Do I need to submit an IRB application?

Adapted from: https://researchservices.cornell.edu/sites/default/files/2019-05/IRB%20Decision%20Tree.pdf

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 → **Contact WCU IRB Co-Chairs with questions.**

YES ↓

Is the information being collected about individuals?

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

YES ↓

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.

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Is this a class project?

— **YES** → Is the sole intent of the project to meet course requirements, with **no intention to use the results in any other way? AND meets WCU course-based research policy requirements?**
  - **YES** → Not human participant research. No application to the IRB office is needed.
  - **NO** → The project may lead to use of the results outside of the course (e.g., for a publication, presentation, thesis, or dissertation). → **YES** → Project is research with human subjects.

NO ↓

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

— **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** ↓ 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** → Project is research with human subjects.

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** → 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** → Project is research with human subjects.

NO ↓

Is this a pilot study?

— **YES** → 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** → 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.** → **Not human participant research. No application to the IRB office is needed.**
  - **NO** → Project is research with human subjects.

NO ↓

Project is research with human subjects.
An application to the IRB office and written notice of approval required before the study can begin.
Questions: IRB@wcupa.edu or Email WCU IRB Co-Chairs.