

Research and Publication

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Protection of Human and Animal Subjects in Research

PROCEDURES FOR OBTAINING INSTITUTIONAL APPROVAL FOR THE USE OF ANIMALS AND HUMAN PARTICIPANTS

The IRB (or the PreBoard Reviewer) will review all projects involving animals and human participants. Projects may be approved, disapproved, approved with modifications, or identified for pending action that will require the submission of additional information requested by the IRB. The IRB will inform investigators of its decision in writing.

1. Criteria for Approval

Projects will not be approved if they do not conform to the Institutional Guidelines for Treatment of Animals and Human Participants in Research (page 3) or the Institutional Guidelines for Animal Use and Care (page 6).

2. Categories of Review

Full Board Review: A review by the entire IRB will be required for all initial studies, and for subsequent studies that do not meet the criteria outlined below.

Expedited Review: Some studies (including, but not limited to, collection of hair/nail clippings, excreta, data using non-invasive procedures typically employed in clinical practice, voice recordings, notes) that clearly and obviously satisfy the Institutional Guidelines for Treatment of Human Participants in Research (page 3) or the Institutional Guidelines for Animal Use and Care (page 6) may receive expedited review by the PreBoard Reviewer if a similar study has been previously assigned an approval number.

Exempt: Some studies (including, but not limited to, some surveys, field interviews, naturalistic observations, educational evaluation and testing) that involve only minimal risk to participants and animals may be exempt from full IRB review. In these cases, researchers must still submit an application requesting exempt status and full review.

3. Review Procedure

Five (5) completed copies of the Application to Use Human Participants in Research or the Institutional Review Board Application to Use Animals in Research and Teaching must be submitted to receive full IRB review; two (2) completed copies must be submitted for expedited and exempt reviews. Applications to use human participants submitted for full or expedited review must include a copy of the proposed informed consent form. Written consent may be waived if (a) the signed consent form may link the participant to his or her data and thus violate confidentiality or (b) the study clearly and obviously presents only minimal risk to participants.

INSTITUTIONAL GUIDELINES FOR TREATMENT OF HUMAN PARTICIPANTS IN RESEARCH¹

- a. It is the investigator's responsibility to ensure that the participants' dignity and welfare are protected and that federal, state, and professional standards governing the conduct of research are met. Approval by the IRB does not preclude the necessity of obtaining approval from other governing agencies related to the study. For example, researchers studying patients in a hospital may also be required to obtain approval from the person or committee overseeing such practices at that hospital.
- b. Participation in any research project must be voluntary. Participants have the right to decline to participate in any study; participants may terminate their participation in any study at any time. The investigator has the responsibility to ensure that participants understand these rights.
- c. Studies may be evaluated to ascertain the degree to which participants are at risk, and any potential risk to participants must be offset by potential benefits of the research to participants or its potential contribution to knowledge. If the risk/benefit ratio is unacceptable, alternative designs must be considered or the study will not be approved and must not be conducted. Research that is redundant or trivial is not an appropriate use of energy and resources will not be approved.
- d. If participants are deemed to be at risk, the investigator must obtain informed consent² prior to their participation. Informed consent requires the obligations and responsibilities of both the investigator and participants to be stated in language that is easily understandable by each. The investigator must honor all obligations detailed in the informed consent procedure (page 5). Participants must be informed of any aspects of the research that might influence their choice to participate; any inquiries about any aspects of the study must be answered to the satisfaction of the participants. Anything other than full disclosure requires additional steps to ensure that the participants' welfare and dignity are protected. Research involving children or people with impairments will require special informed consent procedures to be approved in advance by the IRB.
- e. If the methodological requirements of a study require the use of deception, the risk/benefit ratio must be assessed (as in 3 above). Before such a study is conducted, the investigator must (a) determine whether deception is, in fact, a methodological necessity, (b) investigate the feasibility of using alternative procedures that do not involve deception, and (c) ensure that participants receive a full and sufficient explanation for the use of deception as soon as deception is no longer necessary.

- f. During the conduct of a study, the investigator is responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom must maintain ethical standards of treatment.
- g. It is the responsibility of the investigator to protect the participants from physical and mental discomfort, harm and danger during the course of research. Procedures for contacting the investigator for a reasonable period of time following the conclusion of a study should be established and communicated to the participant in the event that questions or concerns about his or her role in the study arise.
- h. At the conclusion of the study, the investigator will, in a timely fashion, provide all participants with a complete disclosure of the nature of the study; any misconceptions and questions will be settled at this time. Procedures for contacting the investigator for a reasonable period of time following the conclusion of a study should be established and communicated to the participant in the event that questions or concerns about his or her role in the study arise.
- i. The investigator has the responsibility of ensuring and maintaining participants' confidentiality and/or anonymity. Participants must be assured that the information they provide to an investigator during the course of a study is confidential or anonymous unless otherwise agreed upon in advance. All informed consent forms must be retained in a locked storage compartment separate from the study's data in order to ensure confidentiality and anonymity. If others may have access to consent forms and data, participants must be informed that others indeed may gain access to this information. Moreover, in this case every effort must be exerted to maintain confidentiality, and these steps must be explained to participants as part of the informed consent procedure.
- j. The University shall respect the right of students of conscientious refusal to participate in human experimentation. When a student expresses conscientious objections to engaging in a study or exercise that uses human participants, the student and the instructor will attempt to negotiate an alternative that is in the instructor's judgment an effective substitute.
- k. Instructors shall make known in the syllabi any uses of human participants in a course, and students shall make known any reservations about participating in the use of such participants by the second class after receiving the syllabus in order to facilitate planning for alternatives.
- l. Students and faculty unable to reach agreement on accommodation of conscientious refusal may file an appeal for mediation with the appropriate Academic Dean.

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the informed consent of their participants, or the informed consent of parents or legal guardians for participants who are less than 18 years of age. The researcher should have two copies of the consent form signed by the participant who will keep one for future reference, if needed.

In the case of questionnaire research, it is generally not necessary to include an informed consent signature, as a return of the questionnaire implies consent by the participant.

The informed consent statement must include the following:

- i Statement of who is doing the study (class, research organization, researcher, etc.). (This should be the same as item 11 below.)
- ii Statement of the purpose of the study.
- iii Statement of the use that will be made of the data.
- iv Accurate description of the methodology in lay language.
- v Statement indicating the length of time the participant will be involved.
- vi Statement of risks/benefits, if any, to the participant.
- vii Statement of anonymity and data confidentiality. If data is to be analyzed in aggregate, please so specify.
- viii Statement that participant may withdraw from the study at any time without prejudice. For example: If extra credit is given, withdrawal will not penalize participant from receiving course credit.
- ix Statement that participant may choose not to respond to any or all items of a questionnaire.
- x Statement offering to answer any questions the participant may have about the research before and after it is carried out.
- xi Name, title, address, and phone number of principal researcher(s) and names of all collaborators, or if a class project, the name of the class.
- xii Line for the signature of the participant (except in questionnaire/survey research).
- xiii 1. Statement that participants are 18 years of age or older
or
2. If participants are under 18 years old, separate statements of informed consent, appropriately worded for participants (i.e. children or adolescents) and their parents.

INSTITUTIONAL GUIDELINES FOR ANIMAL USE AND CARE³

- a. Animals shall be used only for the purpose of seeking potentially significant knowledge (in research) or for the purpose of significantly advancing students' knowledge (in teaching). The potential benefits of the knowledge shall be weighed against the necessity of using animals to obtain it, the amount of suffering animals would experience, and the number of animals that would be used. The use of animals that is redundant or trivial is not an appropriate use of energy and resources will not be approved.
- b. Care and use of animals shall be in accordance with the National Research Council's *Guide for the Care and Use of Laboratory Animals*⁴ and *The Biomedical Investigator's Handbook*⁵, and the laws and regulations referenced within these publications. Laws and regulations notwithstanding, an animal's immediate protection is the responsibility of the scientist. Investigators studying free-

living animals should take precautions to minimize interference with individuals as well as the populations or ecosystems of which they are a part.

- c. All procedures involving animals shall be closely supervised by a scientist trained in research methods, experienced in the care of laboratory animals, and dedicated to the welfare of the animals.
- d. All experimental procedures (surgical and non-surgical) must be carried out in such a way as to minimize pain and distress to the animal. For example, appropriate anesthetics must be used to eliminate sensibility to pain during surgical procedures. Techniques to avoid infection and minimize pain must be followed during and after surgery. The postoperative care of animals shall be such as to minimize discomfort and pain, and in every case be at least equivalent to accepted practices in veterinary medicine.
- e. If a study requires the death of an animal, the most rapid, painless, and humane method of euthanasia consistent with the study must be used.
- f. When animals are used by students, it is the responsibility of the instructor to ensure that all students under his/her supervision have received explicit instruction in experimental methods and in the care and handling of the species being used. Student work shall be under the direct supervision of an experienced teacher or investigator. Responsibilities and activities of students shall be consistent with their competencies and maturity. Instructors are ultimately responsible for the welfare of all animals used by their students.
- g. Only animals that are lawfully acquired shall be used in laboratory research and teaching.
- h. The University shall respect the right of students of conscientious refusal to participate in activities involving the use of animals. When a student expresses conscientious objections to engaging in a study or exercise that uses animals, the student and the instructor will attempt to negotiate an alternative that is in the instructor's judgment an effective substitute.
- i. Instructors shall make known in their syllabi any uses of animals in a course, and students shall make known any reservations about participating in the use of such animals by the second class after receiving the syllabus in order to facilitate planning for alternatives.
- j. Students and faculty unable to reach agreement on accommodation of conscientious refusal may file an appeal for mediation with the appropriate Academic Dean.

Academic Fraud and Scientific Misconduct

See Section Two.IV.C.

Copyright Law Compliance – In progress.

Sale of Employee-Created Materials to University Students

Faculty and staff members often create materials in which they hold commercial interests and which might be used in courses or programs which the faculty or staff member is teaching or administering for the University. It is the policy of the University that faculty or staff members may require students to purchase materials in which the faculty or staff members holds a commercial interest for courses taught or programs administered by that faculty or staff member. In these situations, however, the faculty or staff member shall assign all income rights for all the materials sold to the University. Any income thus received shall be placed in a special fund which shall then be made available by application to faculty and staff members in order to promote research, publication, or other creative efforts.