

XVIII. POLICY ON STUDIES INVOLVING HUMAN SUBJECTS
(Effective September 24, 2007)

All research conducted by Whitman College faculty or students involving human participants, regardless of its funding source, must be submitted to the Institutional Review Board (IRB) for review. Details of federal guidelines for this review process can be found at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Definitions of Research

Based on U.S. Government regulations that govern this review process, called “The Common Rule” because the same set of regulations applies to 18 different federal agencies, “RESEARCH” is defined as: “[A] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalize-able knowledge”. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

According to “The Common Rule,” a “HUMAN SUBJECT” is defined as: “[A] living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable “private information.”

IRB approval must be obtained prior to any data collection for research involving human participants, if the research is sponsored by the College (this includes activities undertaken as part of the instructional process); is conducted by or under the direction of any faculty, staff, or student of the College in connection with institutional responsibilities or using any property or facility of the College; or involves the use of the College’s non-public information to identify or contact prospective students.

If the results of the work are meant to be published or disseminated to an unrestricted audience, or even if this is viewed as a possibility, then the work counts as research.

The following activities are NOT considered research:

Surveys and interviews for the purposes of:

1. Journalism (as protected by the freedom of the press and subject to journalistic ethics), such as polls done for the College newspaper.
2. Advocacy (as protected by freedom of speech), such as a campaign to get students to stop smoking.

3. Internal College use only, such as surveys of members of the College community where the results are made available to a limited audience within the College community; or evaluations of College faculty, programs, or services.
4. Classroom activities that are part of the instructional process (as protected by academic freedom). However, participation by students in any teaching activity that involves risk to the student, or is not necessary to the course of study or training in which it occurs, must be accompanied by the student's voluntary, informed consent and must be reviewed and approved by the IRB. **If the instructor and/or student wish to present or publish information beyond the classroom (e.g., in a departmental colloquium or in the Undergraduate Conference), the activity is considered research and must be reviewed by the IRB in advance of the research being conducted if it involves human participants.** If the activity involves the entire class, the faculty member may submit one proposal for the class. However, if each student's project is fundamentally different, then separate proposals must be submitted.
5. Activities in which the primary purpose is specific benefit or treatment to the individuals involved such as counseling, social work, physical or psychological therapy, or psychological testing. These activities are subject to the norms of confidentiality and standards of practice of the relevant professionals.
6. Oral histories. Oral history interviewing activities are "not designed to contribute to generalizable knowledge and therefore do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB) (Office for Human Research Protection, 2004)". For additional information, please see:
<http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm>

In general, the following kinds of investigations must be reviewed before data collection begins:

1. Investigations in which the researcher creates or influences the situation in which the human subjects find themselves for the purposes of collecting information about those subjects. This includes naturalistic observational studies in which the presence of the observer may affect the situation, as well as ethnographic or participant observation studies and experimental manipulations whether in the field or the laboratory.
2. Investigations in which the researcher interacts with the human subjects in order to obtain information from those subjects. Biological research in which people are measured or fluids drawn or collected obviously falls under interaction. So do questionnaire and interview research, even when the interaction is an informal conversation, the content of which will be recorded in notes at a later time.

3. Investigations in which the research uses already existing data about human subjects in which the identity of the subjects is knowable from the data or the data are of such a personal nature that people might reasonably expect the data to be held in confidence. Obvious examples would be transcripts or medical records. Less clear cut examples might include email posts to a list-serve or letters written to a public person, depending on when the records are opened.

What need NOT be reviewed are investigations in which secondary data without personal identifications are used (e.g., other researchers' survey data sets) or personally identifiable data that the subjects themselves made publicly available (e.g., letters to the editor).

In general, any research conducted by Whitman students on other Whitman students as part of a class does not require committee approval. Observational research conducted off-campus also does not require approval, unless the primary investigator records (video or audio) behavior. All other types of data collection require approval, including all research involving minors, and surveys of or experiments on adults (those 18 years of age or older).

IRB Criteria

The purpose of the IRB review is to protect the rights and welfare of participants in research projects. In conducting its review the IRB seeks to assure that:

1. Risks to participants are minimized, by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of volunteers is equitable.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of participants.
7. There are adequate provisions to protect the privacy of the participants and to maintain the confidentiality of the data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional

safeguards have been included in the study to protect the rights and welfare of these participants.

What “Risks” Should You Consider?

While physical and health risks clearly need to be considered, several other categories of risk also need to be considered. One is the possibility of creating mental or emotional distress (including embarrassment to the participant). For example, asking questions about some aspects of a participant’s background (e.g., “Have you ever had an abortion?”) might trigger traumatic memories, and could be viewed as emotional risk.

Another category of risk is the risk of the loss of privacy. Asking very personal questions on a questionnaire or in an interview, where the investigator will be able to link the answers to the participant, constitutes a loss of privacy. In addition, there may be potential for compromise of confidentiality, if through publication of your work or inadvertent disclosure some participants could be identified with their responses.

The investigator’s obligations include designing the study so that the incidence of risk and stress are minimized to the greatest degree possible, describing these risks accurately in the protocols, and minimizing the number of participants who are exposed to these risks. The investigator must make appropriate provisions for care of the participants in the course of the study. The investigator is responsible for terminating the study if hazards or risks to participants become apparent or may be incompatible with the benefits of the study. Investigators must report to the IRB any injuries or adverse reactions associated with the study.

What is “Minimal Risk?”

45 CFR 46.102 (i): “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Why Informed Consent?

Participants must be fully informed about the nature of the research, the procedures, the risks, and the benefits, and must agree voluntarily to participate. This agreement is Informed Consent.

Every research project involving human participants must secure signed informed consent from them. If there is minimal or no risk and securing written informed consent is impossible or impractical (e.g., a telephone survey or certain observations of public behavior), the investigator may apply to have the requirement waived by the IRB.

Consent Procedures for Researchers Doing Qualitative Work

Section 116.d of the Federal Common Rule authorizes research with vastly different consent procedures, or no formal consent entirely, if the research is of no more than minimal risk; the change in consent procedures will not hurt the respondents; and the research could not *“practicably be carried out without the waiver or alteration.”* A reasonable interpretation of this section allows such normal qualitative procedures as:

Implied or situational consent: where, due to the nature of the research situation, the respondent is free to converse or not with the researcher, to tell the truth or otherwise, and is free to determine the level and nature of the interaction between participant and researcher. *In many ethnographic situations the proffer of a printed form is in and of itself full of threat and danger for informants and by instilling fear and doubt creates harm instead of ensuring informed consent.* The fact of the conversation is most often the concrete proof of consent. This is of course also the case in most surveys, telephone or in person, where the researcher contacts the respondent who is free to continue the conversation or break it off and continue with their normal activities.

Community consent: the situation where some community authority must approve the research before any individual community member is asked to participate (otherwise the approached individuals may be at risk of sanction for engaging in anti-community activities).

The point is, **ethnographic/qualitative respondents maintain the freedom to engage or disengage from research activities without an inappropriate and in most cases obstructive informed consent form.** This of course in no way absolves the researcher from clearly stating the goals of the study and discussing with respondents the publication plans, data management and identity protection strategies as appropriate (adapted from Stuart Plattner, “Human Subjects Protections and Anthropology.” <http://www.aaanet.org/press/an/infocus/hrp/Plattner.htm>).

Some Research Can Be Exempted from Detailed Review, but You Must Apply for Exemption:

Research can be exempted from detailed IRB review if it does not involve prisoners, fetuses, minors, pregnant women, or human in vitro fertilization, and the only involvement of human participants falls under one or more of the following categories. Only the Chair of the Board (or designate) can grant exemption; investigators cannot exempt themselves, nor can they be exempted by department heads or committees.

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

NOTE: This exemption does not apply to research with children [under age 18], except for research involving observations of public behavior when the

investigator(s) do not participate in the activities being observed. Note too that this exemption is linked to anonymous record keeping.

2. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - a. research on regular and special education instructional strategies,

OR

 - b. research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if
 - a. these sources are publicly available; OR
 - b. if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Some Research Can Be Approved by the Chair of the IRB under “Expedited Review”

Research activities that

1. present no more than minimal risk to human participants, and
2. involve only procedures listed in one or more of the following categories, may be reviewed and approved by the Chair or designate. The categories in this list apply regardless of the age of the participants. We omit unlikely subcategories. Category (7), in bold, covers much of the research activity proposed at the College in recent years.

The expedited review procedure may NOT be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to their financial standing, employability, insurability or reputation; or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) excreta and external secretions (including sweat); (c) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (d) mucosal and skin cell collection by buccal scraping or swab, skin swab, or mouth washings; (e) sputum collection after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and electrocardiography; (e) moderate exercise, muscular strength testing, body composition

assessment, and flexibility testing where appropriate given age, weight, and health of the individual.

5. Research involving materials (data, documents, records, and specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis). This category refers to materials that were originally collected for non-research purposes but that are now being considered for research purposes.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**
8. Continuing review of research previously approved by the convened IRB, under certain circumstances.

All Other Research Requires Review by the Full IRB

Research that does not fit into any of the above categories must be reviewed by the full IRB.

IRB Review of Research

1. An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
2. An IRB shall require that information given to subjects as part of informed consent is in accordance with [§46.116](#). The IRB may require that information, in addition to that specifically mentioned in [§46.116](#), be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
3. An IRB shall require documentation of informed consent or may waive documentation in accordance with [§46.117](#).
4. An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
5. An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and

shall have authority to observe or have a third party observe the consent process and the research.

Student Research

At Whitman College, part of the educational process includes understanding and participating in research. Consequently, we expect students to participate in the full scope of a research project, including formulating research questions, devising protocols, writing a careful description for proposed activities, carrying them out, and reporting the results. In particular, students must learn to take into account the ethical dimension of activities involved and any risks to human participants.

As with faculty and staff research, student research (or research practice) that involves human participants must have approval from the IRB.

Course projects whose results are to be presented only to current class members are not required to be reviewed by the IRB. However, if the instructor hopes that some student projects may produce results of high enough quality to justify public presentation (e.g., to the Whitman Undergraduate Conference or a professional conference), then all projects involving human participants should be reviewed by the IRB. A professor may submit one proposal for the entire class, if appropriate. The results of research projects involving human participants may not be presented outside a classroom setting unless the research was approved by the IRB in advance, and **approval can never be given retroactively to work already done. Because federal law explicitly prohibits retroactive approval, no appeal can be made to any campus body to overturn this requirement of the policy.**

Special note regarding student thesis projects: All student theses that include human participants must be approved by the IRB before the research begins. This requirement serves 2 purposes. First, it enables all student theses to be presented publicly (e.g., at a conference, a professional publication, or filed in Penrose library). More importantly, submitting a proposal serves an educational purpose for students. Senior theses are meant to be an introduction to original research, which in graduate school and beyond, does include the process of considering the ethical implications of one's research project and submitting a proposal to an IRB.

The instructor and the IRB are responsible (i.e., liable) for ensuring that there are minimal risks, not only to the participants of the experiment, but also to the student researchers.

Faculty Research Involving Students

Faculty who involve students in research with human participants, either as participants or as researchers themselves, have special responsibilities to those students.

1. No one may be forced or coerced into being a research participant. When research participation as a participant is a course requirement or an opportunity for extra credit, students must be offered an equitable alternative to being a participant.
2. The instructor should discuss ethical considerations, the nature of risks that may be involved, the role of the IRB, and what safeguards are to be used.

3. The instructor is responsible (i.e. liable) for minimizing risks to student researchers, as well as to the participants.

Special Classes of Participants

IRB's must give special consideration to protecting the welfare of particularly vulnerable participants, such as children, prisoners, pregnant women, mentally disabled persons, etc.

Vulnerability refers to the risks that researchers request their participants to undertake in relation to the ability of the participants to make fully informed consent. Populations routinely considered to be vulnerable include: children, prisoners, pregnant women, the mentally handicapped or disabled, economically or educationally disadvantaged persons, participants engaged in criminal activities, people under medical treatment for an illness relevant to the risk the researcher asks them to undertake, and participants who may risk or feel that they may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study. Non-literate or non-English speaking populations may also be considered vulnerable.

Children are defined as minors in the jurisdiction in which they reside. Washington defines anyone under the age of 18 as a minor. For children to participate as participants in research, parental/guardian informed consent and the child's written informed consent or "assent" (agreement) is required in language that s/he could be reasonably expected to understand. Whitman students who are under 18 years of age are considered children under Washington law, and thus require parental consent to participate in research. Please note that the IRB acknowledges that in many contexts outside of the United States, age does not easily correlate with both cultural and legal definitions of adulthood as defined in the US. In those instances where researchers are working with different criteria for the definition of children and adults, the following clause will apply: Children are defined as minors in the jurisdiction where they reside. It is the responsibility of the researchers-applicant to provide a justification for this exemption.

Research conducted in schools must be approved by the school or the school system, first by the assistant superintendent and then by the principal; approval by an individual teacher is insufficient.

Required Reporting and IRB Oversight

IRB approval of a project does not end its oversight of the project:

Investigators must report any planned procedural or consent form changes to the IRB for approval. Investigators must also report to the IRB any harm that occurs to any participant, within 48 hours of its occurrence. The IRB may, as a result of the complications, withdraw its approval of the project or require the investigator to add additional safeguards for the participants before the study can be resumed. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements or that has been associated with unexpected serious harm to volunteers.

Appointing the IRB:

In order to comply with Department of Health and Human Services directives, the members of the IRB will be appointed using the following guidelines:

1. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
2. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one profession.
3. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
4. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
5. The IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.