

Not Human Subjects Research Determination

If your research does not meet the federal definition of human subject research, you do not need to submit an IRB protocol; the UC IRB must make that determination. In accordance with the federal Office of Human Research Protections guidance, the following definitions are applied for determining whether or not an activity is considered human subjects research:

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 (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual
2. identifiable private information

Intervention includes both physical procedures by which data 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 which has been provided for specific purposes by an individual and the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

If an investigator believes his/her activity is not human subjects research, then a Not Human Subjects Determinations submission must be submitted through the electronic Protocol Administration System (ePAS).

Submission and Review Process

1. After the investigator gains access to the ePAS system, please select "My Home" from the upper right corner.
2. Please select "New IRB Application" from the left margin and answer the questions presented to you.
3. Please ensure that "Not Human Subjects Determinations" on the Research Classification page (4th screen) is selected.
4. Please select "Finish" at the end of the submission.
5. Please select "Submit Study" from the "My Activities" list in the left margin of the screen.

You will receive an email notification from ePAS with either comments/questions or a Not Human Subject Research determination within 2 weeks of submission.