The University of Vermont

Research Protections Office

Introductory and Demographics

Research Not Involving Human Subjects Self-Determination

Projects that do not involve research nor involve human subjects *(as defined by the regulations)* do not require prior IRB review and approval. A determination of research that does not involve human subjects is fairly straightforward and can be self-determined using this IRB-approved determination tool. Upon completion of the survey, you will receive an email that provides the final determination for your records. Please review the Research Not Involving Human Subjects Determination Tool (PDF) in its entirety to prepare yourself for the questions that will posed to you.

Regulatory Definitions

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

- **Systematic:** an activity that is planned in advance and that uses data collection and analysis to answer a question

- **Generalizable knowledge:** information that expands the knowledge base of a scientific discipline or other scholarly field of study

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information

- **Intervention:** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.
- **Interaction:** includes communication or interpersonal contact between investigator and participant
- **Private Information:** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

1. Provide the name of the project.

2. Provide a brief summary of the project.

3. Provide your full name and any credentials you would like to appear on the certification.

4. Provide your email to receive a record of self-determination of Research Not Involving Human Subjects.

5. Provide the sponsor (if departmental, enter "internal")

Self-Determination Questions

6. Does the activity involve research that requires IRB review? *(Not all research requires IRB review. Research is defined in the regulations as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research projects that are Quality Improvement, Program Evaluation or Public Health Service based do not require IRB review.)* **If you are not sure or you have indicated "no", please complete the Research Not Requiring IRB Review Determination to assist and document your determination.**

- ○ Yes
- ○ No

You have indicated that this activity is not research that requires IRB review. Upon completion of this survey, you will receive an email with this determination for your records.

Click on green next button to complete survey and receive documentation of this self-determination.

7. Does the research involve obtaining information about **living individuals** or using or obtaining specimens (does not include de-identified surgical procedure tissue that is discarded) from **living individuals** ?

- ○ Yes
- ○ No

This is research that does not involve human subjects as defined in the regulations. IRB review is not required, however there may be protected health information implications. Upon completion of this survey, you will receive an email with this determination and HIPAA privacy contact information.

8. Does the research involve intervention or interaction with the individuals by either yourself or your study key personnel (*includes communication (in person or electronically) and/or physical contact, e.g. obtaining informed consent, or data/and or specimens directly from the individual for the research)?*

- ○ Yes
- ○ No

9. Will you be able to readily link the data or specimens that you receive directly to identifiable living individuals (*will you have either direct identifiers or the key to the code)? (Readily identifiable does not mean potentially identifiable or identifiable with substantial effort).*

- ○ Yes
- ○ No

10. Is the person or entity providing the data or specimens engaged in the project (*provider listed as key personnel, collaborator in the research, or*

obtaining informed consent)?

- ○ Yes
- ○ No

11. Is the person or entity providing the data or specimens able to link those data or specimens directly to identifiable living individuals?

- ○ Yes
- ○ No

12. Are there protections in place that will prohibit the person or entity providing the data or specimens to you from also releasing the identifiers to you?

Allowed protections: the key to decipher any existing codes is destroyed prior to research activities, an agreement is in place between the person or entity providing the data/specimens and the researcher that identifiers will not be shared, the person or entity that is providing the data/specimens is bound by law to not release identifiers, e.g., ATCC and TriNetX.

- ○ Yes
- ○ No

This is **research that involves human subjects as defined by the regulations and thus requires submission to the IRB** for review and

approval. Upon completion of this survey, you will receive an email with this determination for your records.

Click on green next button to complete survey and receive documentation of this self-determination.

This is **research that <u>does not involve human subjects as defined by the regulations, therefore</u>,** IRB review is not required. Upon completion of this survey, you will receive an email with this determination for your records.

Click on green next button to complete survey and receive documentation of this self-determination.