

1. Does my project need IRB approval?

If the project involves **human participants** and **may contribute to generalizable knowledge**, the activity will require review and approval by the WOU Institutional Review Board (IRB) **before** any recruitment or research involving human participants may begin. IRB review and approval is required for all research projects involving human participants, regardless of the source of funding for the project or the level of risk posed to participants. A study requires IRB approval if it is research which involves human subjects or collecting information from or about human subjects.

2. What is meant by human participants?

Federal Regulations (45 CFR 46.102), define a **human subject** as any living individual about whom an investigator obtains data:

- Through observation of the individual, or
- Through intervention or interaction with the individual, or
- Through private information

Observation includes:

- Counting the frequency or otherwise recording specific behaviors of humans
- Audio or video tape recording of the subject's behavior or interactions

Intervention includes:

- Manipulations of the subject's environment; or
- Applications of procedures or treatments, such as drugs, devices, or biologics; or
- Administration of psychological therapies or counseling to change behavior or promote well-being

Interaction includes:

- Communication with the subject; or
- Interpersonal contact with the subject; or
- Physical procedures to collect data, such as taking blood samples

Private information must be individually identifiable and includes:

- Information about behavior that the subject expects will not be observed or recorded
- Specific information about the individual that the individual can reasonably expect will not be made public

3. What is meant by generalizable knowledge?

Contributions to generalizable knowledge mean public presentation of the study data through any of the following:

- Meetings, conferences, seminars, poster presentations, et al;
- Publications distributed beyond WOU including evaluation reports, journal articles, papers, dissertations; and,
- Master's Theses and Projects