

# Is it Human Subjects Research?

If any pathway exists for which all answers are **YES**, the project is a human subjects research project.

Is the project **designed** to produce generalizable knowledge?

Generalizable knowledge concerns the level of interest others might have in the project if its results became public. Generalizable knowledge builds the knowledge base of the profession in some material way. The outcomes hoped for must have some predictive value so concepts or principals elucidated by the research can be applied to other circumstances.

Is the research systematic?

Systematic means carried on using step-by-step procedures organized according to a set of interrelated ideas or principles. These find their expression in the objectives of the research and in the research plan.

Is the information **about** a living individual?

Data is either directly obtained (survey, interview etc.) or indirectly obtained (existing data, records etc)

Is the information about the participants gathered through any interaction with those participants, such as interpersonal contact or communication of any sort (direct or indirect?)

Is any **private information** obtained or used in the research **individually identifiable**?

**Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., 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 to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

Is there any intervention via physical procedures (use of sensors, drawing blood, etc.) or manipulation of a subject's environment?

If any pathway exists for which all answers are **YES**, the project is a human subject research project. If you are uncertain read "When is Research Human Subject Research" If still uncertain, contact the Research Compliance Office at (605) 677-6184.