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?

Start here.

Is it research?

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

Activity is research. Does the research involve human subjects?

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

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

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

Activity is research involving human subjects. Is it covered by the regulations?

Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

The research involving human subjects is covered by the regulations.

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

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 46.102(f)(2)]

Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A applies to the research, and as appropriate subparts B, C, and D also apply.

The research involving human subjects is NOT covered by the regulations.

Go to Chart 2

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

February 16, 2016