Decision Tree for Determination of Human Subjects Research

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
  - information will only be distributed to those directly involved in its planning, management and implementation

If yes, proposed project is **not** research

If yes, human subjects not involved

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

If yes, 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 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:
- Data about or specimens from one or more living individuals

YES, human subjects involved

Submit to COMIRB for determination

Determination of Human Subject Research – Decision Tree, Effective 4-26-2010