Does Your Project Require an Application to the Cornell IRB Office?
Decision Tree #1

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

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.

Is this a **class project**?

YES → 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?**

NO → The project may lead to use of the results outside of the course (e.g., for a publication, presentation, thesis, or dissertation).

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

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.**

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 → 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.**

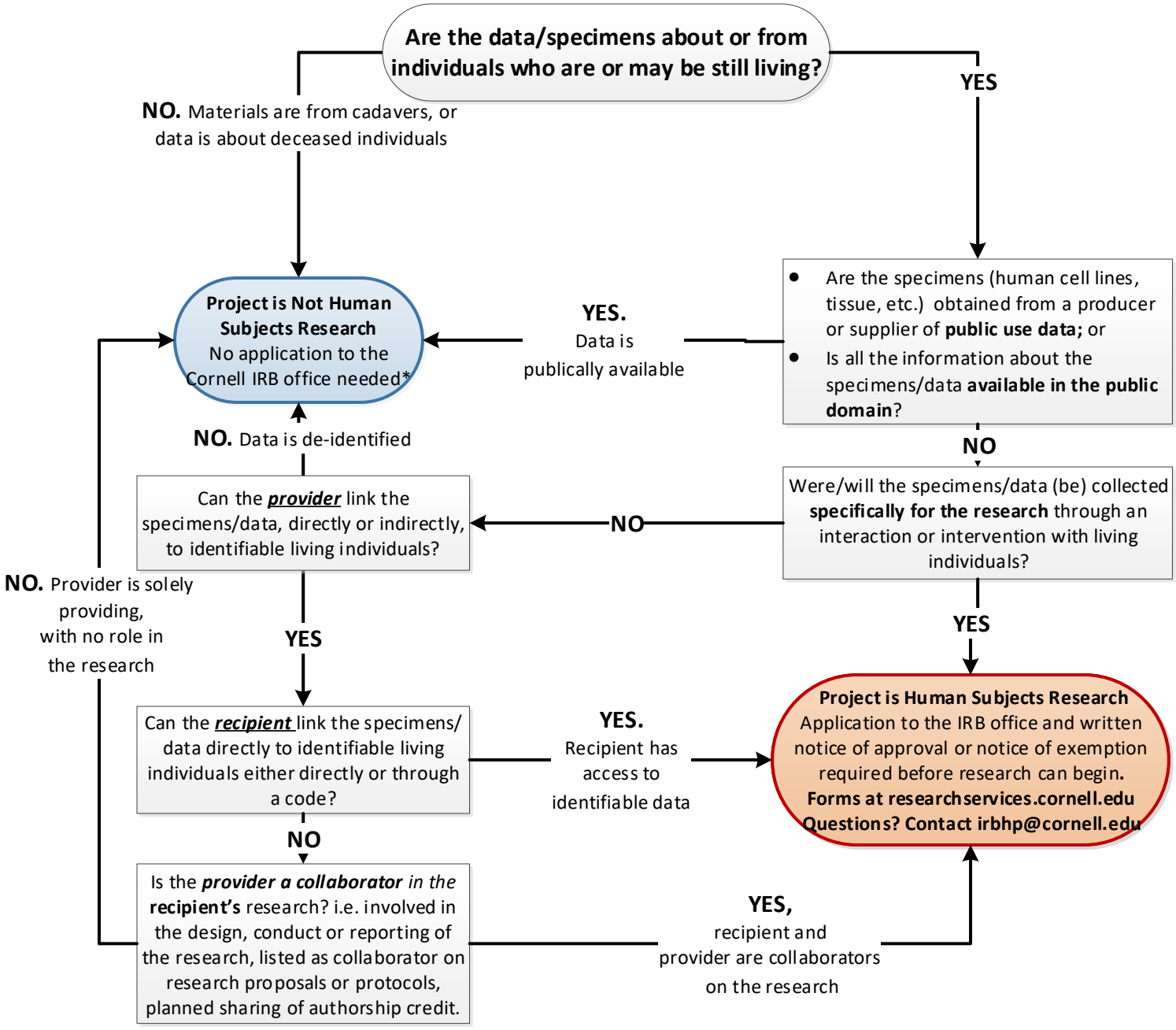
NO

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**?

NO → **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

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



*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:

"Research Involving Private Information or Biological Specimens Flowchart", National Institute of Health (NIH), January 2006, https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf