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

###### Request for Determination of “*Not Research*”

### For Assessing Projects such as Quality Assurance, Quality Improvement, Program Evaluation,

### or Public Health Practice

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| **1.** | | **Protocol/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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| **3.** | | **Source of Support** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Is there any external funding for this project? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | | | |  | | | No | |  | |
|  | | | If “Yes”, provide Sponsor Name | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| **4.** | **Does this project meet the definition of “*research”***?  Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.  Quality Assurance/Quality Improvement, Program Evaluation or Public Health Practice projects are conducted to assess a process, program or system with the intent to improve that same process, program or system **or** primary intent to identify/control a health problem. Many of these projects also may contain elements of research. Information usually will be shared beyond those involved in or overseeing the program/process/system. Intent to publish is an insufficient criterion alone for determining if a project is research. There are other purposes for publishing descriptions of non-research activities, e.g., QI projects are often disseminated outside the institution for the purpose of sharing the process (the QA/QI methodology) not the health care outcomes or implications. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | **Answer all of the following questions to help us confirm this project does not meet the definition of research:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | 4.a. | | | | Is the activity intended to generate new knowledge that will contribute to the scientific literature (i.e., that revises or improves upon an existing principle, theory, or knowledge)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | **No** | |  |
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|  | 4.b. | | | | Are any of the project activities experimental, i.e., is there any testing of new or unproven treatments or strategies that are not yet known to be efficacious? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | **No** | |  |
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|  | 4.c. | | | | Are the participants in the activity randomized to an intervention so that results of the activity can be generalized to a larger population? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | **No** | |  |
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|  | 4.d. | | | | Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | **No** | |  |
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|  | 4.e. | | | | Is there an evaluation/performance assessment as part of your project that is designed to develop or contribute to generalizable knowledge (info will be shared beyond those involved in or overseeing the program/process/system?) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Yes** | | | | |  | | **No** | |  |
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|  | If you answered “Yes” to ***ANY*** of the questions in number 4 above - **STOP!!!** Do not submit this form!!! This project meets the definition of “research” and if it involves “human subjects” it requires further IRB review. Refer to our Research Manual, Section 7, to identify which type of IRB review is required and the corresponding submission process. If you are unsure if this project involves human subjects, see the flow chart: *Assessing whether there are “Human Subjects” in Research* (link). If you believe your “research project” does NOT involve “human subjects” you can complete and Submit the *Request for Determination of “Not Human Subjects*” *Research* form to the IRB  If you answered “No” to ***ALL*** of these questions, this project is not research. To obtain a formal IRB determination of “not research”, CONTINUE to complete the remainder of this form and submit. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **5.** | **Lay Language Summary:***(Use non-technical language that would be understood by nonscientific IRB members to summarize the proposed project. The information must include: (1) objectives or aims, and (2) a brief but specific description of procedure(s). Do not exceed one single-spaced 8 ½ X 11” page.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **6. AGREEMENTS** |

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| **PRINCIPAL INVESTIGATOR**  As Principal Investigator of this study, I assure the Committees on Human Research that theinformation that is provided in this form is correct. | | | | | | |
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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)** | | | | | | |
| As the faculty sponsor for this project, I certify that the student will conduct this project under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this project. | | | | | | |
|  |  |  | | | |  |
| Signature of Faculty Sponsor |  | Date | | | | |
|  |  |  | | | | |
| Printed |  | Email and Phone | | | | |
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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.