At this time, the only requests to rely that will be considered are for NIH-funded protocols. This request is to be submitted through the UVMClick- IRB System. You must complete the SMART form questions at both the Study and Site levels. The submission must include:

* Human Subjects Protocol – attached at Study Level
* This completed and signed form – attached at Site Level
* Sponsor Provided Consent Template Document(s) – attached at Site Level
* [Data Management and Security Plan](https://www.uvm.edu/rpo/human-subjects-research#IRB_Initial) (UVM-specific form) - attached at Site Level
* Any required reliance agreements – attached at Site Level

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| --- | --- | --- |
| **Study Title** | | |
| Click or tap here to enter text. | | |
| **Designated Contact Person for UVMMC/UVM research team** | | |
| Who on your research team will manage matters related to the reliance on an external IRB. (communication with both UVM IRB and external IRB)  Click or tap here to enter text. | | |
| **External IRB Federalwide Assurance (FWA)** | | |
| Click or tap here to enter text. | | |
| **Does the External IRB Request that UVM Use the SMART IRB System?** | | |
| Yes  No | | |
| **Will this External IRB also act as the HIPAA Privacy Board? (will they be making the determination as to whether written authorization or a waiver of authorization is appropriate)** | | |
| Yes  No | | |
| **Protocol-Specific Questions** | | |
| Identify level of risk as determined by External IRB. Choose an item. | | |
| What is the phase of study? Choose an item. | | |
| Written Consent | Waiver of Documentation of Consent | Waiver of Consent |
| Does this protocol intend to use legally authorized representatives to obtain subject consent? Yes  No | | |
| **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 | | |
| Radiation Safety Committee | | |
| Institutional Biosafety Committee Review | | |
| Other Ancillary Committees (e.g. waivers of HIPAA may require ancillary review by Privacy Officer.) | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of the UVMMC/UVM Principal Investigator Date | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of the Department Chair Date | | |