###### The University of Vermont Committees on Human Research

### Initial Review of an Administrative Tool

### or Projects to be Developed

*Administrative Tool review is recognized by the IRB only as a compilation of research being conducted under a specific grant. It does not constitute a review of the risk/benefit ratio of protocols to be conducted under it. Those protocols (including informed consent documents) must be submitted for IRB review and approval separate from this request. The grant will also be reviewed and approved with the separate protocol submissions.*

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| **1.** | | | | **PROJECT TITLE** | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **2.** | | | | **PRINCIPAL INVESTIGATOR INFORMATION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | Principal Investigator (PI): | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | Degree: | | | | | | |  | | | | | | | | | | | | | | | |
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|  | | | | Dept. | | | | |  | | | | | | | | Phone: | | | | |  | | | | | | | | | E-Mail: | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Campus/Office Address: | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Fax | | | | | | | |  | | | | | | |
|  | | | | 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 PI a Fellow, Resident, or Student? | | | | | | | | | | | | | | | | | | | Yes | | | | |  | | No | |  | If yes, complete number 6 below. | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | Please check graduate status if applicable: | | | | | | | | | | | | | | | | | | |  | |  | | Graduate | | | | | | | |  | | Undergraduate | | | | | | | | | | | | | | | | | | | |
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|  | | | | **DO YOU WANT TO APPOINT A PRIMARY CONTACT OTHER THAN PI?:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | | | | | |  | | No | | | | |  | |
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|  | | | | Investigators wishing to appoint a contact for **all** IRB communications related to this protocol should complete the contact information requested below. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Contact Full Name | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Department / Address | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Campus Phone Number/Pager | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Fax Number | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Email | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **3.** | | | **SOURCE OF SUPPORT** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | Name of Funding Agency | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | InfoEd Proposal # | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Funding Agency Grant Number | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | What is the status of the grant? | | | | | | | | | | | |  | | Awarded | | | | | | |  | | Pending | | | | |  | | | | | Just in Time Request | | | | | | | | | | | | | | | | | | | | |
|  | | | | | If the award is pending or Just-In-Time, do you intend to begin research activities prior to obtaining the funding? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | Yes | | | | | |  | | | | No | | | | | | | |
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|  | | | | |  | | Attach corresponding grant proposal. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **4.** | | | | **Is this review request for** (check applicable) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | **Individual Training Grant** (salary support only –research activities occurring under separate approved protocol(s)) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | **Program Project** (all research activities occurring under separately submitted protocols) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | **Grant when the research has yet to be developed.** (no research activities contained within the initial grant submission) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | ***If this is checked, skip to #6.***  ***\*Note: When the human subject research activities are developed, you must submit a human subject protocol for review and approval prior to the research activities beginning.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **5.** | | | **List the IRB Protocols**  List the IRB#, study PI, the study titles and the corresponding grant page numbers, associated with this Administrative Tool. If the protocols are yet to be developed, indicate the anticipated number of protocols to be submitted at a later date in the chart below. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | **IRB #** | | | | | | | **PI** | | | | | **Study Title** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Grant Page Number \*** | | | | |
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|  | | | \* provide the page number in the grant where the study is mentioned | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| **6. AGREEMENTS** | | | | | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR**  **As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:   |  |  | | --- | --- | |  | I understand that Review of an Administrative Tool or Projects to be Developed is recognized by the IRB as,  1. A compilation of research being conducted under a specific grant or,  2. A grant which has no human subject activities at the time of award.  It does not constitute a review of risk/benefit in human subject research. | |  | |  | |  | I understand that protocols must be submitted for IRB review and approval separate from this request. | | | | | | | | | | | | | | | | | | | |
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| Original Signature of PI | | | | |  | | Date | | | | | | | | | | | |
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| **FACULTY SPONSOR (if applicable and referenced on page one, section 2, of this form)** | | | | | | | | | | | | | | | | | | |
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| Name: |  | | | | | Phone: | | | | | |  | | | | | | |
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| Date of Human Subjects Tutorial Completion | | | | |  | | | | | |  | | | | | | | |
| ***Policy Statement from the Research Manual:*** *“As the responsible investigator, the faculty sponsor or course instructor is required to complete the Human Subjects in Research tutorial. Protocol approvals will not be released until that requirement has been met.” Completion of this requirement is every three years. More information on required training can be found at* [*http://www.uvm.edu/irb/?Page=training\_faqs.html*](http://www.uvm.edu/irb/?Page=training_faqs.html) | | | | | | | | | | | | | | | | | | |
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| 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. | | | | | | | | | | | | | | | | | | |
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| Original Signature of Faculty Sponsor | | | | |  | | | | Date | | | | | | | | | |
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