Women/Fetuses/Neonates: Choose an item: | | |
| Special Determinations: Identify the determinations made by the External IRB for:   * Device Risk: Choose an item: * Deception Risk: Choose an item: | | |
| **Consent and HIPAA Questions** | | |
| *Indicate which of the following consent processes are approved by the External IRB for UVM:* | | |
| Written Consent | Waiver of Documentation of Consent | Alteration of Consent |
| Waiver of Consent | Parental Permission | Child Assent |
|  | | |
| *Indicate which of the following HIPAA Authorization processes are approved by External IRB for UVM:* | | |
| Written HIPAA | Partial Waiver of HIPAA for Recruitment | Alteration of HIPAA |
| Waiver of HIPAA |  |  |
|  | | |
| *Does this protocol intend to use any of the following to obtain participant consent at UVM?* | | |
| Impartial Witness | Legally Authorized Representative | Exception from Informed Consent |
| Electronic Consent | Long Form Consent for Non-English Speaking Subjects | Short Form Consent for Non-English Speaking Subjects |
| **Ancillary Reviews** | | |
| *Prior to beginning any protocol activities under an external IRB, the local PI must ensure institutional approval or review is obtained from all applicable stakeholders. Check all that apply to this protocol:* | | |
| UVMMC Coverage Analysis and Billing Plan (any use of UVMHN resources, staff, patients, etc) | | |
| Radiation Safety Committee (any non-SOC exposure to ionizing radiation) | | |
| Institutional Biosafety Committee Review (protocols using biohazardous materials) | | |
| Clinical Research Center (protocols using CRC resources) | | |
| Protocol Monitoring and Review Committee (oncology protocols requiring PRMC submission) | | |
| Investigational Drug Services (protocols using approved or unapproved investigational products) | | |
| Other Ancillary Committees (e.g. UVMHN Privacy Officer, UVMHN Data Management Office) | | |