Does your activity fall under IRB oversight? (45 CFR 46.101-102)

Start here.

Is the activity a systematic investigation (a study or examination involving a methodical procedure or plan)?

- **NO**: Activity is not research, IRB review is not needed.
- **BUT**: Is this systematic investigation designed to develop or contribute to generalizable knowledge (i.e. determining research vs. program evaluation/quality improvement/quality assessment)?

Generalizable knowledge means conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.

- If the primary goal of the activity is to develop or contribute to generalizable knowledge, the activity is research.
- A major goal of research is to learn something for the purpose of benefiting people other than the research subjects.
- Would this project be conducted as proposed if you knew that you could not publish or present the results? If no, the activity should be reviewed by the IRB.
- If the primary goal is to improve the performance of institutional practice in relationship to an established standard, for example, the activity is not research.

Design refers to the purpose of the investigation. Some investigations are exploratory or are intended to train students and are not designed to produce generalizable knowledge. It is important to note that although some projects involving qualitative data collection or projects that are exploratory in nature may not have specific aims and hypotheses at the outset of the research, these are still systematic investigations designed to contribute to generalizable knowledge if the purpose of the project is to archive results for future research, compare results to other assessments, or draw conclusions.

- If a project involves randomization or an element that may be considered less than standard of care, the IRB should determine whether the activity is research.

Activity is research. Does the research involve obtaining information about living individuals?

- **YES**: The research is not research involving human subjects. IRB review is not needed.
- **NO**: Does the research involve intervention or interaction with the individuals?

- **NO**: Is the information individually identifiable (the identity of the subject is or may readily be ascertained by investigator or associated with the info)?

- **NO**: Is the information private?

  Private means 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.

  - **YES**: Other Federal, State and local laws and/or regulations may apply to the activity.
  - **NO**: Activity is research involving human subjects. Please complete a Human Subject Research Review Form.