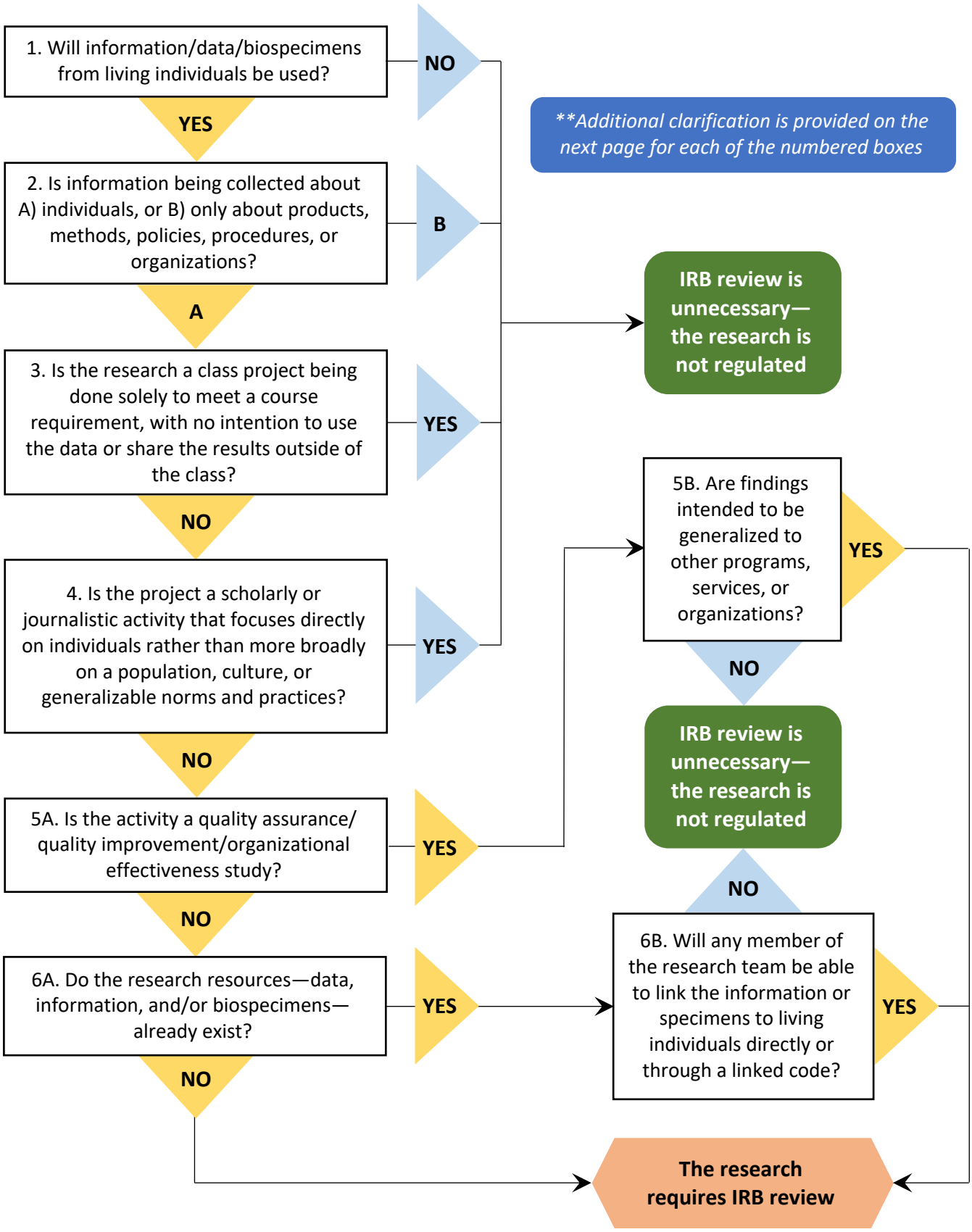
Does the Research Require Review by the IRB?



Tips and Guidance

Additional information about each of the numbered boxes in the decision tree is provided below. ***When in doubt, please contact the IRB administrator at instrb@utc.edu with your questions.***

1. Research involving data from deceased individuals or specimens from cadavers is not subject to IRB review.

2. Any research that asks participants to report their age, gender, education level, income, family status, or other demographic details is collecting information about individuals. Research that seeks to better understand people or factors that affect them—rather than products, policies, procedures/methods, or organizations—is also collecting information about individuals.

3. If a student is conducting research to satisfy a course or degree program requirement and intends to present the study findings at UTC's annual ReSEARCH Dialogues event, IRB review is required before participants are recruited or data collection begins.

4. In answering this question, consider the purpose of the project. Is the goal to record and report the experiences of individuals for historic preservation, investigative journalism, or documentary purposes, or to test a hypothesis or answer a research question about a broader group of people?

5A. These types of projects typically seek to evaluate how well a group of people is doing at their work and how they could improve their processes.

5B. For quality assurance/improvement or organizational effectiveness studies to be generalizable, they typically must collect data from multiple organizations or programs. The generalizability of findings from a single program or organization may be limited by factors such as cultural values of individuals and institutions, the types of people served by the program or organization, or other variables that may be unique to the study context. Findings from these types of research are often presented as case studies or "lessons learned," but the improvement methods may not be broadly transferable and may not yield the same results elsewhere.

6A. A Data Use Agreement or a Materials Transfer Agreement between the provider and recipient may be required in order to acquire protected or proprietary data from an external source (e.g., data from a hospital's electronic health record system, blood samples from a specimen bank). Contact the UTC Office of Research and Sponsored Programs for assistance.

6B. Research team members include anyone who is involved in the design, conduct, or reporting of the research; persons listed as collaborators in a research proposal or protocol; and persons who will share authorship credit when study findings are presented and/or published. Data providers may qualify as research team members if they will be involved in the project in the ways noted.

References and Resources

National Institutes of Health (2020, January 13). *Definition of Human Subjects Research.* U.S. Department of Health and Human Services, NIH. https://grants.nih.gov/policy/humansubjects/research.htm. Includes additional decision tools, infographics, and flowcharts.

Protection of Human Subjects. 45 Code of Federal Regulations § 46 (2018).