



Human Subjects Research at OSU

Behavioral & Social Sciences IRB questions

Michael Donovan donovan.6@osu.edu or 292-6950

Jacob Stoddard stoddard.13@osu.edu or 292-0526

Joni Barnard barnard.15@osu.edu or 688-3405

Exempt and “Not Human Subjects Research” questions:

Cheri Pettey pettey.6@osu.edu or 688-0389

Guidance

The Office of Responsible Research Practices has developed an Investigator Guide to help researchers navigate the various requirements for conducting human subjects research at OSU. Contents include determining when scholarly or scientific activities are research involving human subjects and explanations of the exempt, expedited, and convened review processes. Examples, resources, and helpful links are also included. Additional sections on obtaining initial and ongoing IRB approval will be added to the Guide in the near future. The Investigator Guide can be found at <http://orrp.osu.edu/irb/guidance/>.

How do I know if I am doing human subjects research?

Research projects involving human subjects require either review and approval by an IRB, or a determination that the research is exempt. The first question a researcher should consider with respect to IRB review is whether the research project fits the federal regulatory definition of *research*, and if so, whether it also involves *human subjects*. In light of the responsibility to protect human subjects and the potential regulatory consequences of not obtaining IRB review and approval, the investigator should err on the side of caution and consult with ORRP when uncertain whether a study constitutes human subjects research.

The following sections provide regulatory definitions to consider when determining whether a project falls under regulatory definitions of “human subjects research,” as well as some examples. In addition, the federal Office of Human Research Protections provides “Chart 1: Is an Activity Research Involving Human Subjects?” at www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm.

Question 1 – Do federal regulations require ORRP review of the research?

DHHS regulations require review of research that constitutes “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)). As described in the Belmont Report, “...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

This definition of “research” generally does not include operational activities such as defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. This definition of research generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is an intent to contribute to generalizable knowledge.

Some examples of common activities that are **not** considered “*research*” as defined by DHHS regulations:

- **Data collection for internal departmental, school, or other University administrative purposes.** Examples: teaching evaluations and customer service surveys. Service surveys issued or completed by University personnel for the intent and purpose of improving services or programs of the University or for developing new services or programs for students, employees, or alumni are not research, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, survey participation is voluntary, and there is no intent to generalize the findings. This includes surveys by professional societies or University consortia. Note: If at a future date, an opportunity arose to contribute identifiable or coded survey data previously collected for an administrative purpose to a study producing generalizable knowledge, IRB review may be required before the data could be used in the new project.
- **Independent contract for activities carried out for an external agency.** Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or other credit), public park usage, IT usage, and software development.
- **Quality improvement projects.** These are not generally considered research unless there is intent to contribute to generalizable knowledge beyond use of the data derived from the project internally to improve or alter the quality of care or the efficiency of an institutional practice. If the data is to be re-examined or reanalyzed and/or new information surfaces that could be used to contribute to generalizable knowledge, an application must be submitted for IRB review or exemption. Any individual who is unsure whether a proposed quality improvement project would be considered research (as defined above) should contact ORRP for guidance.
- **Consultant activities.** Such activities are not considered research when an institution's employees or agents act as consultants but at no time obtain, receive, or possess the identifiable private information of research participants. Other examples (that are not research) include performing commercial services for investigators and informing prospective participants about the availability of research. Note: The examples above are not an all-inclusive listing. Please see the following website for further information <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>.

Question 2 – Does the research require review as work with Human Subjects?

DHHS regulations define a human subject as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information” ([45 CFR 46.102\(f\)\(1\)\(2\)](#)).

Relevant Definitions:

- **Living individual** refers to data/specimen(s)/information collected from live subjects. Cadavers, autopsy specimens, or specimens/information from subjects now deceased are not human subjects.
- **Intervention** includes physical procedures, manipulations of the subject or the subject's environment for research purposes.
- **Interaction** refers to communication between the investigator and the subject. This includes face-to-face, mail, and phone interactions, as well as other modes of communication.
- **Individually identifiable** means the identity of the subject is or may be readily ascertained by the investigator or the investigator's staff, or is associated with the information.
- **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, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

For additional information and examples, please see the OSU Policy at: <http://orpp.osu.edu/irb/osupolicies/>.

How do I get a written determination about the review requirements necessary for my research?

If an investigator is unsure whether the project is research involving human subjects, the PI should contact ORRP and submit applicable materials to an ORRP Administrator for review. The designated ORRP Administrator will make one of three determinations and will notify the PI as follows:

- The proposed activity is *not* research involving human subjects and may be conducted without further IRB review or exemption; or
- The proposed activity *is* research involving human subjects and meets the criteria for IRB exemption; or
- The proposed activity *is* research involving human subjects and requires IRB review.

Upon receipt of complete information, determinations regarding review requirements are usually made within five business days. Projects determined to be research involving human subjects require documented IRB approval or exemption before starting any research activities, including advertising, recruitment, and pilot studies. Please note that “retroactive” IRB approval or exemption is not permitted under federal regulations and University policy.

Exempt Info: <http://orrrp.osu.edu/irb/exempt/index.cfm>

IRB Info: <http://orrrp.osu.edu/irb/forms/>

International Sites

The international appendix (appendix U) is located on the same page as the exempt application.

International studies often require additional safeguards to protect the rights and welfare of research participants. OSU investigators wishing to perform research in international locations must consider the language spoken/understood by potential participants, local customs or laws that might influence how the research is carried out, and possible risks due to social or political conditions. Investigators who will be conducting research internationally need to be prepared to gather and submit the following information for review:

- Description of where the research will be conducted (including geographic location and specific performance site, where applicable). Note: In some areas, government-issued research visas are required.
- Information about the local research context, including the current social, economic, and political conditions of the area, including a description of the investigator’s personal experience conducting research (or studying or residing) in the region.
- Any additional risks participants might face as a result of the population being studied and/or the local research context.
- The language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the investigator is fluent in this language or whether a translator will be required. If a translator will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized.
- Names of potential contacts not affiliated with the research who can act as cultural consultants

Consent, Assent, and Parental Permission:

Please note that the requirements of consent for IRB research and Exempt research differ. See <http://orrrp.osu.edu/irb/consent/index.cfm> for IRB templates guidance on the required elements of consent for IRB-reviewed research.

- *Consent*—For adult participants
- *Assent*—For children and/or those who cannot consent for themselves.
- *Parental Permission*—almost always required for the participation of children.
- *Waiver of Documentation of Consent*—still obtaining consent, but not a written signature (used, for example, with online, phone, or mailed surveys). Can be requested in both exempt and IRB research--for IRB research, fill out appropriate application appendix.
- *Waiver of Consent*: When consent or parental permission is not obtained (used, for example, when accessing large amounts of existing data where it is impracticable to obtain consent). Very specific criteria

needed to qualify for both Exempt and IRB research—for the IRB, fill out appropriate application appendix.

Exempt Research Consent/Recruitment Script Elements:

Remember that the consent/recruitment script should contain at least the following information:

- Identify yourself and explain why you are doing the study. Use a style of language that simply and clearly explains the research to your subjects. Subjects must be informed that the project is for research purposes.
- Subjects must be told what they will be asked to do if they agree to participate, how long it will take, and how you will protect their confidentiality (or, if participants are anonymous, how will you assure anonymity). Include information about audio or video taping as applicable.
- Subjects must be told that their participation is voluntary, they can refuse to answer questions that they do not wish to answer, and stop participation at anytime. In studies that are not anonymous, subjects should be told they can withdraw at any time without penalty or repercussion.
- Provide a means for subjects to contact the investigator(s) if they have questions or concerns about the research. Make it clear to the subjects that you are affiliated with The Ohio State University.

Retaining Identifiable Data:

Please remember that you can retain identifiable data, quote individuals, etc. You just need to be sure that both your application and participant materials specify how this will be done. The application is written assuming that identifiers will be removed, you just have to explain that they will not be destroyed and how they will be maintained.

Links:

ORRP www.orrp.osu.edu

- Forms: <http://orrp.osu.edu/irb/forms/>
- Research Training (CITI): <http://orrp.osu.edu/irb/training/>
- Education/help sessions: <http://orrp.osu.edu/irb/workshops/>
- Walk-in help for student researchers & advisors: <http://orrp.osu.edu/news/detail.cfm?News=195>
- Outreach for investigators: <http://orrp.osu.edu/irb/workshops/>

Protocol lookup – access to protocol information for investigators: <http://orrp.osu.edu/plink/>

PI Portal – Direct access to current awards and protocols for PIs: <http://www.eresearch.osu.edu>

OSU:pro – Searchable database created to serve as a comprehensive, single-point resource of faculty and staff expertise and scholarly activity: <https://pro.osu.edu/index.cfm>

International

- OHRP's links to international research resources: <http://www.hhs.gov/ohrp/international/>
- *The International Compilation of Human Research Protections* is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world: <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>

Some key things to keep in mind:

- **Do NOT begin without approval!** You cannot begin recruitment, consent, collecting data, etc. until your exempt determination or IRB approval is received. Submission of materials for review is not sufficient—you must wait for approval.
- **Do NOT make changes without approval!** If you need to make a change to any part of your approved research materials or methods (e.g. increase subject numbers, add or delete questions/instruments, revise scripts/consent forms, change personnel, etc.), you must submit an amendment for IRB review and obtain IRB approval prior to implementing the changes. Instructions, as well as the amendment form, can be found at

<http://orrrp.osu.edu/humansubjects/amend.cfm>. Exempt research currently does not have an amendment process. Please contact ORRP if changes are needed: a new submission will most likely be required.

- **Research Activities:** When describing research procedures, be sure to differentiate between what is being done solely for research purposes vs. what is occurring regardless of the research. This distinction is important as it changes both what participants are agreeing to and what the IRB is being asked to assess.
- For IRB research: If your research will continue past the expiration date found on your IRB approval letter, you will need to submit a continuing review application approximately two and a half to three months prior to the expiration date. This early submission ensures that ORRP screening, IRB review, and IRB approval can occur before the expiration date. Instructions, as well as the continuing review form, can be found at <http://orrrp.osu.edu/irb/conrev/index.cfm>.
- Exempt research is approved as written and does not require continuing reviews or final study reports at this time.
- Please remember that OSU policy requires that all study-related materials be kept for at least three years following the close of the study. The data should be stored according to the arrangements set forth in your protocol.

Exempt Category 2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

*Note: The exemption under Category 2 does **not** apply to research involving survey or interview procedures or observation of public behavior when children are the subjects of the activity, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.*

- If the data collected could harm participants in any way, additional measures to protect confidentiality of the data are required, and such research will generally require IRB review. For example, questions regarding sexual preference or illegal behavior could reasonably place subjects at risk if responses were known, and therefore, cannot be exempt from IRB review if there is any way to identify the respondents. This kind of research should contain an unsigned consent form (or recruitment script or letter) that clearly describes the risks of the research. In some studies, even when the data collected are anonymous the potential for social stigma of an identifiable group can make IRB review a requirement. Surveys that contain invasive questions that may cause participants to experience emotional distress or discomfort while answering are also not exempt from IRB review, even if the data are collected from participants who remain anonymous. Research employing cognitive or diagnostic tests is not exempt if the testing is psychologically invasive and could potentially cause the participant some discomfort or distress.

Common questions:

- **Can I submit samples of stimuli?** Yes—if your stimuli is all similar in content (simple pictures, lists of words) you can just provide samples.
- **For open-ended interviews, do I have to submit every question?** No—you can give a list of topic questions and explain the direction you wish to pursue. It is also good to address what topics you do not wish to pursue, especially if sensitive information could come up.
- **Do I have to have people sign consent forms?** No, you can use verbal scripts, online scripts, emails, etc.—you still need to submit these, but signatures are usually not necessary.
- **Do I need to submit translated materials?** For exempt research, no. For IRB research, yes--along with translation verification.

Some key things to keep in mind:

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- **Do NOT make changes without approval!** If you need to make a change to any part of your approved research materials or methods (e.g. increase subject numbers, add or delete questions/instruments, revise scripts/consent forms, change personnel, etc.), you must submit an amendment for IRB review and obtain IRB approval prior to implementing the changes. Instructions, as well as the amendment form, can be found at <http://orrrp.osu.edu/humansubjects/amend.cfm>. Exempt research currently does not have an amendment process. Please contact ORRP if changes are needed: a new submission will most likely be required.
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