



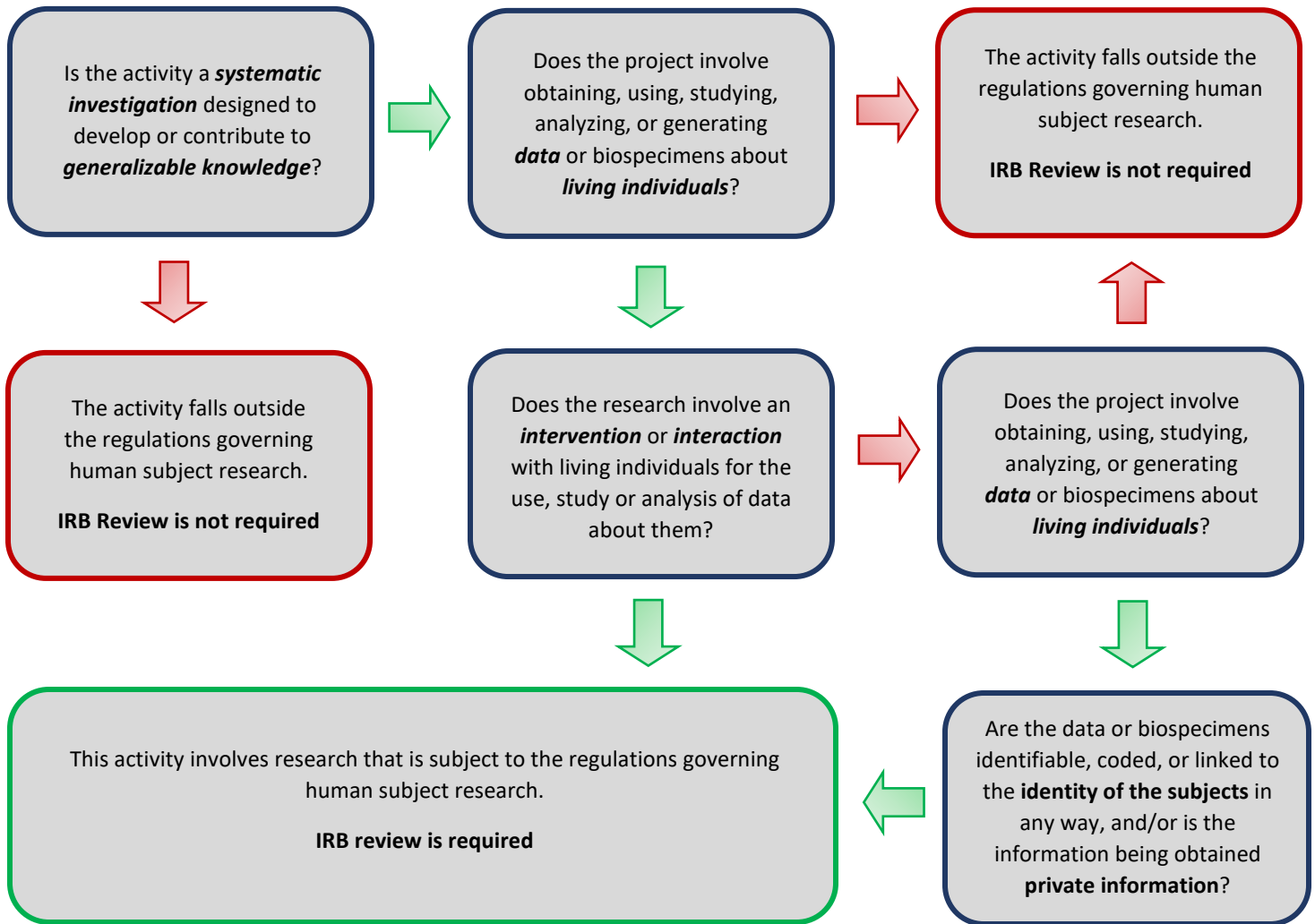
Does your Project Require Institutional Review Board (IRB) Review?

Only projects that fall under the criteria of the regulations require review by the IRB. Under 45 CFR 46, **Human Subjects Research** is defined:

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. **Human subject** means a living individual about whom an investigator conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Use this decision matrix to guide you in submitting your project to the HRPP Office for IRB Review.

If you have questions or are still uncertain, please contact the HRPP Office at hrpp@brandeis.edu or 781 736 8133 for further guidance.



Definitions

Systematic Investigation is typically a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es) or developing theory.

Generalizable Knowledge is work that is intended to be shared, published, presented, and/or is intended to have an impact (theoretical or practical) on others within one's discipline, science, or society. Activities that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge. This includes theses that will be on file in the university library.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).