



**Illinois Institute of Technology
Institutional Review Board
Handbook of Procedures
for the Protection of Human Research Subjects**

The Basics of Human Subject Research Protection

Federal regulation (*Title 45, Code of Federal Regulations, Part 46*, see Appendix A) requires that all institutions receiving federal funds which conduct research using living humans as subjects establish and operate an Institutional Review Board (IRB). The purpose of the IRB is to ensure the protection of these human subjects. IRBs are guided by the ethical principles embodied in *The Belmont Report* (see Appendix B), and by additional local standards and expectations. Illinois Institute of Technology has a policy (*Policy for the Protection of Human Subjects*, see Appendix C) that establishes our institution's IRB. This policy provides both background and direction for the mission of the Illinois Institute of Technology IRB.

This document, the *Handbook of Procedures for the Protection of Human Research Subjects*, describes how the Institutional Review Board at Illinois Institute of Technology will accomplish its mission. This handbook describes the processes to be used for the review of research protocols from initial submission through modifications and renewal, as well as procedures to be used to investigate assertions of harm to subjects or potential research non-compliance. This handbook also describes the roles that different members of the IRB can be expected to play, and provides guidance for how these roles ought to be executed.

Important Terms and Concepts

Several critical terms are used throughout this procedures manual. It is important that all Principal Investigators, other researchers, and members of the IRB share a common understanding of these terms.

Research means any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. It is the nature of the research activity that will involve human subjects itself that necessitates the need for IRB review and approval. It is the IRB, not the researcher, who determines in each case whether or not a particular activity is research and where it exists in the review and approval process. Investigators may not avoid the requirements of the IRB by referring to their research activities by other names (e.g., holistic investigations, naturalistic interactions, preliminary inquiries). Nor do the planned results of a research activity (e.g., a paper to be presented at a meeting, one submitted for journal publication, or not intended for dissemination at all) alter the requirements for an IRB review.

Research Protocol is a description of a planned research activity written in sufficient detail to allow for a review of the proposed research activities by the IRB. Research protocols submitted for IRB review are required to follow a specified outline, detailing just the information necessary for a proper IRB review in clear and plain language. Incomplete protocols, protocols containing confusing or unnecessarily technical language, or protocols involving excessive and unnecessary detail (e.g., the entire first three chapters of a dissertation) are unacceptable and will be returned without review.

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 their potential benefits. Research protocols are classified into one of two groups (expedited review or full review) depending on the

nature of the research activities and the anticipated risks to the human subjects.

Approval means that the IRB has determined that, for a particular research protocol, the benefits outweigh the risks to the human subjects. The IRB signifies its approval of a research protocol by issuing a letter to the Principal Investigator stating that the research protocol has been reviewed and approved, and may be conducted. Research protocols having little risk to the subjects may be approved even if the benefit to be gained is likewise small (e.g., class projects where the primary gain is for the student to experience a research process). Research protocols having higher degrees of risk for the human subjects must demonstrate both sound methodology and importance of the information that would be gained.

Approval Period is a length of time, typically one year or less, throughout which an approved research protocol may be conducted. Research protocols having certain risks or special circumstances may be approved for a shorter period. The IRB may require additional reporting to the IRB before additional time (an extension of the approval period) is granted.

Approved with Conditions means that a research protocol has been reviewed by the IRB but cannot yet be approved. A protocol review status of Withheld Pending most typically means that a minor issue or issues needs either correction or clarification. Such minor issues are typically corrected through additional communication between the Principal Investigator and both the Chair and Executive Officer of the IRB without the necessity for further review. More substantive changes to a protocol with a status of Withheld Pending may require re-review by the IRB. A protocol is most typically held as Withheld Pending for no more than 30 days, during which time it is approved, sent out for additional review, or administratively denied due to insufficient information.

Denial means that the IRB has determined that, for a particular research protocol, the risks to the human subjects outweigh the benefits to be gained by conducting that research. Research protocols might also be denied because:

- the protocol is confusing or convoluted and not understood by the IRB (e.g., poorly written or containing excessive technical language or jargon);
- inappropriate procedures are being proposed to recruit research subjects and/or to secure their participation in the research (e.g., in the informed consent documents and procedures);
- the Principal Investigator has not convinced the IRB of his or her capacity (training and experience) to conduct the proposed research; or
- the methods being proposed are inadequate for the research, lack sufficient rigor or merit, or are unlikely to provide data that would allow the Principal Investigator to answer the main questions driving the research.

A protocol may also be administratively denied when a Principal Investigator has not responded to a request for additional information and/or modifications from the IRB in a timely fashion (most typically 30 days).

Modification is a requested change to an approved protocol. It is not uncommon for Principal Investigators to desire a change to a working research protocol based on initial experiences in the laboratory or in the field. The proposed changes to the research protocol must be requested in writing either in a short letter (if the proposed modifications are relatively minor) or in a submission of a revised protocol (if the proposed modifications are more substantial). Minor modifications that do not change the overall nature of the approved research protocol (e.g., changing the size of a subject pool, adding additional investigators, changing a field site) may be approved upon a review by the IRB Chairperson. More substantive modification requests are reviewed in the same way as the original protocol and may be approved as submitted, may generate questions and/or requested modifications upon IRB review, or may be denied.

Continuation is a requested re-approval of an approved protocol. As with modifications, it is not uncommon for a researcher to desire to continue his or her research beyond the time allowed in the initial approval period. A request for a continuation is handled in the same way as a new submission. The investigator(s) must complete an IRB application. To assist in the review, it is recommended that a cover memo be included which specifies:

- any changes to the research protocol that are desired, with a description of those changes,
- the length of the new approval period up to one year maximum, and
- the research activities completed to date and a report of the nature, type and frequency of any adverse reactions encountered by any human subjects participating in the research.

Requests for continuation are reviewed in the same way as the original protocol. Requests for a continuation of the approval period may be approved as submitted, may generate questions and/or requested modifications upon IRB review,

or may be denied.

Suspension of research activities, during which no research involving human subjects may be conducted, may be required by the IRB. Although rare, a suspension is sometimes necessary to temporarily withdraw the IRB's approval for a particular research protocol when evidence exists that harm has occurred, or is believed likely to occur, to a human subject participating in a research activity. The IRB Chairperson may suspend the IRB's approval for a protocol if he or she believes that harm has occurred and/or is likely to occur (or re-occur) if the research is allowed to continue. A suspension automatically begins an investigation of the circumstances resulting in the suspension. Such an investigation will comply with IRB and university procedures for investigating research misconduct. Within two weeks of a suspension, the IRB meets to consider the circumstances of the suspension and the findings of the resulting investigation to determine if the suspension should be lifted or if the IRB's approval should be withdrawn.

Termination of research activities results when a prior approval from the IRB is withdrawn due to substantiated instances of harm (or the potential for previously unrecognized harm) to human subjects and/or confirmed circumstances of non-compliance.

Adverse Reaction occurs whenever a human subject of a research activity experiences a physical, psychological, social, or other negative impact as a result of participation in the research activities. Participation in a research activity by a human subject always involves some degree of risk although, in most cases, this risk is minor and the researcher takes significant steps to ensure that risks are minimized. All instances of a research subject's experiencing an adverse reaction as a result of participation in a research activity will be reported by the IRB to the designated university official for IRB oversight. Some instances might require reporting to other university, local, state, or federal departments or agencies.

Non-Compliance occurs when a Principal Investigator, or other researcher(s) under the direction of the Principal Investigator, either: (a) engage(s) in research activities other than those approved in the original (or modified) research protocol; (b) continue(s) to engage in approved research protocol activities beyond the time period specified in the approval period, or (c) engage(s) in any research activities involving human subjects without a research protocol's having been previously approved by the IRB. Instances of non-compliance will be addressed with IRB and university procedures for investigating research misconduct. All instances of non-compliance will be reported by the IRB to the designated university official for IRB oversight. Some instances might require reporting to other university, local, state, or federal departments or agencies.

Qualifications and Training refers to the requirement that every person acting as a reviewer of proposals or IRB member be properly qualified through education, experiences, and training to conduct his or her duties. The IRB requires that each member have on file a current resume or curriculum vitae attesting to personal education and experiences. In addition, each member is required to participate in annual training. This annual training will include:

- the historical contexts that have resulted in the creation of IRBs;
- the role and function of the IRB;
- the structure and operation of the IRB at Illinois Institute of Technology;
- procedures to be used for submission and review of protocols;
- procedures to be followed for requests for continuations and/or modifications;
- procedures to be followed for the investigation of adverse reaction and non-compliance;
- the forms used for submission and review of protocols;
- the standard letters used to communicate IRB queries and decisions to the Principal Investigator, and
- an introduction to the Office of Sponsored Research and Programs (OSRP) staff supporting the operation of the IRB.

Process for the Initial Review of Human Research Subject Proposals

The following section describes the process that will be followed for the initial review of research covered under this policy.

I. Research Investigator Completes a Proposal Submission Form

The first step in obtaining IRB approval for research involving human subjects is for the research investigator to complete the *IRB Application Form* (see Appendix D). This form may be obtained from the Office of Sponsored

Research and Programs by calling the office or downloading from the website. The form asks for: the title of the project; the name, mailing address, and telephone number of the Principal Investigator; and the names, mailing addresses, and telephone numbers of any co-investigators. Only university faculty or staff may serve as Principal Investigators for an IRB research protocol. A student investigator must be named on the form as being a co-investigator, with the faculty or staff member providing appropriate direction to the student researcher.

Each item in the IRB application must be completed or indicated as being not applicable. No particular length of submission is required. Rather, the narrative should explain each of the recommended areas in sufficient detail for a review to be made.

The Principal Investigator then signs the submission form attesting to the submission materials' correctness and agreeing to follow the procedures established by the IRB. The signed form, along with eight copies, is then given to the Office of Sponsored Research and Programs (OSRP).

II. Routing by the Office of Sponsored Research and Programs

The administrative assistant (AA) in the Office of Sponsored Research and Programs (OSRP) receives completed proposals. The AA assigns an IRB tracking number and enters the proposal into a computer database. The secretary then routes each proposal according to the following criteria:

- (1) The application is indicated as a submission for expedited review,

Proposals submitted for expedited review are sent to the IRB Chairperson/designee for review and designation as exempt.

- (2) If the application is classified as requiring a full review.

The AA sends a copy of each IRB application for full review that is received to all members of the IRB, along with the agenda for the next meeting. A copy of the agenda is sent to each investigator, advising him or her of the date, time, and place of the IRB meeting.

III. IRB Committee Meetings for Full Proposals

Research proposals that require a full review must come before the entire IRB at a regular or special meeting. Prior to that meeting each IRB member and the IRB Chairperson will have read and considered the proposal. An investigator from each proposal submission must attend the meeting to present the IRB application. During the time allotted at the meeting the chair will ask the investigator to briefly summarize the proposal. IRB members may ask questions of or make suggestions to the investigator(s). As necessary, experts in the area may be consulted by the IRB for their opinion. This may require postponing discussion and/or decision until the next IRB meeting. After discussion is concluded, voting is conducted by ballot. As in all business before the IRB, a majority vote of those present is required before any action may be taken.

IV. Review Outcomes: Approvals, Approved with Conditions, and Denials

All research proposals brought before the IRB, whether exempt through expedited review or full review, must be approved as submitted, approved pending minor revisions, or denied with recommendations for major revisions. The IRB Chairperson/designee is empowered, on behalf of the IRB committee, to approve all expedited proposals that have received satisfactory review. Proposals that, in the opinion of the Chairperson/designee, are still deficient after a Principal Investigator's response to a request for minor revisions must be brought before the IRB for consideration. Only the IRB may approve a proposal requiring a full review, or deny approval to any proposal.

After an expedited proposal has been read by the IRB Chairperson/designee and approved, the Chairperson/designee will inform the Executive Officer of the IRB. An approval letter, signed by the IRB Chairperson/designee, will then be sent to the Principal Investigator. A copy of this letter is also kept in the IRB files.

On other occasions the Chairperson/designee may determine that approval of the proposal as submitted is not

warranted. In this case the Chairperson/designee will write a letter to the Principal Investigator indicating that approval for the proposal is being withheld pending certain minor revisions that must be made to the proposal. The letter will detail the items or questions requiring attention and a time frame for submitting revisions. The Principal Investigator will be invited to submit these revisions directly to the OSRP office. In certain cases the Chairperson/designee might also elect to contact the Principal Investigator directly to ensure that the needed revisions are understood or to discuss ways the Principal Investigator might meet the requirements of the IRB. If the Principal Investigator responds to the issues raised in this letter to the satisfaction of the Chairperson/designee, the Chairperson/designee may approve the proposal as revised. If no revisions are made, or the revisions are not satisfactory to the Chairperson/designee, the proposal will be maintained as withheld pending and will be scheduled for presentation and discussion at the next regular meeting of the IRB committee.

The Principal Investigator may enact research protocols approved under this procedure for a period not to exceed the approval period, typically one year. The starting and ending dates of the approval period will be stated on the approval letter sent to the Principal Investigator. In certain cases the IRB may require a shorter approval period and/or interim reporting on the progress of the research and the status of the human subjects as a condition of approval. The exact period of approval, and any conditions, will be stated in the approval letter. Protocols will not be approved for a period greater than one year

V. Questions and Appeals

Any person may request an appointment with the IRB Chairperson, or an opportunity to address the IRB at a regular or special meeting, for any purpose related to the business of the IRB including appeals of decisions by the IRB or IRB Chairperson. The two most common reasons for such an appointment or hearing are to answer questions concerning proposals in development or research in progress, or to resolve difficulties related to the approval of a proposal.

The IRB Chairperson should strive to make him/herself available for questions from Principal Investigators. Experience has shown that most issues can be addressed through a short telephone conversation or email exchange. As necessary the Chairperson will be available for personal meetings, discussions with research teams or laboratories, and presentation meetings before academic units. Frequent, positive interactions can improve the quality of later submissions and reduce the number, severity, and frequency of difficulties.

Process for Special Reviews of Human Subject Research Proposals

Modification Reviews

On occasion a research study may need to be modified from the protocol that was originally approved by the IRB. The Principal Investigator must request a modification review when a change in the research protocol is desired. Such a request must be in writing and may be in the form of a simple letter detailing the reasons for the modification and the proposed modification. This letter and any supporting documents (such as changes to instruments or informed consent documents) should be sent directly to the OSRP office.

The IRB Chairperson is empowered to approve all requests for modification that are minor in nature. Minor modifications are those that do not change the basic nature of the research effort. Examples of minor modifications might include: expanding the subject pool size (due to a low initial participation rate), changing a data collection form to make it easier for subjects to read it, or adding an additional field site similar to those already being used.

Requested modifications that are not minor in nature will initiate a review of the revised protocol at the same level (full review) as the initial proposal. As with an initial review, the requested modification may be approved, approved with conditions pending minor revisions, or denied. If approved, the revised protocol will carry the same approval period as the original approval.

Process for Investigating Adverse Reactions and Possible Non-Compliance

The IRB has the responsibility of overseeing the protection of human subjects of research. The IRB addresses this responsibility by investigating complaints of subjects suffering adverse reactions to a research process, or of Principal Investigator or co-investigators not following their approved research protocols. Principal Investigators are required, under this policy, to follow the research protocols that they have submitted to, and that have been approved by, the IRB. Principal Investigators are also required to promptly report to the IRB any adverse reactions experienced by research participants.

Initial reports of adverse reactions or possible non-compliance should be brought to the attention of the IRB Chairperson and the OSRP office. The Chairperson, in consultation with the institutional representative to the IRB and any other IRB members as might be required, conducts the initial investigation. The purpose of the initial investigation is to determine, as quickly as possible, two points. First, does the assertion of adverse reaction or non-compliance have any merit (is it worth further investigation)? Second, are any human subjects at risk if the research study is allowed to continue?

To answer these questions the Chairperson may: interview the Principal Investigator and co-investigators, selected human subjects, and others; examine research records requested from the investigators; and personally inspect research facilities and equipment. This initial investigation should take place as quickly as possible, typically within a few days of receiving the initial information. If no adverse reaction or possible non-compliance is uncovered, no further action is necessary. The IRB Chairperson is empowered, however, to temporarily suspend the research protocol if this initial investigation uncovers information supportive of an adverse reaction or non-compliance and if human subjects might be at risk if the study is allowed to continue. Should this occur the Chairperson will notify, verbally and in writing, the Principal Investigator, his or her academic unit head, and the institutional representative to the IRB that the research has been temporarily suspended.

Complaints of adverse reaction or possible non-compliance that the Chairperson has found to have merit, regardless of whether a research protocol has been temporarily suspended, will be brought by the Chairperson to a special meeting of the IRB committee within two weeks of the Chairperson's determination. At this meeting the IRB committee will be presented with whatever facts have been collected thus far. The Principal Investigator, co-investigators, and any others with relevant information will be invited to present information to the committee. The IRB will then decide if further investigation is needed or if sufficient information is available to determine whether an adverse reaction or non-compliance has occurred. The IRB will also decide if the research protocol should be continued as originally approved, reinstated (if temporarily suspended by the Chairperson), suspended pending a further investigation by the IRB or revisions by Principal Investigator, or terminated (the IRB withdraws approval for the study).

The sole function of the IRB is to provide protection for the human subjects of research by approving, requiring modification in, or denying approval of proposed research. When the IRB suspends approval for a research project, no further research involving human subjects may be undertaken. The Principal Investigator will need to submit to the IRB modifications to the protocol sufficient to satisfy the conditions of the suspension before the research can be resumed. When the IRB withdraws its approval for a research project, the project is considered terminated and no further research involving human subjects may be undertaken. A new protocol will need to be submitted, reviewed, and approved.

There may be certain agencies, both within and outside the university, which require notification whenever a research protocol involving human subjects is suspended or terminated. The IRB Chairperson and the institutional representative ensure that these notifications are made in a timely fashion. Principal Investigators must be aware that a suspension or termination of IRB approval can result in the freezing of internal or extramural grant accounts, the return of equipment or other resources, and further investigation by other entities (such as the student affairs office, academic unit heads, deans, as well as outside funding and governmental bodies).

Appendices

- A: Title 45, Code of Federal Regulations, Part 46
- B: The Belmont Report
- C: Illinois Institute of Technology Policy for the Protection of Human Subjects
- D: IRB Application Form