



# Piedmont

## HEALTHCARE

The PHCIRB considers the following in making the initial assessment of whether or not a project would be categorized as human subjects research or something else. The research determination is based on the project meeting the following definitions:

- Research: This requirement has two key elements, 1) a systematic investigation (including research development, testing, and evaluation, and 2) the design – meaning goal, purpose, or intent is to develop or contribute to *generalizable knowledge*
  - Systematic investigation (all):
    - Attempt to answer research questions
    - Is methodically driven – collection of information or data in an organized and consistent way
    - The information or data is analyzed – quantitative or qualitative
    - Conclusions are drawn from the results.
  - Generalizable knowledge (one or more):
    - knowledge that contributes to the theoretical framework of an established body of knowledge
    - the primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study
    - publication, presentation or other distribution of the results is intended to inform the field of study
    - the results are expected to be generalized to a population beyond the site of data collection
    - the results are intended to be replicated in other settings.
- Human subject: a *living* individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.

**NOTE:** projects not meeting the definitions of ‘human subjects’ AND ‘research’ are NOT subject to the regulatory authority of the IRB.

Consider Chart 1 below:

# Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

February 16, 2016

