

Willamette University Institutional Review Board (IRB): The basics

Purpose: The IRB seeks to protect human subjects who agree to participate in university-sponsored research. The IRB reviews applications from members of the Willamette University community to determine 1) whether the activity described comprises research as defined in 45 Code of Federal Regulations, part 46 (CFR; attached); 2) if so, whether the research protocols described are adequate to protect research participants from serious physical, emotional, social and/or legal harm; and 3) whether mechanisms are in place to inform participants of risks inherent to the research before they participate and to obtain their prior written consent. All Willamette community members who conduct research with human subjects must secure IRB approval BEFORE any data are collected. To collect data before IRB approval has been secured is a violation of federal regulations and constitutes research misconduct.

All members of the IRB complete formal training in IRB history, purpose, and procedures. Willamette's IRB maintains a 'federal wide assurance.' As a result, Willamette IRB decisions are recognized and accepted across federal agencies (e.g., federal research funding agencies) and by other entities (e.g., publishers) that require proof of IRB approval before they will act.

What constitutes 'research'?: As described in the CFR, 'research' is any activity involving human subjects that is 1) systematic; and 2) designed to contribute to 'generalizable' knowledge.

Example 1: A double-blind drug trial involving an experimental medication and a placebo given to a randomized population of human subjects would require IRB review because it is systematic and because there is a reasonable expectation that the published results could be generalized to the entire human population. The IRB would be especially concerned with safety of the human subjects; equitable and ethical assignment of individuals to experimental groups; disconnection of each participant's medical results from his/her identity (anonymity); and how confidentiality of medical records would be maintained.

Example 2: Students in a class develop a systematic survey of college students' sexual habits. They plan to present the results of the survey at a professional meeting and submit the results for publication in a professional journal based on the assertion that students at Willamette are typical of students at similar liberal arts colleges across the United States. The study is both systematic and designed to collect 'generalizable' data; thus, IRB review is required. The IRB would be especially concerned with a) maintenance of confidentiality if the survey were to be conducted through individual interviews; and b) with disconnection of responses from the individual who provided them when data are aggregated. In addition, if any records linking individual participants to their responses were to be maintained, the IRB would be very concerned with how data would be securely stored and what would become of data once the study had ended.

Example 3: Ten 'baby-boomer' residents of Salem, OR are asked to provide historical recollections of childhood in Salem. Free-form interviews and oral histories usually do not qualify as research because they are not systematic; nor are the results generalizable.

Example 4: A Willamette University administrator surveys students to determine their degree of satisfaction with the food service. While the survey may be systematic, the data are not generalizable and are for internal business purposes only. Internal business audits do not require IRB review.

No self-exemption: Many activities that involve human subjects do not require IRB review. However, members of the Willamette community may not 'self-exempt' projects from IRB review. All community members should file an application that describes fully the activity and the methods to be used so that the IRB can make a determination of whether the project requires review. In general, activities may not require review if 1) they do not meet the definition of research in the CFR; or 2) they are eligible for certain pre-determined exemptions described in the CFR. Only the IRB can determine whether conditions for exemption have been met.

IRB exemption does not mean exemption from sensible professional practice and/or legal action. Exemption from IRB review does not mean that those who employ human subjects in activities are exempt from sensible professional practices and common courtesies that also afford legal protection. For example, suppose a student were to decide to interview five holocaust survivors and post edited videos to YouTube. Minimally, the student

should inform each interviewee in writing of how the footage will be used and secure written permission to publish the interviews online.

What the IRB looks for in major sections of the application:

- 1) A *brief description of the project and its purpose*. Do not belabor the introductory sections of the application with discipline-specific jargon and journal references; just make a clear, succinct statement of the project and its purpose.
- 2) An *extensive description of methodologies with a description of inherent risks*. The IRB seeks to protect human subjects from undue physical harm and from psychological and/or emotional distress. In most (not all) cases, the IRB also wants to know a) how individual participants' identities will be disconnected from the data they provide (anonymity); and b) how the confidentiality of research data will be maintained. The methodology section must describe in detail the exact methods and protocols to address these risks. Researchers should consider whether the methods by which data are collected, analyzed, stored, or published could cause individual subjects to be physically and or emotionally harmed; embarrassed socially; punished; fired by an employer; or made to face legal action if data were to be stolen, revealed, published, or subpoenaed by a court. This section of the application must be detailed enough to allow the IRB to see the risks inherent in the methodologies and determine whether the methods and protocols are sufficient to minimize those risks. Vague statements are not sufficient and applications containing vague methodological descriptions will be returned without review.

Example:

BAD: A blood sample will be taken. (This application would probably be returned for revision without further review, delaying approval).

GOOD: Each subject will be seated. A gloved student trained by the supervising professor will swab the end of the participant's forefinger with and isopropanol-soaked swab; allow the isopropanol to dry; and use a pre-sterilized lancet to puncture the end of the finger. A small capillary tube will be used to collect ca. 100 microliters of blood. The finger will be swabbed with a clean isopropanol-soaked pad and the participant will be offered a small bandage to cover the puncture site.

- 3) Supporting documents including the exact informed consent document that will be given to participants.

Securing informed consent: Prior to data collection, each prospective participant should sign a document that gives his/her informed consent. The researcher must provide enough information on the informed consent document for the prospective participant to be able to make a well-informed decision about whether or not to participate. After the project has been briefly introduced, the methodologies to be used should be described in clear, simple layman's language so that the prospective participant can understand exactly what he/she will be asked to do. The prospective participant should also be informed of any and all foreseeable physical, emotional, psychological, social, and/or legal risks, and the informed consent document should explain how the methodologies are expected to minimize these risks. The form should describe how data will be used and/or published. Where published risk data for standard procedures are available, the prospective participant should be directed to such studies. Prospective participants should be informed of their right to withdraw from the study at any time without stating a reason and without fear of penalty, retribution, or loss of relationship with Willamette University. The participant should acknowledge that he/she understands and accepts the risks as described to him/her with a signature and date. Participants should receive a copy of the signed consent form. MINORS should sign their 'assent' to participate on one line of the form and a parent or guardian should sign and date the form on a separate 'consent' line. The parent or guardian should receive a copy of the signed form.

All informed consent forms should contain the following statement: "This research has been reviewed for the protection of human subjects by Willamette University's Institutional Review Board. Questions about the review process or comments about physical or psychological safety, anonymity, confidentiality, or use or storage of data should be addressed in writing to Dr. Gary Tallman, IRB chair at gtallman@willamette.edu."

Special considerations – faculty research in which students are used as research subjects: Because professors hold authority and sway, both stated and implied, over advisees and students enrolled in their classes, special attention should be paid to project methodologies in which students are to be engaged as research subjects. First, students should be given the option to participate or not participate. They should be informed in writing at the beginning of the study that if they choose not to participate there will be no grade penalty; no change in their relationships with the professor and/or other students; and no change in their relationship with the University. Second, if study participation is part of the grade (i.e., treated as an assignment), students who choose not to participate must be offered an alternate assignment of equal time commitment, difficulty, and value so that they have an equal chance of achieving the same grade as students who choose to participate. Onerous alternative student assignments must not be employed to increase research participation. If the activity is treated as an assignment, and if monetary incentives, awards, or prizes are to be given to those who successfully complete the assignment, both research participants and non-participants should have equal access to cash, awards or prizes.

The IRB is not an educational committee: The IRB does not have an educational function; its sole purpose is to protect human research subjects. The IRB now receives between 80-90 applications each year and an equal number of inquiries. Thus, an educational mission is impractical. Members of the Willamette community who engage human subjects in research are expected to understand the disciplinary methodologies required to protect their subjects. *Faculty members are expected to review student applications in advance of submission to correct mistakes and repair deficiencies before such applications come to the IRB.* Failure to do so may impede students' progress as they attempt to complete projects before the end of a given semester.

Any community member (faculty, staff, administrator, student) may take the same online training required of IRB members.

Go to: <https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English®ion=1>

- a. Register as a user with affiliation with Willamette University – On the CITI Program page, click on “Register” in the upper right hand corner of the screen and follow the instruction to register.
- b. After you log in to CITI with your username and password, select “Main Menu.”
- c. In the Main Menu under “My Learning Tools for Willamette University” select “Add a Course or Update Learner Groups” and then on subsequent screens answer the following questions:
Question 1 – Getting Started – Select “Human Subjects Research Course” and hit “Next.”
Question 2 – Human Subjects Research Course Enrollment – Select “IRB Members” and hit “Next.”
The system will direct you back to the main menu, and you'll see a course called “IRB Members – Basic” in your list of Willamette University Courses. This is the course you should complete.
If you run into trouble with the system give Kendra Mingo in OFFRR a call at 6617.

Disciplinary colleagues who have completed IRB reviews successfully may also be a good source of advice.

More detailed help is available at: <http://willamette.edu/dept/irb/index.html>

Important notes on the online application process: All applications, new and revised, should be submitted through the IRB's online form at:

<http://willamette.edu/dept/irb/human/application/index.php>

IMPORTANT NOTE 1: The form is not a ‘save-and-continue’ form; if you walk away and return the system will have erased your previous entry even though you may still see text on your screen. Thus, you should complete your application and supporting documents in a word processor; cut, paste, and attach as needed; and then hit the submit button immediately.

IMPORTANT NOTE 2: Applications received by 8 a.m. each Monday are distributed to the IRB the same day; those that arrive after 8 a.m. are not distributed until the next week. Allow two to four weeks for review and decision.