



Is your project research?

- The intent of the proposed project:
- Innovative **medical therapy** to improve the health of an individual patient
  - **Operational activity** of an organization (e.g. customer service initiative, teaching evaluation, disease outbreak investigations, auditing)
  - **Journalism**
  - **Political poll**
  - **Oral history, biographies, or medical case history** that is not generalizable beyond that individual
  - **Classroom or training activities** where the only objective is to teach a student proficiency on a topic
  - **Quality Improvement or Quality Assurance**
    - program initiated by an institution to compare performance to established standards or measure the value of a program to its participants  
AND
    - information will only be distributed to those directly involved in its planning, management and implementation

- The intent of the proposed project:
- **Systematic investigation** intended to develop or contribute to **generalizable knowledge**.
    - Systematic investigation means carried out using step-by-step procedures organized according to a set of interrelated ideas or principles.
    - Generalizable knowledge may include:
      - Benefits that extend beyond immediate population- to society, other researchers, scholars, or practitioners in field
      - Drawing conclusions, testing or generating a hypothesis
      - Publication or presentation to inform the field of study
      - Contributes to a theoretical framework or body of knowledge
  - **Test a new device, product, drug or biologic material**

If YES, proposed project is research

Are human subjects involved?

- The proposed project involves:
- **Individuals that are not living**
    - cadavers
    - autopsy specimens
    - data or information on deceased individuals\*
  - **Animals, animal specimens or animal cell lines\*\***
- \* PHI requires clearance from Privacy Officer  
\*\* IACUC review required

- The proposed project involves:
- Data about or specimens from one or more living individuals

If yes, proposed project is not research

**NOT HUMAN SUBJECTS RESEARCH- COMIRB Submission Not Required**

If yes, human subjects not involved

YES, human subjects involved

**Submit to COMIRB for determination**