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

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

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| **1.** | **Protocol/Project Title** |
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| **2.** | **Principal Investigator Name** |
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| **3.**  | **Lay Language Summary:***(Use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) objectives or aims, and (2) a brief but specific description of procedure(s).*  |
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| **4.** | **Determination Questions** |
|  | 1. **Does the activity involve research?**
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| Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.  |
|  |  | Yes |  | No |  |  | Unsure |
|  | **If yes,** continue.**If** **no, stop** – the IRB only reviews projects that meet the definition of research.  |
|  |  |
|  | **b. Does the research involve obtaining information *about living individuals* OR using or receiving specimens obtained *from living individuals?*** |
|  |  | Yes |  | No |
|  | **If yes,** continue.**If no, stop.** Please refer to the [Decedent Form](https://www.uvm.edu/rpo/uvmclick-irb-forms-library). |
|  |  |
|  | **c. Does the research involve *intervention* or *interaction* with the individuals by the researcher or any key personnel?** *(includes communication and/or physical contact, e.g. obtaining informed consent, or data and/or specimens directly from the individual for the research)* |
|  |  | Yes |  | No |  |
|  | **If yes, stop.** Cannot be considered Not Human Subject Research, contact the office for guidance on submission requirements.**If no,** continue. |
|  |  |
|  | **d. Does the research include *private* information (data/specimens) about the individual?** *(i.e. individual would reasonably expect no recording/observation or would not expect information to be shared/made public)* |
|  |  | Yes |  | No |  |
|  | **If yes,** continue.**If no, stop.** This would be considered Not Human Subject Research, but the IRB will make that formal determination. Submit through Click-IRB.  |
|  |  |
|  | **e. Are the data or specimens *individually identifiable***? *(e.g., is there a code or other method that could potentially connect the subject’s identity with the associated information or specimen)* |
|  |  | Yes |  | No |
|  | **If no, stop.** This would be considered Not Human Subject Research, but the IRB will make that formal determination. Submit through Click-IRB. **If yes,** describe the data being collected/used as well as the source of the data. If the data is coming from an existing approved protocol provide the IRB number. |
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|  | **f. Are you as the “*recipient”* able to link the data/specimens directly to identifiable living individuals?** *(e.g., will you have either direct identifiers or the key to a code)* |
|  |  | Yes |  | No |
|  | If yes, stop. Cannot be considered Not Human Subject Research, contact the office for guidance on submission requirements. If no, continue. |
|  |  |
|  | **g. Is the “*provider” of the data/specimens considered “engaged”* in the protocol** *(engaged typically means that the person is listed as key personnel, is a collaborator in your research, or is conducting informed consent for obtaining the data or specimen****)*** |
|  |  | Yes |  | No |  |
|  | **If yes, stop.** Cannot be considered Not Human Subject Research, contact the office for guidance on submission requirements.**If no,** continue. |
|  |  |
|  | **h. Can the “*provider*” link the data/specimens directly to identifiable living individuals?** |
|  |  | Yes |  | No |  |
|  | **If no**, **stop**. This would be considered Not Human Subject Research, but the IRB will make that formal determination. Submit through Click-IRB. **If yes, continue.** |
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|  | **i. Are there protections in place that will prohibit the “*provider”* from releasing identifiers to you?** *(e.g., will the key to decipher any existing codes be destroyed, is there an agreement in place between the provider and you to prevent release of the key, is there law preventing release, etc.)* |
|  |  | Yes |  | No |  |
|  | **If no, stop**. Cannot be considered Not Human Subject Research, contact the office for guidance on submission requirements.**If yes, continue.** |
|  |  |
|  | j. Indicate below how you are prevented from ascertaining identities from the “*provider”*: |
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|  | The key to decipher the code is destroyed before the research begins; |
|  | The investigators and the holder of the key enter into an agreement prohibiting the release of the key to |
|  | the investigators under any circumstances, until the individuals are deceased; |
|  | There are IRB-approved written policies and operating procedures for a repository or data with the  |
|  | management center that prohibit the release of the key to the investigators under any circumstances, |
|  | until the individuals are deceased; or |
|  | There are other legal requirements prohibiting the release of the key to the investigators, until the  |
|  | individuals are deceased. |

**Attach this completed form to the eClick submission under section 10.**