Is the Proposed Project Human Subjects Research?

Start here

Is the project a **systematic investigation**, including research development, testing and evaluation? A systematic investigation: 1) attempts to answer a research question(s) that is methodologically-driven (i.e., collects data or information in an organized and consistent way); 2) involves data or information being analyzed in some way (e.g., quantitative or qualitative data); and 3) a conclusion(s) is drawn from the results.

Is the project designed to develop or contribute to **generalizable knowledge** (i.e., with the intent to collect information about some individuals to draw general conclusions about other individuals that are predictive of future events and that can be widely applied as expressed in theories, principles, and statements and that enhance scientific or academic understanding)?

**Project is research**

Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]

Does the research involve **intervention or interaction with individuals**? [45 CFR 46.102(f)(1). (2)]

Activity is research involving human subjects per HHS definition and CUNY SOPPs.

**Proceed with creating IRB application in IDEATE**

Is the information **individually identifiable** (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information)? [45 CFR 46(f)(2)]

Is the information **private**? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 102(f)(2)]

**NO**

**YES**

**NO**

**NO**

**NO**

**NO**

**NO**

**YES**

Project is **not** considered research per 45 CFR 46 and CUNY SOPs