**Committees on Human Research**

**University of Vermont**

### Request for Change in Principal Investigator

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information. | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **A. IRB Protocol Information** | | | | | | | | | | | | | |
| **CHRMS** | | |  | **CHRBSS** |  | **#** |  | | **Current PI** |  | | | |
| **Protocol Title:** | | |  | | | | | | | | |
| **Do you want to remove the current PI from the study?** | | | | | | | |  | Yes |  | No |
| **If no, what is their new role?** | | | | | |  | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **B.** | | New Principal Investigator Information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | \*Principal Investigator (PI): | | | | | |  | | | | | | | | | | | | | | | | Degree: | |  | | | | |
|  | | Dept. |  | | | | | | | | | | | | Phone | | | |  | | | | | E-Mail: | |  | | | | |
|  | | Campus/Office Address: | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
|  | | PI’s Dept. Chair(s) | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
|  | | Is PI UVM Faculty?\* | | | | Yes | | | |  | | No | |  | | | Is PI UVM Medical Center Employee?\* | | | | | | | | Yes | |  | No |  |  |
|  | | Is PI UVM Employee only? | | | | | | | | | Yes | | |  | | | No |  | |  | |  | | | | | | | | |
|  | | Is the PI a | | Fellow |  | | Resident | | | | | |  | | | Or Student? | | | | |  | | If yes to any, complete Faculty Sponsor Section G. | | | | | | | |
|  | | Check graduate status if applicable: | | | | | | | | | | |  | | | Graduate | | | | |  | | Undergraduate | | | | | | | |
|  | | **\*NOTE:** Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If this person is not affiliated with either you must stop here and contact the RPO office for additional guidance. | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **C.** | | Training Requirements | | | | | | | | | | |
| **PLEASE DO NOT SUBMIT UNLESS THE PI HAS COMPLETED THE TRAINING REQUIREMENTS**  **All investigators are required to complete the Human Subjects in Research Training** [**https://www.uvm.edu/rpo/citi-program-training**](https://www.uvm.edu/rpo/citi-program-training) | | | | | | | | | |
| **Date of Human Subjects Completion:** | |  | |  | | | | |
| **GCP Training must also be completed if this study meets the NIH definition of a Clinical Trial.** | | | | | | | | | | | | | |
| *If you answer “Yes” to all four of the questions below, this study meets the definition of a Clinical Trial and GCP training is required.\*\** | | | | | | | | | | | | | |
| Does the study involve human participants? | | | | | | |  | Yes |  | No | |
| Are the participants prospectively assigned to an intervention? | | | | | | |  | Yes |  | No | |
| Is the study designated to evaluate the effect of the intervention on the participants? | | | | | | |  | Yes |  | No | |
| Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome? | | | | | | |  | Yes |  | No | |
| *\*\*If yes, the PI and all key personnel are required to complete*[*Good Clinical Practice training*](http://www.uvm.edu/rpo/citi-program-training#IRB)*.  Additionally, all Larner College of Medicine investigators/staff are required to complete Good Clinical Practice training* ***regardless*** *of whether the human subjects project meets the NIH clinical trial definition.* | | | | | | | | | | | |
| **Date of GCP Training Completion** | | | | |  | | Completions can be found [here](http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm). | | | |  |  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **D.** | Required Consent Changes | | | | | | |
| 1. Are you currently enrolling using a written consent form? | |  | Yes |  | No |
| *If yes, you must submit an amendment form along with the revised consent form. Attach both to this submission.* | | | | |
|  | | | | |
|  | | | | |
| 2. Are you currently handing out information sheets to subjects? | |  | Yes |  | No |
| *If yes, you must submit an amendment form and the revised information. Attach both to this submission.* | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| E. Disclosure of Financial Interest for the New Principal Investigator | | | | | | | | | | | | | | | | |
| **If yes, to any of the questions below, disclosure in the consent may be required by the Institutional Review Board (IRB) and you must also complete section F below. *Refer to the Research Manual for the IRB policy and the consent form language.*** | | | | | | | | | | | | | |
| **a.** Does the PI or any of his/her immediate family 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.** Does the PI or any of his/her immediate family 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 you or any of your immediate family 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.** Does the PI or any of his/her immediate family 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 | |  | |
|  | | | | | | | | |
| **F.** | **If you answered “yes” to any question in section E., answer the following questions.** | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **a.** Is an FDA Financial Disclosure Form (3455) required for the new principal investigator? | | | | | | | | | | | | | |
|  | | | Yes | | |  | No | | | | | | |
| *If yes, attach a copy. If disclosure is required and not attached, this request will be withheld until this is provided.* | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | |
| **b.** Is disclosure to UVM (any UVM Grant or Contract processed by SPA Pre-Award Services) of a financial interest for this project required for the new principal investigator? | | | | | | | | | | | | | |
|  | | | Yes | | |  | No | | | | | | |
| *If yes, attach a copy. If disclosure is required and not attached, this request will be withheld until this is provided.* | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | |
| **c.** Is disclosure to UVM Medical Center (any Clinical Trial Contract or Agreement processed through OCTR) of a financial interest for this project required for the new principal investigator? | | | | | | | | | | | | | |
|  | | | Yes | | |  | No | | | | | | |
|  | | | | | | | | | | | | | |
| **d.** Provide the names of all individuals with potential conflicts with a description of their roles and activities in this project, e.g., determine eligibility, recruitment, obtain consent, data analyses, conduct study procedures (describe), etc. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **e.** What is the amount (dollar value) and nature of the conflict (consulting fees, serving as director or on advisory board, intellectual property royalties, etc.)?, conduct study procedures (describe), etc. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **f.** Describe how the project outcome may or may not affect this financial interest, e.g., a good result would lead to more consulting or a product that I have invested in may appear more effective and have higher sales. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **g.** What actions do you think are appropriate to reduce or manage any potential harmful effects on human subjects arising from the potential conflict? Consider actions to preserve scientific objectivity, guard against coercive recruiting, objectively determine subject eligibility, etc. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **h.** Please provide any additional information that may be helpful to the IRB in reviewing the potential conflict. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **G. AGREEMENT - NEW PRINCIPAL INVESTIGATOR** | | | | | | | | | | | | | | | | | | |
| **As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:  The information that is provided in this form is correct. I will seek and obtain prior written approval from the 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 not begin my research until I have received written notification of IRB approval. 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 PHI 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. If I am seeking IRB approval for a sponsored project, I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in this application. Agreement allows invoicing and collection of IRB review fees. | | | | | | | | | | | | | | | | | | |
| x | | | | |  | |  | | | | | |  | | | | | |
| Signature of New PI | | | | |  | | Date | | | | | | | | | | | |
|  | | | | |  | |  | | | | | | | | | | | |
| Printed Name | | | | |  | |  | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | |
| **FACULTY SPONSOR (If New Principal Investigator is non-faculty, this section needs to be completed by the faculty.)** | | | | | | | | | | | | | | | | | |  |
| *A non-faculty researcher includes, but is not limited to, any of the following: fellow, resident, post-doctoral fellow, post-doctoral associate, post-doctoral trainee, and any student (graduate or undergraduate). Non-faculty researchers cannot conduct human subject research without having a faculty sponsor or faculty course instructor who is responsible for overseeing the conduct of the research activities. The faculty sponsor must be employed by the institution (UVM or UVM Medical Center) and these duties must fall within their role.* | | | | | | | | | | | | | | | | | | |
|  | | | | |  | |  | | | | | | | | | | | |
| Advisor’s Name: | |  | | | | Telephone Number: | | | | | |  | | | | | | |
|  | | | | | |  | |  | | | | | | | | | | |
| Dept. Address | |  | | | | E-mail | | | |  | | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| Is there is a thesis or dissertation committee reviewing this research? | | | | | | | | | | | Yes | | |  | No |  |  | |
| If yes, date of approval: | | |  |  | | | | | | | | | | | | | | |
| **As the faculty sponsor for this protocol,** I certify that the student will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all University of Vermont and Federal Regulations relating to human research as outlined above and in the Human Subjects Research Manual. | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| x | | | | |  | | | |  | | | | | | | | | |
| Original Signature of Faculty Sponsor | | | | |  | | | | Date | | | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| Printed Name | | | | |  | | | |  | | | | | | | | | |