

# Human Subjects Research

FEDERAL REGULATIONS REQUIRE APPROVAL FROM AN INSTITUTIONAL REVIEW BOARD (IRB) FOR RESEARCH INVOLVING HUMAN SUBJECTS.

You are doing human subjects research that requires IRB review if...

1

**Your project meets the definition of research**

**Research** is a systematic investigation designed to develop or contribute to generalizable knowledge

AND

2

**Your research involves human subjects**

**Human subjects** are living individuals who are the subject of research

AND

3

**Data is obtained by an investigator through an intervention or interaction with the individual**

OR

4

**Data contains identifiable private information**

**Private information** is information an individual can reasonably expect will not be made public (such as a medical record or medical examination)

Information is considered identifiable if the the individual's identity could be ascertained directly or indirectly



IRB approval is required before conducting research with human subjects. Work with your IRB to determine what type of IRB review is required before starting any human subjects research.

All information is derived from 45CFR46 guidelines available at:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>