

When Does the IRB Need to be Involved?

From IRB perspective, the project is either

- Non- Human Subjects Research, which does not require IRB oversight

or

- Human Subjects Research that meets Exempt, Expedited, or Full Board review criteria

Tool: Human Subject Research Determination Form



Questions to ask

1. Is it Research?
 2. Are Human Subjects Involved?
- If YES to both, it is Human Subjects Research, and the IRB needs to review



Is it Research?

- [45 CFR 46.102 \(d\)](#)

Research means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.



Are Human Subjects Involved?

- [45 CFR 46.102 \(f\)](#)

Human subject means a **living individual** about whom an investigator (whether professional or student) conducting research obtains

1. Data through **intervention or interaction** with the individual,

OR

2. **Identifiable private information**



What is Considered Identifiable Private Information?

- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
- information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)
- the identity of the subject may readily be ascertained by the investigator or associated with the information

