Is the activity a systematic investigation, including research development, testing and evaluation? A systematic investigation is an activity that attempts to answer a research question or questions that is methodology driven in that it collects data or information in an organized and consistent way, and the data or information is analyzed in some way, be it quantitative or qualitative data and conclusion or conclusions are drawn from the results.

NO

Activity not considered research per 45 CFR 46 and UCSD SOPPs

YES

Is the activity designed to develop or contribute to generalizable knowledge? Generalizable knowledge is defined as an activity that is designed (with 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.

NO

Activity not considered research per 45 CFR 46 and UCSD SOPPs

YES

Activity is research

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

NO

The research is not research involving human subjects per 45 CFR 46 and UCSD SOPPs

YES

Non-human subject

NO

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

NO

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)]

YES

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

Activity is research involving human subjects per HHS definition and UCSD SOPPs