

IRB REVIEW: A QUICK GUIDE FOR UW OSHKOSH

The purpose of a research project and the investigator's plans for how the data involving human subjects will be used are usually the determining factors in deciding whether IRB review is mandated.

The regulatory definition of research that triggers IRB review is: "a systematic collection of data designed to produce generalizable knowledge".

Generalizable Knowledge: Investigations designed to draw general conclusions that will be disseminated to populations outside of the local setting. Examples of dissemination of results are publication of results in a scholarly journal, presentation at a professional conference, or placement of a report in a library.

There is a wide range of activities that we call "research" in everyday parlance that do not meet this definition.

Routine classroom "teaching" assignments:

- A. IRB review is NOT required unless the data collected from surveys or interviews are being used to produce generalizable knowledge outside of the classroom.
- B. Internal class projects do not require IRB review; however it is the Instructor's responsibility to insure that students conduct their assignments in an ethical manner.
- C. If the faculty member or students wish to use data collected from class assignments for research and publication, application to the IRB for permission to use the data is required.
- D. If there is any doubt as to whether or not your activities could qualify as human subject research, please contact IRB staff to determine the best way to proceed.

Independent research projects conducted by students, such as theses, honors projects, and independent study projects:

- A. IRB review is required if data is collected through interactions with living people or access to private information. Application to the IRB for these student research projects must include an endorsement and acceptance of overall responsibility by a faculty member.

Marketing surveys, program evaluations and related data collections MAY be considered "research" requiring IRB review:

- A. IRB review is NOT required if the project is a work for hire where the client owns the resulting data, all rights to use the data belong to the client, and the University has no intention to use the data for other purposes.
- B. IRB review MAY be required if the project is a work for hire, where the client owns the data, but the University reserves the right to use the data for research and instructional purposes.
- C. IRB review is DEFINITELY required if the project is University research (student or faculty), where the University owns the data (even if it may be reported to a client), and

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the University (student or faculty) intends to use the data (immediately or long-term, alone or in combination with other data) in development of a scholarly product.

Activities clearly NOT research under the regulations requiring IRB review include:

- A. Data collection related to practices, policies, demographics, or other information where the respondent is asked to report only factual information, and is NOT asked to report personal opinions, attitudes, beliefs or ideas.
- B. An instructor polling a class for information that will be used to plan further class/course activities.
- C. Use of survey software for program registration/attendance information.
- D. Data collection for purposes of program planning or evaluation.
- E. Oral histories, biographies, and reporting (journalism) do not normally require IRB review because they are typically descriptive of specific events or individuals, and not “designed to produce generalizable knowledge”. Researchers using these methods should abide by (and/or train their students to abide by) the code of ethics prescribed by their respective disciplines and to treat respondents with courtesy and respect. In cases where the work might be construed as “designed to produce generalizable knowledge”, researchers are advised to consult with IRB staff for recommendations on the best way to proceed.

Whether or not IRB review is required, risks to the participant should be minimized to the fullest extent possible. For most social/behavioral research, breach of confidentiality is the greatest risk involved in the work.

- A. Risks can be biomedical, psychological, social (risks to reputation or potential embarrassment), legal (disclosure of illegal activities) and/or economic (loss of employment).
- B. Anonymity is the best protection and should be considered whenever possible.
- C. When anonymity is impossible, question asking opinions rather than asking an individual to disclose their actual behaviors entail less risk. (For example: What do you think about college students who use marijuana? As opposed to: How often do you use marijuana?)
- D. When anonymity is impossible, there should be protections in place to safeguard the identities of the respondents.

When IRB review is required, the level of review is determined primarily on the basis of the level of risks to participants.

- a. EXEMPT review – risks must be no greater than minimal and data must include no participant identifiers.
- b. No greater than minimal risk = the level of risk an individual normally encounters in the course of routine daily activities.
- c. Signed informed consent is not required.
- d. Exempt protocols are reviewed by the IRB administrator and the IRB Chair.
- e. Review can usually be completed in one week or less.

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- B. EXPEDITED review – risks must be no greater than minimal and identifiers are included in the data.
 - a. Signed informed consent may or may not be required.
 - b. Expedited protocols are reviewed by a subset of the IRB membership.
 - c. Review can usually be completed in 1-2 weeks.
- C. FULL BOARD review – risks are greater than minimal OR participants are members of a group for which the law requires additional protections.
 - a. Signed informed consent is nearly always required.
 - b. Protocols are reviewed by a convened quorum of the IRB membership in a face to face meeting. On occasion the investigator is asked to attend.
 - c. Review can usually be completed in 2-4 weeks.

Other Participant Protections Considerations:

- A. Research involving certain protected classes of participants **REQUIRES** full board review. These include minors (in most cases), and prisoners, and may also include others who lack the legal or mental capacity to consent to participate.
- B. IRB review is **PROSPECTIVE** review. If review is required, review and approval must be complete before participant recruitment and/or data collection begin.
- C. Faculty who may want to use their survey responses in an article or conference presentation should be aware that an increasing number of journals and professional conferences require evidence of IRB approval before they will accept a submission for consideration.
- D. If the work as originally conceived did not require IRB approval, later IRB approval **MAY** be possible for use of an existing data set not originally intended for research purposes.