Will you, a member of your research team or a collaborator observe, interact with, or intervene with individuals to gather information that will be used for research?

Examples:
- Surveys, questionnaires, focus groups, interviews
- Games, experiments in physical or in electronic environments
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures
- Diet, nutrition studies, taste tests
- Studies examining effectiveness of educational tools or curricula
- Use of instruments or devices, including phones, to collect data or monitor or influence behavior
- Passive observation of public behavior (in physical or online environments, including social media)
- Studies examining individuals’ responses to manipulation of their physical or online environment
- Another activity that involves observation of, or interaction with, individuals to gather information for research

NO, research will use only existing data

The focus of the project is only on products, methods, policies, procedures, organizations: e.g., interviewing transportation staff and officials about parking or transportation policies and procedures.

Refer to IRB Decision Tree #2 on Existing/Secondary data

Not human participant research. No application to the IRB office is needed.

Is the sole intent of the project to meet course requirements, with no intention to use the results for something other than the course assignment?

YES

Is the project an oral history, ethnographic, or journalistic piece?

NO

YES

Does the project involve stories that will or may draw broad conclusions about the population, cultures, norms and practices; even if no research hypothesis is being tested or validated?

NO

YES

Published materials will be limited to only documenting or reporting on events, situations, policies, institutions or systems without the intent to form hypotheses, draw conclusions, or generalize findings.

Not human participant research. No application to the IRB office is needed.

YES

Outcomes will remain specific to the organization, programs or services, although other organizations may use the results for their own programs.

Project is research with human subjects.
An application to the IRB office and written notice of approval required before the study can begin.
Questions? Contact sponsored.programs@millersville.edu
Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require Review by the Millersville University IRB Committee?

Decision Tree #2

**Are the data/specimens about or from individuals who are or may be still living?**

**NO.** Materials are from cadavers, or data is about deceased individuals

**Project is Not Human Subjects Research**
No application to the MU IRB office needed* 

**NO.** Data is de-identified

Can the *provider* link the specimens/data, directly or indirectly, to identifiable living individuals?

**NO.** Provider is solely providing, with no role in the research

**YES**

Can the *recipient* link the specimens/data directly to identifiable living individuals either directly or through a code?

**NO**

Is the *provider a collaborator in the recipient’s research?* i.e. involved in the design, conduct or reporting of the research, listed as collaborator on research proposals or protocols, planned sharing of authorship credit.

**YES, recipient and provider are collaborators on the research**

**YES.** Data is publically available

Are the specimens (human cell lines, tissue, etc.) obtained from a producer or supplier of public use data; or

• Is all the information about the specimens/data available in the public domain?

**NO**

Were/will the specimens/data (be) collected specifically for the research through an interaction or intervention with living individuals?

**YES**

Project is Human Subjects Research
Application to the IRB office and written notice of approval or notice of exemption required before research can begin.

**NO**

Recipient has access to identifiable data

Can the *recipient* link the specimens/data, directly or indirectly, to identifiable living individuals?

**NO**

Data is de-identified

**YES**

Can the *provider* link the specimens/data, directly or indirectly, to identifiable living individuals?

**NO**

*Contact the MU Office of Sponsored Programs (www.millersville.edu/spra/irb) if acquiring the data requires a Data Use Agreement or a Materials Transfer Agreement between the provider and recipient.

**Reference:**