What is a **Human Subject**?
According to the federal regulations (45 CFR 46.102.f) a Human Subject means a living individual about whom an investigator conducting research obtains:
I. Data through intervention or interaction with individual
II. Identifiable private information

According to the federal regulations (45 CFR 46.102.d) **RESEARCH** means a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.

The IRB is responsible for reviewing “human subjects” + “research” as defined in the applicable federal regulations. Only projects meeting both definitions require IRB review:

1- Project must involve **“human subjects.”** Human subjects means a living individual about whom an investigator (whether professional or student) conducting research obtains:
   - data through intervention or interaction with individual and uses, studies, or analyzes the information
   - uses, studies, analyzes, or generates identifiable private information

2- The project must be **“Research.”** Research is defined under the regulations as a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

   **“Generalizable Knowledge”** is knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts:
   - Knowledge that contributes to a 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;
   - dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research “designed to contribute to generalizable knowledge”);
   - the results are expected to be generalized to a larger population beyond the site of data collection; the results are intended to be replicated in other settings.

What this mean is that determining whether a project requires IRB review and approval or not is based, not only on the type of activity to occur, but also the purpose/intent.

**Important Note:** The results of a “non-research” activity could be used to develop or contribute to generalizable knowledge after the initial project is complete. If the initial purpose or a project is not to develop or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if later someone decides to use identifiable private information from that project with the aim of developing or contributing to generalizable knowledge, that analysis may require IRB review and submitted for use of the data before such use.