### Notification of Approval from External IRB

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

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

|  |  |
| --- | --- |
| **1.** | **Protocol Title** |
|  |  |
| **2.**  | **Principal Investigator (PI):** |  |
| **3.**  | **Designated Contact** |
|  | Contact Full Name |  | Email |  |
|  | Phone Number |  |
| **4. Institutional Ancillary Reviews** |
| **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?** |
|  | In Progress |
|  | Complete |
|  | Not applicable |
| **b.** | **Radiation Safety Committee** |
|  | If the research involves the application of radioactive materials, radioisotopes, and/orradiation 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  |
|  | UVM’s [Radiation Safety Committee](http://www.uvm.edu/~radsafe/?Page=rso.personnel.html) or |
|  | UVM Medical Center’s Radiation Safety Committee for review. |
|  | Not Applicable |
| **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.** |
|  | If applicable, provide the UVM assigned IBC protocol number. |
|  | Not Applicable |
| **5.** | 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) | Since we are a member of SMART IRB, the status is complete. |
|  |  | Reliance Agreement (Western IRB) | Since we contract with Western IRB, the status is complete. |
|  |  | Reliance Agreement (StrokeNET IRB) | Since we are a member of the Stroke Network, the status is complete. |
|  |  | Reliance Agreement (NCI CIRB) | Since we are a member of NCI CIRB, the status is complete. |
|  |  | Reliance Agreement (other, list) |  |
|  |  | Clinical Trials Agreement |  |
|  |  | Subaward Agreement |  |
|  |  | Data Use Agreement  |  |
|  |  | Other, list |  |
| **6.**  | Subject Information |
| Total Number of Subjects Locally |  |
| Note: This requested number should include all subjects who are expected to screen fail, drop, and/or number of tissues/data, etc.  |
| Are the participants |
|  | Male or |  | Female |
|  | Adults, provide age range |  |  or |  | Minors, provide age range |  |
|  | Healthy or |  | Persons with a specific disorder list disorder |  |
|  **7.** | Protocol Information |
|  **a.** | Study will begin (month/year) |  |
|  b. | 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>) |
| **c.** | If a clinical trial, indicate the phase. |  |
|  |  | Phase I |  | Phase II |  | Phase III |  | Phase IV |  | Not applicable |
| **d.** | Does this protocol require Clinical Trials.gov registration? |  | Yes |  | No |
|  | *For guidance, see* [*Clinical Trials Registration Information*](http://www.uvm.edu/~irb/ClinicalTrialRegistryInstruction.pdf)*.* |
| e. Type of Approved Consent Process (check which applies) |
|  | Written Consent |
|  | If written consent, is there more than one written consent document? |  | Yes |  | No |
|  If yes, how many consent documents. \_\_\_\_\_\_\_\_\_\_ |
|  | Waiver of Informed Consent |
|  | Alteration of Informed Consent Procedures |
|  | Waiver of Documentation of Informed Consent |
| **8.** | Location of Research Activities (check all that apply) |  |
|  | UVM Medical Center |  | University Campus (specify) |
|  |  | 111 Colchester Ave |  |  |
|  |  | ACC/Main Hospital |  | Schools/School Systems (specify) |
|  |  | Clinical Research Center |  |  |
|  |  | 1 South Prospect (UHC) |
|  |  | Other Medical Center Locations (list) |
|  |  |  |  |
|  |  | Other Location |  |
| **9.** | **Types of Procedures (check all that apply)** *(Please do not use the “other” option unless the procedure is not listed.)* |
|  | Survey (mail, telephone, in-person) |  | Blood drawing: |  |  |  |  |
|  | Medical exams/history |  | Tissue (obtained solely for research) |  |  |
|  | Deception **\*see below** |  | Surgery |  | Collection of Urine and/or Feces |
|  | Observation |  | Drug Administration |  | HIV Testing |
|  | Photographs |  | Device Use |  | Ultrasound (e.g. echocardiogram) |
|  | Audio taping or videotaping |  | Exercise |  | X-Rays (e.g. CT scan, DEXA, mammogram) |
|  | Interviews in person or by phone |  | Diet |  | Use of Radiation |
|  | Focus Groups |  | Pathology Specimens (retrospective) |  | Use of Radioactive substances |
|  | Review of prospective data |  | Genetic Materials (DNA) |  | MRI (for treatment studies) |
|  | Review of retrospective dataRecording Identifiable Data |  | Questionnaires |  | MRI (not for treatment studies)  |
|  |  | Diaries |  | Tissue (obtained for clinical purposes) |
|  | Electrocardiograms |  | Pregnancy Tests |  |  |
|  | Sensitive Data (criminal or sexual conduct, drug or alcohol conduct or use) | (specify): |  |
|  | Other (specify) |  |
| **10.** | FDA Regulated Items (check those that apply and complete) |
|  |  |
|  | a. Investigational New Drug |
|  | Name of Drug |  | Drug Company (Sponsor) |  |
|  | FDA IND Number |  |  |
|  | b. 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 |  | Drug Company (Sponsor) |  |
|  | FDA IND Number |  |  |
|  | c. FDA-Approved Drug Use in an Investigational Manner (i.e., different indication) |
|  | Name of Drug |  | Drug Company (Sponsor) |  |
|  | **\*If checked**, does its use meet all of the following conditions below for exemption from an IND? |
|  | Yes |  | It is exempt from filing an IND application and can be IRB reviewed. |
|  | No |  | PI must submit an IND application to the FDA prior to final IRB approval. |
| If available | FDA IND Number |  | Investigator Holding IND |  |
|  | All of the following conditions must be met for exemption from an IND. |
|  | 1. It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug; |
|  | 2. it is not intended to support a significant change in the advertising of the product; |
|  | 3. it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreased the acceptability of the risks) associated with the use of the drug product; |
|  | 4. it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively; |
|  | 5. it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and  |
|  | 6. it does not intend to invoke 21 CFR 50.24. |
|  |  |  |
|  | d. Investigational Device |
|  | Name Of Device |  | Manufacturer (Sponsor) |  |
|  | FDA IDE Number |  |  |
|  | Exempt from IDE? | Yes |  | No |  | If yes, list exemption category. |  |
|  | To be exempt from a IDE the device needs to fall into one of the following categories:1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.2. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of aprt 807 in determining substantial equivalence.3. A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing: (i) is noninvasive; (ii) does not require an invasive sampling procedure that presents significant risk; (iii) does not by design or intention introduce energy into a subject, and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.4. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.5. A device intended solely for veterinary use.6. A device shipped solely for research on or with laboratory animals and labeled in accordance with Sec. 812.5 (c).7. A custom device as defined in Sec. 812.3 (b), unless the device is being used to determine safety or effectiveness for commercial distribution. |
| **e. Device Risk Level** |
|  | Significant Risk (Per FDA definition)? | **Or** |  | Non-Significant Risk |
| f. \*\*List all (investigational and non-investigational) drugs and or devices here. |
|  | Investigational Drugs: |  | Investigational Devices: |
|  |  |  |  |
|  | Non-Investigational Drugs: |  | Non-Investigational Devices: |
|  |  |  |  |
| **11.** | **Conflict of Interest** |
|  | Is there an Industry partner providing any financial or material (drugs, devices, testing) support. |
|  |  | Yes If yes, continue. |  | No If no, skip to 13.  |
|  | **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? |
|  |  | Yes |  | No |  |
| **12.** | **If you answered “yes” to any question in number 11, answer question 12. Otherwise skip to 13.** |
|  | **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 the 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. |

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| **13. Agreement** |
| **Principal Investigator****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.
* 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.
 |
| x |  |  |  |
| Original Signature of PI |  | Date |
|  |  |  |