**NOTE: Research Activities cannot begin at UVM until the PI has received an**

**“Approval to Begin Research Activities Reviewed by an External IRB” memo from the UVM IRB.**

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###### Submit completed form electronically to the UVM IRB once you have received approval from the External IRB. Include the following materials in the submission:

* + External IRB approval letter;
	+ Final approved protocol;
	+ Final approved local consent form(s) with HIPAA language;

Or IRB determination of waiver of consent and HIPAA;

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

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| --- |
| **Study Title** |
| Click or tap here to enter text. |
| **PI** |
| Click or tap here to enter text. |
| **Designated Contact** |
| Click or tap here to enter text. |
| **Institutional 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: |
| **a. UVM Medical Center Compliance Coverage Analysis and Billing Plan Approval** If this study involves any UVM Medical Center patients (including data and or specimens) or any equipment, facilities, supplies or personnel of UVM Medical Center, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff, a **Coverage Analysis and Billing Plan is required.** What is the status of the review? |
| [ ]  Not applicable |
|  [ ]  In progress |
|  [ ]  Complete |
| **b. Radiation Safety Committee**If the research involves the application of radioactive materials, radioisotopes, and/or radiation treatment to humans**or** involves application of imaging, excluding MRI and ultrasounds, for non- standard of care purposes *(not used for treatment or diagnosis, e.g. on UVM equipment or x-rays required for protocol purposes only)* **Radiation Safety Committee Review is required.**Confirm, by checking, that you have been in contact with either |
| [ ]  Not applicable |
|  [ ]  UVM’s Radiation Safety Committee |
|  [ ]  UVM Medical Center’s Radiation Safety Committee |
|  |
| **c. Institutional Biosafety Committee**If the research involves any work with biohazardous materials including but not limited to, infectious biological agents, toxins, pathogens, gene therapy or recombinant DNA, **Institutional Biosafety Committee review is required.** |
| [ ]  Not applicable |
|  [ ]  In progress |
| [ ]  Complete, provide the UVM assigned IBC protocol number. Click or tap here to enter text. |
| **Institutional Required Agreements** |
| Reliance on an External IRB requires, at a minimum, an executed Reliance Agreement prior to beginning research activities. However, other types of agreements may be necessary as required by either the sponsor or UVM/UVMMC. Check all agreements that apply to this protocol. |
| Type of Agreement  | Status of Agreement |
| [ ]  Reliance Agreement (SMART IRB)  | Institution has completed. |
| [ ]  Reliance Agreement (Western IRB)  | Institution has completed. |
| [ ]  Reliance Agreement (StrokeNet IRB)  | Institution has completed. |
| [ ]  Reliance Agreement (NCI CIRB)  | Institution has completed. |
| [ ]  Reliance Agreement (other list)  | Click or tap here to enter text. | Click or tap here to enter text. |
| [ ]  Clinical Trials Agreement  | Click or tap here to enter text. |
| [ ]  Subaward Agreement  | Click or tap here to enter text. |
| [ ]  Data Use Agreement  | Click or tap here to enter text. |
| [ ]  Material Transfer Agreement  | Click or tap here to enter text. |
| **Subject Information** |
| How Many Subjects Click or tap here to enter text. | Or how many records Click or tap here to enter text. |
| [ ]  Male [ ]  Female |
| [ ]  Adults, age range Click or tap here to enter text. | Or [ ]  Minors, age range Click or tap here to enter text. |
| [ ]  Healthy or [ ]  Persons with specific disorder described here Click or tap here to enter text. |
| **Protocol Information** |
| a. Does this protocol meet the NIH definition of a clinical trial? [ ] Yes [ ]  No |
|  *If yes, Good Clinical Practice Training applies. (*[*https://www.uvm.edu/rpo/frequently-asked-questions#GCP*](https://www.uvm.edu/rpo/frequently-asked-questions#GCP)*)* |
| b. If a clinical trial, indicate the phase. Choose an item. |
| c. Does this protocol require Clinical Trials.gov registration? [ ] Yes [ ]  No |
|  *For guidance, see* [*Clinical Trials Registration Information*](http://www.uvm.edu/~irb/ClinicalTrialRegistryInstruction.pdf)*.* |
| d. Type of Approved Consent Process (check which applies) |
| [ ]  Written Consent/HIPAA |
|  If written consent, is there more than one written consent document? [ ] Yes [ ]  No |
|  If yes, how many consent documents. Click or tap here to enter text. |
| [ ]  Waiver of Informed Consent/HIPAA |
| [ ]  Alteration of Informed Consent/HIPAA Procedures |
| [ ]  Waiver of Documentation of Informed Consent |
| **Location of Research Activities (check all that apply)** |
| [ ]  UVM Medical Center | [ ]  University Campus (specify below)  |
| [ ]  111 Colchester Ave | Click or tap here to enter text. |
| [ ]  ACC/Main Hospital | [ ]  Schools/School Systems (specify below) |
| [ ]  Clinical Research Center | Click or tap here to enter text. |
| [ ]  1 South Prospect (UHC) |
| [ ]  Other Medical Center Locations (list here) Click or tap here to enter text. |
| [ ]  Subject’s Home or Living Facility |
| [ ]  Subject’s Place of Work |
| **FDA Regulated Items** |
| Is the protocol FDA regulated? [ ] Yes [ ]  No |
| If yes, complete the section that applies to this protocol. |
| [ ]  **Investigational New Drug** |
| Name of Drug Click or tap here to enter text. Company Supplying Drug Click or tap here to enter text. |
| FDA IND Number Click or tap here to enter text. |
|  |
| [ ]  **Investigational Biologic** |
| *A biologic is a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from living organisms or their products and used as a diagnostic, preventive, or therapeutic agent.* |
| Name of Biologic Click or tap here to enter text. Company Supplying Drug Click or tap here to enter text. |
| FDA IND Number Click or tap here to enter text. |
|  |
| [ ]  **FDA-Approved Drug Used in an Investigational Manner for a Different Indication** |
| Name of Drug Click or tap here to enter text. Company Supplying Drug Click or tap here to enter text. |
| Is it exempt from an IND application? [ ] Yes [ ]  No |
| If yes, provide the [FDA exemption category](https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf)(ies) Click or tap here to enter text. |
| If no, provide the FDA IND Number Click or tap here to enter text. |
|  |
| [ ]  **Investigational Device** |
| Name of Device Click or tap here to enter text. Company Supplying Device Click or tap here to enter text. |
| Is it exempt from an IDE application? [ ] Yes [ ]  No |
| If yes, provide [FDA exemption category](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#ide_exempt)(ies) Click or tap here to enter text. |
| If no, provide the FDA IDE Number Click or tap here to enter text. |
| Is the Device Significant Risk (per FDA’s definition) [ ] Yes [ ]  No |
|  |
| **Financial Conflict of Interest** |
| Is there an Industry partner providing any financial or material (drugs, devices, testing) support. [ ] Yes [ ]  No |
| If no, skip to the Investigator Agreement Section. |
| If yes, answer the following questions.a. Do any members of the investigative team or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed $5,000 in any twelve month period? |
| [ ] Yes [ ]  No |
| b. Do any members of the investigative team or members of their immediate families have an equity interest that exceeds $5,000 in value or represents more than 2% ownership interest in the sponsoring entity? |
| [ ] Yes [ ]  No |
| c. Do any members of the investigative team or members of their immediate families have any intellectual property rights (inventorship, patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s), or other material(s) that will be involved in this research? |
| [ ] Yes [ ]  No |
| d. Do any members of the investigative team or members of their immediate families have any financial interests similar to those described in a.,b.,c., above in an entity other than the sponsor that would, to a reasonable objective observer familiar with such issues, appear to affect or be affected by the research being undertaken? |
| If yes to any of the above, answer the additional following questions.a. Does the FDA Financial Disclosure Form (3455) for the principal investigator or co-investigators disclose any conflicts that require a management plan? |
| [ ] Yes [ ]  No If yes, attach a copy of management plan. |
| b. Is disclosure to UVM of a financial interest for this project required for the principal investigator or co-investigators?  |
| [ ] Yes [ ]  No If yes, attach a copy of the disclosure. |
|  |
| **Investigator Agreement** |
| As Principal Investigator of this study, I assure the UVM IRB that the following statements are true:•I will not begin my research until I have received written notification of UVM IRB approval to begin research activities. •I will seek and obtain prior written approval from an IRB for any modifications in the proposal, including changes in procedures, co-investigators, etc. •All of the members of the research team have completed the applicable institutional credentialing processes required to conduct this research. •I will promptly forward any reportable adverse events and unanticipated problems to subjects or others that may occur in the course of this study. •I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to participation. •I will comply with all IRB requests to report on the status of the study. •I certify that the research team will collect only information essential to the study in accord with the HIPAA Minimum Necessary Standard and I will limit, to the greatest extent possible, access to the information. I assure that the information I obtain as part of this research including protected health information will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek prior IRB approval. •I will maintain records of this research according to applicable guidelines.  |