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. Click here for a pdf of the entire survey tool.

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.

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

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

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

Self-Determination Questions

Does the activity involve research? (Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.)

- [ ] Yes
- [ ] No
You have indicated that this activity is not research. Activities that do not meet the federal definition of research do not require prior IRB review and approval. Upon completion of this survey, you will receive an email with this determination for your records.

*If you believe your activities better align with Quality improvement, Program Evaluation or Public Health Surveillance, please go to https://www.uvm.edu/rpo/forms/research-not-requiring-irb-review, where you can find additional information and a "Research Not Requiring IRB Self-Determination Tool."

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

Does the research involve obtaining information about **living individuals** or using or obtaining specimens 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.
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

Will you be able to 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)?

☐ Yes
☐ No

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

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

This is **research involving human subjects and 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 does not involve human subjects**. 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.