

Illinois Institute of Technology

Policy for the Protection of Human Research Subjects

I. Ethical Principles

- A. Illinois Institute of Technology is guided by ethical principles regarding all research involving human subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (also known as *The Belmont Report*). These principles include:
1. **Respect for Persons**
Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
 2. **Beneficence**
Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. The term beneficence is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do no harm, and (2) maximize possible benefits and minimize possible harms.
 3. **Justice**
An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are: (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.
- B. The university is also guided by, and will comply with, the requirements set forth in Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) for the U.S. Department of Health and Human Services, as well as those of other applicable federal, state, and local agencies.

II. Institutional Policy

- A. The University will establish and maintain an Institutional Review Board (IRB).
- B. The IRB will review all research involving human subjects, and will approve those research protocols that comply with its requirements for approval. Research means any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to knowledge. Human Subject means 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 or records. Review is a process by which the members of the IRB weigh the risks of the research activities against its potential benefits. Approval means that the IRB has determined that the benefits outweigh the risks to the human subjects in a particular research protocol, and has issued a letter that the research may be conducted.
- C. All research activities involving human subjects which are:

1. sponsored by the university, or
 2. conducted by or under the direction of any employee or agent of the university in connection with his or her university responsibilities, or
 3. conducted by or under the direction of any individual or agent using the property or facilities of the university,
- are subject to the review and approval of the IRB.

D. The IRB will establish and implement procedures for the review of research involving human subjects. These procedures will detail the processes to be used for:

1. the initial review of a newly proposed research protocol, including the classification of that protocol (i.e., expedited or full) and the manner for its review by the IRB,
2. the review of proposed modifications to approved research protocols,
3. the consideration of requests for the continuation and/or extension of approved protocols nearing the end of their approval periods, and
4. the investigative reports of possible harm to human subjects and/or possible non-compliance by any person covered by this policy, including the suspension or termination of approved protocols and reporting to necessary offices or agencies.

E. The IRB will approve of research involving human subjects which meet the following criteria:

1. Risks to the subjects are minimized.
2. Risks to the subjects are reasonable in relation to the anticipated benefits.
3. Selection of the subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent shall be documented, or conditions in (a) or (b) below shall be met:
 - a) The IRB will give careful consideration to requests for waivers or alterations of elements of informed consent. When approving waiver or alteration of some or all of the required elements of informed consent, the IRB will consider and document each of the four specific criteria required by the HHS regulations 45 CFR 46.116(d). The four criteria are: a) the research involves no more than minimal risk to the subjects; b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; c) the research could not practicably be carried out without the waiver or alteration; and d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
 - b) When a researcher wishes to waive the requirement for the investigator to obtain a signed consent form for some or all subjects, the IRB shall consider and document the criteria required by the HHS regulations at 45 CFR 46.117(c). Those regulations state: "An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research."
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

F. The IRB may stipulate conditions for the approval of human subjects research, including specific requirements for the monitoring of human subject rights and/or welfare and limited periods of approval prior to re-authorization. The IRB may temporarily suspend its approval for research pending an investigation (see

section V below) of potential harm to human subjects. The IRB may terminate its approval for any research following an investigation of potential harm to human subjects.

G. The IRB will comply with federal, state, and local laws as they might relate to the activities covered by this policy.

III. Institutional Review Board (IRB) Membership

- A. The IRB will consist of a minimum of five (5) members appointed by the Vice Provost for Research, to whom this authority has been delegated by the IIT President. In making appointments to the IRB the Vice Provost for Research will consider individuals having varying backgrounds in order to promote a complete and adequate review of research activities commonly conducted by the university. The Vice Provost for Research will ensure that the IRB members will be sufficiently qualified through the expertise, experience, and diversity in race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, to promote respect for IRB 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, members appointed by the Vice Provost for Research will 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.
- B. The membership of the IRB will include:
 - 1. one member who will serve as the Chairperson,
 - 2. at least one member whose primary concerns are in scientific areas,
 - 3. at least one member whose primary concerns are in nonscientific areas, and
 - 4. at least one member who is not otherwise affiliated with the university and who is not part of the immediate family of a person who is affiliated with the university.
- C. The Vice Provost for Research will appoint an institutional representative who will serve as an ex officio member of the IRB.
- D. Members will be appointed for a term of three (3) years. Consecutive terms may be served. Members unable to serve some portion, or the remainder, of their term may be excused for that portion, or the remainder of their term with the Vice Provost for Research appointing a suitable replacement.
- E. The exact number of members of the IRB may vary, depending on such factors as: member availability during university vacations and closings, individual member vacations and sabbaticals, and conflicts in work and teaching schedules. In no case will the membership drop below the five (5) members described in (A) and (B) above.

IV. Meetings

- A. Regular scheduled meetings of the IRB will be held as needed to conduct the timely review of proposed human subjects research. A special meeting of the IRB may be called by the Chairperson (or his or her designee in his or her absence) to consider any matter related to the protection of the rights and welfare of human research subjects.
- B. All IRB meetings will be conducted in accordance with Roberts Rules of Order.
- C. A quorum will consist of fifty percent (50%) of the membership plus one. Actions of the IRB will be directed by a majority of those members present and voting.

V. Investigation and Reporting Responsibilities

- A. The IRB will have the authority to and will, at its discretion and for any reason whatsoever, investigate any activity, persons, or records covered by this policy. The IRB will investigate all unanticipated problems

involving risk and/or injury to human subjects. The IRB Chairperson, or his or her designee, may:

1. interview a principal investigator, co-investigator(s), subject or any other person connected with research involving human subjects,
2. examine the research records involving human subjects, including informed consent documents and collected data, and
3. inspect any facilities, laboratories, equipment, or supplies used in human subjects research.

B. The IRB will prepare and maintain adequate records of its activities.

C. The IRB will report its findings and actions to the institution. The procedure for the IRB reporting its findings and actions to the institution is that IRB meeting minutes and other IRB reports shall be transmitted to the Institutional Official (the Vice Provost for Research) on a regular basis. In addition, the IRB will report promptly to the Vice Provost for Research and, if appropriate, the federal Office for Human Research Protections (OHRP) or other state or federal office(s) knowledge of:

1. any serious or continuing noncompliance with the requirements of the IRB
2. any suspension or termination of IRB approval,
3. injuries to human research subjects, and
4. any changes in the membership composition of the IRB.

D. The IRB will require investigators to:

1. promptly report all unanticipated problems involving risks or injury to human research subjects or others,
2. not initiate changes to a research protocol previously reviewed and approved by the IRB without requesting and receiving IRB review and approval for those specific modifications, and
3. maintain complete records of all research activities involving human subjects research.

VI. University Responsibilities

A. The university will provide adequate administrative support and oversight for the activities of the IRB, including the preparation, maintenance, and appropriate distribution of adequate documentation of IRB activities. This includes, but is not limited to:

1. copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects,
2. minutes of IRB meetings which will be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the notes on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution,
3. records of continuing review activities,
4. copies of all correspondence between the IRB and the investigators,
5. a list of IRB members,
6. written procedures for the IRB.

B. The records required by this policy will be retained for at least three (3) years, and records relating to research that is conducted will be retained for at least three (3) years after the completion of the research. All records will be accessible for inspection and copying by authorized representatives of the federal Office for Human Research Protections (OHRP) or of other state or federal office(s) at reasonable times and in a reasonable manner.

C. The University will provide adequate meeting space for the IRB.