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 on products, methods, policies, procedures, organizations: e.g., interviewing transportation staff and officials about parking or transportation policies and procedures.

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

Is this a class project?

NO

Is this a quality assurance/quality improvement/organizational effectiveness study? I.e. to assess, improve, or develop programs or services for an organization?

YES

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

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.

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

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?

NO

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

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

YES

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

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

Project is research with human subjects. An application to the IRB office and approval required before the study can begin.
Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require IRB Review?  
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 IRB application needed*

NO. Data is de-identified

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

YES

Project is Human Subjects Research
An IRB Application is required before research can begin.

NO

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

Can the provider 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 has access to identifiable data

YES, recipient and provider are collaborators on the research

*Contact the Wright State IRB if acquiring the data requires a Data Use Agreement or a Materials Transfer Agreement between the provider and recipient.

Reference:
"Research Involving Private Information or Biological Specimens Flowchart", National Institute of Health (NIH), January 2006
Developed by Cornell University IRB, https://researchservices.cornell.edu/offices/IRB