

DOES MY PROJECT REQUIRE IRB REVIEW?

Determining if Activities Involve Human Participants Research

This checklist is intended to assist investigators in determining if their activity is considered human participants research involving human participants and would therefore require IRB review. This checklist does not need to be submitted to the IRB. If there is any doubt as to whether or not your activities would qualify as human participant research, please contact the Institutional Review Board.

Section A: Is it Research?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Generalizable knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated). A useful definition of dissemination is that the material will be shared beyond the local settings. Examples of disseminated work include publication in a scholarly journal, presentation at a professional conference (e.g., ACE Day), or placement of a report in a library. Examples of work not considered disseminated include oral presentations to a departmental group in fulfillment of a university requirement, sharing of results with an agency that cooperated in information collection, or internal presentation for utilization and review purposes.

Note: If you do not submit for IRB approval, you will not be able to publish or publicly present (e.g., ACE Day) the results of your study.

- 1. Is your activity a systematic investigation designed to develop or contribute to generalizable knowledge?** YES NO

If you answered **YES**, your activity is considered research. Continue to section B to determine if your research involves human participants.

If you answered **NO**, your activity is not research and IRB review is NOT required.

Section B. Does your activity involve Human Participants?

1. Is the data being collected about living individuals?

YES NO

If you answered **NO**, your research does not involve human subjects and IRB review is not required.

If you answered **YES**, continue to question 2.

2. Is the data collected through intervention or interaction with the individuals?

YES NO

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant (45 CFR 46.102 (f)) (e.g., surveys, focus groups, and/ or interviews).

If you answered **YES**, your research does involve human subjects and IRB review is required.

If you answered **NO**, continue to question 3.

3. Does the data contain identifiable information about individuals?

YES NO

For example, the identity of the participant is or may be readily ascertained by the investigator or associated with the information (45 CFR 46.102 (f)).

If you answered **NO**, your research does not involve human subjects and IRB review is not required.

If you answered **YES**, continue to question 4.

4. Is the information private?

YES NO

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for a specific purpose by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute as research involving human participants (45 CFR 45.102 (f)).

If you answered **YES**, your research involves human subjects and IRB review is required.

If you answered **NO**, your research does not involve human subjects and IRB review is not required.

Please note there are other activities that are not considered Human Participant Research:

Classroom Activities: Those which fulfill course requirements or to train students in the use of particular methods or devices and for which you have no intention of publishing or sharing the information outside the classroom (e.g., at conference, on a website, in a publication, etc.)

Internal Data Collection: Those which are used for departmental, or other institutional administrative purposes only e.g., teaching evaluations, customer service surveys) and for which you have no intention of sharing or publishing

Information Gathering: In which questions focus on objects, products, or policies rather than people or their thoughts or behaviors (i.e., canvassing regarding inter library loan policies or rising journal costs)

Coded Data: Those which were not collected for the currently proposed projects, as long as the investigator receiving the data cannot link the data back to the participants (e.g., national dataset with no identifiers)

Pilot Studies: Those which are used to develop or test measures that are not considered human participant research as long as you will not publish or share this information. If it is possible that the data collected in your pilot study will be used solely or in combination with other data for publication purposes, IRB review and approval is required **BEFORE** data collection begins

Additional Information

If there are any doubts as to whether or not your activities could qualify as human participant research, please contact the Institutional Review Board at (541)-349-7440 or email at irb@bushnell.edu

Credits

The above includes information adapted from the following institutions:

University of Oregon

Research Compliance Services

U.S. Department of Health and Human Services

Code of Federal Regulations, Title 45 Public Welfare