

Determining Whether a Proposed Activity is Human Research

PROTOCOL NUMBER: _____
PERSON REQUESTING DETERMINATION: _____
BRIEF TITLE OF STUDY: _____

KEY Solid box: All items in the box must be true

Dotted box: One item in the box must be true

- The activity involves research because all of the following are true:

- The activity is 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.
 - The activity is 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.

- The activity involves human participants because both of the following are true:

- The investigator will obtain data about living individuals
 - Either or both of the following is true
 - The investigator will obtain that data through intervention (physical procedures by which data are gathered and manipulations of the participant or the participant's environment for research purposes) or interaction (communication or interpersonal contact between investigator and participant) with those individuals.
 - The information obtained is both private and identifiable

- Private, because the information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place OR the individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record).
 - Individually identifiable, because the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

The activity involves an FDA-regulated test article because one or more of the following is true:

- The activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice.
- The activity involves the use of a device to evaluate safety or effectiveness of that device.
- Data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

The activity involves human participants because one or more of following is true:

- The test article will be used on one or more humans.
- Data obtained from controls will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.
- Data obtained from use of a device on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

Determined to be human research (Meets either definition)

Determined to **NOT** be human research (Meets neither definition)