

Decision Tree for Determination of Human Subjects Research

Is your project research?

The intent of the proposed project:

- **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-** [Requires COMIRB biomedical review]

If YES, proposed project is research

Are human subjects involved?

The proposed project involves:

- **Individuals that are not living**
 - data or information on the deceased
- **Animals**

The proposed project involves:

- Data about one or more living individuals

If yes, proposed project is not research

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

If yes, human subjects not involved

YES, human subjects involved

Submit to HSRC for determination