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**

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.

**YES**

Is the information being collected ‘about’ individuals?

**NO**

The focus of the project is on people or their opinions, perceptions, choices, decisions regarding themselves or how methods, policies, procedures, organizations etc. affect them or their environment.

**YES**

Is this a class project?

**NO**

Is this a pilot study?

**YES**

Will outcomes be generalized for other organizations, programs or services?

**NO**

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

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**NO**

Results of this type of pilot will not contribute to generalizable knowledge. Investigators should still take care with participants (e.g., informed consent, data security). **NOTE:** Consult with the IRB Office if your pilot will involve vulnerable populations or more than minimal risk research.

Is the purpose of the pilot to serve as a small scale (<10) feasibility study, with no intent to use the findings as research data?

**YES**

The project may lead to use of the results outside of the course (e.g., for a publication, presentation, thesis, or dissertation).

**NO**

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?

**YES**

The project may lead to use of the results outside of the course (e.g., for a publication, presentation, thesis, or dissertation).

**NO**

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**

Non human participant research. No application to the IRB office is needed.

**NO**

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.

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

**NO**

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

**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?

**YES**

Project is research with human subjects. An application to the IRB office and written notice of approval required before the study can begin. Forms available at researchservices.cornell.edu. Questions? Contact irbhp@cornell.edu

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

**NO**

Research will use only existing data

Refer to IRB Decision Tree #2 on Existing/Secondary data
Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require Review by the Cornell IRB Office?

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 Cornell IRB office needed*

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.

Forms at researchservices.cornell.edu

Questions? Contact irbhp@cornell.edu

NO

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

NO

Was/will 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

NO.

Provider is solely providing, with no role in the research

*Contact the Cornell Office of Sponsored Programs if acquiring the data or specimens will require a Data Use Agreement or a Materials Transfer Agreement between the provider and recipient.

Reference: