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 (obtaining specimens from a subject is interpreted as being "about" a living individual)?

NO → Your project may not be considered "**research.**" Complete the *Request for Determination of "Not Research"* Form and Submit to the IRB for official determination.

Does the research involve obtaining information ***about living*** individuals (obtaining specimens from a subject is interpreted as being "about" a living individual)?

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)?

NO → **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/

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YES → HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination

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NO → 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.

NO → **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

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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 → HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination

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NO → 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 → HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination

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NO → Can the ***provider*** (person or entity providing the data or specimens to the researcher) link the data/specimens directly to identifiable living individuals?

YES → 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 → **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

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NO protections are in place that prohibit the ***provider*** from releasing identifiers to the ***recipient.*** → HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination

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