At this time, the only requests to rely that will be considered are for NIH-funded protocols. This request is to be submitted as a new protocol 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 approved by External IRB – attached at Study Level
* Sponsor Provided Consent Template Document(s) with required local content – 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

|  |
| --- |
| **UVM PI** |
|  |
| **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 Federal wide Assurance (FWA). If no FWA put in NA.**  |
| 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 study risk as determined by External IRB. Choose an item. |
| Identify level of child risk as determined by External IRB. Choose an item. |
| Identify level of device risk as determined by External IRB. Choose an item. |
| What is the phase of the study?  |
|  |
| **Consent and HIPAA Questions** |
| *Please indicate which of the following processes have been approved by the External IRB:* |
| Written Consent [ ]  | Waiver of Documentation of Consent [ ]  | Waiver of Consent [ ]  |
| Waiver of HIPAA [ ]  | Partial Waiver of HIPAA for Recruitment [ ]  | Alteration of HIPAA [ ]  |
| *Does this protocol intend to use any of the following to obtain subject consent:*  |
| Impartial Witness [ ]  | Legally Authorized Representative [ ]  | Child Assent [ ]  |
| 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 |
|  [ ]  Radiation Safety Committee |
|  [ ]  Institutional Biosafety Committee Review |
|  [ ]  Clinical Research Center |
|  [ ]  Protocol Monitoring and Review Committee |
|  [ ]  Investigational Drug Services |
|  [ ]  Other Ancillary Committees (e.g. waivers of HIPAA may require ancillary review by Privacy Officer.) |
|  |