ASSESSING WHETHER THERE ARE “HUMAN SUBJECTS” IN RESEARCH

Does the activity meet the definition of research (see “Assessing Whether Project is Research” to determine if the activity is research)?

YES ➔

Does the research involve obtaining information about living individuals or using or obtaining specimens from living individuals?

YES ➔

Does the research involve intervention or interaction with the individuals by the researcher or 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 ➔

Does the research involve private information (i.e. individual would reasonably expect no recording/observation or would not expect information to be shared/made public) or individually identifiable specimens?

YES ➔

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)?

NOTE: For data/specimens from a provider (person or entity that is providing the data or specimens) who is prohibited from releasing identifiers to the recipient (you as the receiving researcher) or for human cell lines obtained from a commercial provider, the answer is “NO” - Not Human Subjects.

YES ➔

Are you as the recipient (researcher(s)) able to link the data/specimens directly to identifiable living individuals (e.g., will you (the researcher) have either direct identifiers or the key to a code)?

YES ➔

Is the provider of the data or specimens engaged in the project (engaged typically means the person is listed as key personnel, is a collaborator in your research, or is obtaining informed consent)?

YES ➔

Can the provider (person or entity providing the data or specimens to the researcher) link the data/specimens directly to identifiable living individuals?

YES ➔

NOT HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination

See Website for more info: http://www.uvm.edu/irb/

YES ➔

Are you as the recipient (researcher(s)) able to link the data/specimens directly to identifiable living individuals (e.g., will you (the researcher) have either direct identifiers or the key to a code)?

NOT HUMAN SUBJECTS RESEARCH and thus requires submission of the Request for Determination of “Not Human Subjects” Research Form for the decision to be made by the Research Protections (IRB) Office

See Website for more info: http://www.uvm.edu/irb/

NO protections are in place that prohibit the provider from releasing identifiers to the recipient.

There are protections in place that will prohibit the provider from releasing identifiers to the recipient (e.g., key to decipher code to be destroyed, agreement in place preventing release of key, law preventing release, etc.)

NO ➔

NO ➔

NO ➔

NO ➔

NO ➔