How do I know if my research involves human subjects?

Federal regulations* and The Ohio State University Human Research Protection Program (HRPP) policies define when an activity is research involving human subjects.

**Research**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Human Subject**

A living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, analyzes, or generates identifiable private information or identifiable biospecimens.

*Food and Drug Administration and Department of Health and Human Services regulations (which vary slightly) can be found at [orrp.osu.edu/irb/irbregulations](http://orrp.osu.edu/irb/irbregulations).

Your research probably involves human subjects if it includes:

- Investigations of drugs or medical devices
- Review of personally identifiable medical or educational records
- Surveys, interviews or questionnaires
- Collection and storage of private information or specimens for future research purposes
- Pilot studies
- Activities performed in support of a doctoral dissertation, honors project or master’s thesis

For more information and other examples, see HRPP policy, Research Involving Human Subjects, posted at: [orrp.osu.edu/files/2012/02/Research-Involving-Human-Subjects.pdf](http://orrp.osu.edu/files/2012/02/Research-Involving-Human-Subjects.pdf).
Do I need approval for my human subjects research?
Yes. Before you begin your research involving human subjects, it must be reviewed and approved by one of the university’s Institutional Review Boards (IRBs) or determined by the Office of Responsible Research Practices (ORRP) to be exempt.

IRB Review
An IRB is a committee whose primary responsibility is to protect the rights and welfare of human research subjects. There are three internal IRBs at Ohio State. Ohio State also works with many independent and/or external IRBs which review Ohio State research.

Exempt Review
Designated staff in the Office of Responsible Research Practices apply regulatory criteria to determine if IRB approval is needed. If not, an exemption from further review and oversight can be granted.

How do I get approval for my human subjects research?
Submit protocols for IRB review electronically at go.osu.edu/Buck-IRB.

Are there any additional requirements?
Before research is reviewed, individuals who participate in the design, conduct or reporting of human subjects research must complete (and update as necessary) the following:

- CITI (Collaborative Institutional Training Initiative) education program in human subjects protection available at orrp.osu.edu/irb/training-requirements/citi
- Conflict of interest disclosure form available at orc.osu.edu/regulations-policies/coi/ecoj
- CITI Responsible Conduct of Research (RCR) training available at orc.osu.edu/regulations-policies/rcr

Where can I get assistance?
The Office of Responsible Research Practices (ORRP) is a team of professionals within the Office of Research.

ORRP provides administrative support to the institutional review boards (IRB) and is committed to delivering excellent customer service.

Consult the ORRP directory at orrp.osu.edu/contact for specific staff member contact information or visit the ORRP website at orrp.osu.edu.