

**Illinois State University Institutional Review Board
Policy and Procedures Manual for the
Protection of Human Research Subjects**

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I. Human Subject Research Protection

A. Basics

Federal regulation, *Title 45, Code of Federal Regulations, Part 46*, 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* and by additional local standards and expectations. This policy provides both background and direction for the mission of the Illinois State University IRB.

B. Important Terms and Concepts

There are several critical terms that are used throughout this procedures manual. It is important that all Principal Investigators and other researchers; department, school and unit IRB representatives; and members of the IRB Executive Committee 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. Research activity that will involve human subjects necessitates IRB review and approval. It is the IRB, not the researcher, that will determine in each case whether 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, or preliminary inquiries). Nor do the planned results of a research activity (e.g., a paper to be presented at a meeting or one submitted for journal publication,) alter the requirements for an IRB review.

Research Protocol is a written description of a planned research activity in sufficient detail to allow for a review of the proposed research activities by the IRB. Research protocols submitted for IRB review are to follow a particular outline, detailing just the information necessary for a proper IRB review in clear and plain language. Incomplete protocols, protocols containing confusing or highly technical language, or protocols involving excessive and unnecessary detail (e.g., the entire first three chapters of a dissertation) are unacceptable.

Human Subject means a living individual about whom a research investigator (whether faculty, staff or student) 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. Research protocols are classified into one of three groups (exempt review, 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 that the research protocol has been reviewed, 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 some measure of benefits to the participants.

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

Withheld Pending means that a research protocol has been reviewed by the IRB, but cannot yet be approved. Protocols with a review status of Withheld Pending most typically are due to one (or more) minor issues needing either correction or clarification. Such minor issues are typically corrected with additional communication between the Principal Investigator and the Chair of the IRB without the necessity for further review. More substantive changes to a protocol with a status of Withheld Pending may result in a re-review by the IRB. A protocol is most typically held in a Withheld Pending for no more than 30 days, after which 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 overly confusing or convoluted and not understood by the IRB (e.g., poorly written or uses excessively technical language or jargon);
- Inappropriate procedures are being proposed to recruit research subjects and/or to secure their participation in the research (e.g., inadequate informed consent documents or coercive 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 from the field. The proposed changes to the research protocol must be requested in

writing either as a short letter (if the proposed modifications are relatively minor) or as a re-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, or changing a field site) may be approved upon a review by the IRB Chairperson. More substantive modification requests are reviewed in the same way (expedited review or full review) as the original protocol. Requests for modification 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 of the approval period must be made in writing to the IRB, and should specify:

- Any changes to the research protocol are desired (and what those changes are),
- 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.

The IRB Chairperson may approve a request for continuation to a protocol to which no major changes have been made and no adverse reactions have occurred upon a review. Other requests for continuation are reviewed in the same way (expedited review or full review) 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. In addition, no protocol may be operated for more than three years without undergoing a complete re-review.

Suspension of research activities, during which no research involving human subjects may be conducted, may be required by the IRB. Although rare, 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 Executive Committee will meet to consider the circumstances of the suspension and the resulting investigation to determine whether the suspension should be lifted or the IRB's approval terminated.

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 his/her participation in the research activity. 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 insure those risks are minimized. All instances of research subjects experiencing an adverse

reaction as a result of his/her 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 local, state, or federal departments or agencies.

Non-Compliance occurs when a Principal Investigator, and/or another researcher under the direction of the Principal Investigator, either: (a) engages in research activities other than those approved in the original (or modified) research protocol; (b) continues to engage in approved research protocol activities beyond the time period specified in the approval period, or; (c) engages in any research activities involving human subjects without a research protocol previously approved by the IRB. All instances of non-compliance will be reported by the IRB to the designated university official for IRB oversight. Violations can be technical or substantive. Some instances might require reporting to other local, state, or federal departments or agencies. And some instances of non-compliance might be reported to other appropriate university units.

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

- The role and function of the IRB;
- The structure and operation of the IRB at Illinois State University;
- 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 Research Ethics and Compliance Office (RECO) administration and staff supporting the operation of the IRB.

II. Illinois State University Policy for Protection of Human Research Subjects

A. Ethical Principles

Illinois State University 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. Respects 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.

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 Department of Health and Human Services, as well as those of other applicable federal, state, and local agencies.

B. Institutional Policy

1. The University will establish and maintain an Institutional Review Board (IRB).
2. The IRB will review all research involving human subjects and will approve those research protocols that comply with its requirements.
3. All of the following research activities involving human subjects are subject to the review and approval of the IRB:
 - a. Sponsored by the university, or
 - b. Conducted by or under the direction of any employee or agent, including students, of the university in connection with his or her university responsibilities, or

- c. Conducted by or under the direction of any individual or agent using the property or facilities of the university,

Projects being conducted on Illinois State University premises, but not directed by an Illinois State University employee, need not be reviewed by the Illinois State University IRB but should have documented IRB approval from another university or agency with a Federal-Wide Assurance Number.

- 4. 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:
 - a. The initial review of a newly proposed research protocol, including the classification of that protocol (i.e., exempt, expedited, or full) and the manner for its review by the IRB,
 - b. The review of proposed modifications to approved research protocols,
 - c. The consideration of requests for the continuation and/or extension to approved protocols nearing the end of their approval periods, and
 - d. The investigation 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/agencies.
- 5. The IRB will approve of research involving human subjects that meet the following criteria:
 - a. Risks to the subjects are minimized,
 - b. Risks to the subjects are reasonable in relation to the anticipated benefits,
 - c. Selection of the subjects is equitable,
 - d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative,
 - e. Informed consent will be documented,
 - f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects,
 - g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and

- h. 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.
- 6. 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 of potential harm to human subjects. The IRB may terminate its approval for any research following an investigation of potential harm to human subjects.
- 7. The IRB will comply with federal, state, and local laws as they might relate to the activities covered by this policy.

C. Institutional Review Board (IRB) Membership

- 1. The IRB will consist of a minimum of five (5) members appointed by the President of the university. In making appointments to the IRB the President will consider individuals having varying backgrounds in order to promote a complete and adequate review of research activities commonly conducted by the university. The President will insure that the IRB members will be sufficiently qualified through the experience and expertise of its members, and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to issues such 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 President will appoint members who 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.
- 2. The membership of the IRB will include:
 - a. One member who will serve as the Chairperson.
 - b. At least one member whose primary concerns are in scientific areas,
 - c. At least one member whose primary concerns are in nonscientific areas,
 - d. 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, and
 - e. One member who is a practicing physician.
- 3. The membership of the IRB may include:

- a. Two members each appointed from each of the academic colleges: the College of Arts and Sciences, the College of Business, the College of Applied Science and Technology, the College of Education, the College of Fine Arts, and the Mennonite College of Nursing.
4. The President will appoint an institutional representative who will serve as an *ex officio* member of the IRB.
5. 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 President appointing a suitable replacement.
6. The exact number of members of the IRB may vary from semester to semester, depending on such factors as: member availability during university vacations and closures, 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. At the beginning of each semester the IRB Chairperson will certify the names of those individuals serving as members of the IRB for that semester and insure that these members' qualifications comply with federal regulations.

D. Meetings

1. Regular scheduled meetings of the IRB will be held monthly or 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.
2. All IRB meetings will be conducted in accordance with Robert's Rules of Order.
3. A quorum will consist of fifty percent (50%) of the membership for that semester plus one. Actions of the IRB will be directed by a majority of those members present and voting.

E. Investigation and Reporting Responsibilities

1. 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:
 - a. Interview a principal investigator, co-investigator(s), subject or any other person connected with research involving human subjects,

- b. Examine the research records involving human subjects, including informed consent documents and collected data, and
 - c. Inspect any facilities, laboratories, equipment, or supplies used in human subjects research.
2. The IRB will prepare and maintain adequate records of its activities.
3. The IRB will report promptly to the Illinois State University Associate Vice-President for Research and, if appropriate, the federal Office of Human Research Protections (OHRP) or other state or federal office(s), knowledge of:
 - a. Any serious or continuing noncompliance with the requirements of the IRB,
 - b. Any suspension or termination of IRB approval,
 - c. Injuries to human research subjects, and
 - d. Any changes in the membership composition of the IRB to agencies with which the university has filed an assurance.
4. The IRB will require investigators to:
 - a. Promptly report all unanticipated problems involving risks or injury to human research subjects or others,
 - b. Not initiate changes to a research protocol previously reviewed and approved by the IRB without requesting and receiving an IRB review and approval for those specific modifications, and
 - c. Maintain complete records of all research activities involving human subjects research.

F. University Responsibilities

1. The university will provide adequate administrative support and oversight for the activities of the IRB, including the preparation and maintenance of adequate documentation of IRB activities. This includes, but is not limited to:
 - a. 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.
 - b. 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 controverted issues and their resolution,

- c. Records of continuing review activities,
 - d. Copies of all correspondence between the IRB and the investigators.
 - e. A list of IRB members containing the detail required by federal regulations,
 - f. Written procedures for the IRB.
2. 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 of Human Research Protections (OHRP) or other state or federal office(s) at reasonable times and in a reasonable manner.
 3. The University will provide adequate meeting space for the IRB.

III. Process for Reviews 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.

A. Research Investigator Completes a Proposal Submission Form

The first step in obtaining IRB approval for research involving human subjects is for the principal investigator to complete the *Use of Human Subjects in Research Proposal Submission Form*. This form may be obtained from department/school/unit representatives or directly from the IRB. 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 a Principal Investigator for an IRB research protocol. Any 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.

A narrative describing the research is then written, following the guidelines which are available through the research and sponsored programs website. These guidelines describe several areas that should be addressed in the narrative, providing suggestions of issues and questions that are important to consider. It is not always necessary to address every item listed in these guidelines, nor is a particular length of submission required. Rather, the narrative should explain each of the areas in sufficient detail for a review to be made.

The completed narrative is stapled to the submission form. 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 submission form, together with the attached narrative, is then given to the Principal Investigator's department/school/unit IRB representative for the first step in processing. If there is no department/school/unit IRB representative, or if the department/school/unit IRB representative is the principal investigator, the paperwork may be sent directly to the Research Ethics and Compliance Office.

B. Department/School/Unit IRB Representative Review

The department/school/unit IRB representatives receive proposal forms from Principal Investigators within his/her department/school/unit. The first step in each review process is to examine the material submitted for each of the following:

- Is the "Proposal Submission Form" cover sheet legible, complete, and signed?
- Are single copies of supporting documents attached to the submission form?
- Is the supporting documentation organized and of sufficient detail to allow for a review?
- Does the investigator provide a response to each of the submission guideline areas (the nature of the response will vary depending on the research)?

Any incomplete or illegible submission should be returned to the Principal Investigator for re-submission. It is strongly suggested that the department/school/unit representative then work with Principal Investigators to insure successful re-submissions.

The department/school/unit representative then reads complete and legible submissions, to make a judgment regarding the additional review required for each proposal. Each proposal must be evaluated, according to the IRB criteria (*Department/School/Unit Representative Protocol Review Form*). The department/school/unit representative uses this form to summarize the important IRB review elements out of the submitted protocol and then determines whether the necessary requirements have been met. The form provides space for the department/school/unit representative to comment on each element. Finally, the department/school/unit representative indicates his/her opinion on the need for further review of the protocol by recommending a classification of:

Exempt from further review,

Eligible for an **Expedited** review, or

Requiring a **Full** review.

The department/school/unit representative then signs and dates the form and forwards all of the material to the Research Ethics and Compliance Office for further processing.

Department/school/unit representatives should strive to complete the review of each proposal as quickly as possible. If a proposal is to be returned to a Principal Investigator, the department/school/unit representative should detail in writing the deficiencies that need to be corrected for a review to proceed. Department/school/unit representatives, in evaluating their proposals, should tell Principal Investigators of any unforeseen delays. If speed is necessary and the department/school/unit representative cannot evaluate a proposal in the required time, a Principal Investigator may elect to send the proposal directly to the IRB. However, all researchers should allow at least three (3) working days for this first stage of the review process.

No department/school/unit representative may act as a department/school/unit representative on any proposal on which s/he is named as a Principal Investigator or co-investigator. This would represent a conflict of interest and potentially unfair review. If there is a second department/school/unit representative from that same department/school/unit, that second representative may review such a proposal of the other representative. Otherwise the proposal should be forwarded to the Research Ethics and Compliance Office for this first review (the Research Ethics and Compliance secretary will route the protocol to a different department/school/unit representative for review).

It may be advantageous for a single department/school/unit to have more than one representative to the IRB. Several representatives are usually warranted when the department/school/unit generates a large number of protocols for review, the usual representative becomes unavailable for a period of time (due to other duties or a sabbatical), or the department/school/unit representative is himself/herself submitting a number of protocols for review. All representatives from a department/school/unit must be qualified to serve as a department/school/unit IRB representative, including completing annual training. Once qualified and trained, each representative from a particular department/school/unit may fulfill the duties and responsibilities of a department/school/unit representative. When a department/school/unit has more than one representative, the IRB Chairperson will designate one of those representatives to serve as that department/school/unit's Point of Contact (POC). The POC will receive a copy of all official correspondence from the IRB and will be responsible for disseminating it to all of the representative's in his or her department/school/unit. At the beginning of each semester the RECO will update a list of individuals qualified, trained, and willing to serve as department/school/unit representatives for that coming semester. Only those individuals may sign a review as a department/school/unit representative and forward signed materials to the RECO for IRB review – materials signed by others will be returned to the department/school/unit for proper processing.

Certain departments/units might experience such a large volume of protocols that additional review options are appropriate. These departments/units, upon the approval

of the IRB Executive Committee, may elect to form a Department/school/unit Expedited Review Panel (DERP). Members of the DERP are additional members of the department/school/unit who are qualified and trained as department/school/unit representatives. In addition to regular their duties as alternate department/school/unit representatives, these individuals may also serve as content reviewers for proposals that have been classified for expedited or full review. The purpose of the DERP is two-fold: to speed the review of expedited proposals from that department/school/unit, and to interject necessary subject-matter expertise into the review process. Proposals classified as exempt by a DERP's department/school/unit representative should be forwarded to the Research Ethics and Compliance Office following the same procedure as if the proposal had been generated out of a non-DERP department. Proposals classified as requiring expedited review or full review by a DERP's department/school/unit representative, however, should be sent to at least one of the department/school/unit's DERP members (in addition to the department/school/unit representative initially reviewing the proposal). The DERP member(s) reviewing the proposal should complete a *Proposal Review and Comment Form*. Typically the department/school/unit's POC coordinates the activities of the DERP. Once all department/school/unit representative and DERP reviews have been completed, the entire proposal packet consisting of the original proposal, *Department/school/unit Representative Protocol Review Form*, and one (or more) *Proposal Review and Comment Form*, will be forwarded by the POC to Research Ethics and Compliance Office.

C. Routing by the Research Ethics and Compliance Office

The IRB secretary in the Research Ethics and Compliance Office receives completed proposals. The secretary reviews each proposal. Incomplete proposals are returned to the Principal Investigator with a short note indicating its deficiency. Complete proposals are given an IRB tracking number and entered into a computer database. The secretary then routes each proposal according to the following criteria:

1. Department/school/unit representative has not reviewed the proposal - A copy of the proposal, together with an appropriate cover letter, is forwarded to a selected department/school/unit IRB representative or IRB member for initial review. The original proposal is held in an "in review" file until the initial review determination has been returned.
2. The department/school/unit representative has indicated that the proposal should be classified as exempt from further review - Experience has shown that almost all of those proposals classified by the department/school/unit representative as exempt are, in fact, exempt from further IRB review. The secretary generates a standard exempt letter. Proposals classified as exempt are neither approved nor denied; rather, they have been determined to be exempt from further IRB review and oversight. Proposals classified as exempt do not have approval time periods, and the research may be conducted indefinitely. This proposal is then held in a

“Chairperson’s review” file awaiting final review and sign-off by the IRB Chairperson.

3. The department/school/unit representative has indicated that the proposal should be classified as eligible for an expedited review - One reviewer in addition to the department/school/unit representative must read proposals eligible for an expedited review. The secretary will send a copy of the proposal, together with a cover letter and a *Proposal Review and Comment Form*, to a member of IRB Executive Committee selected through a continuing rotation process. The original proposal is held in an “expedited proposals in review” file until the committee member’s comments are received. Once the additional reviewer’s comments are returned to the IRB office, the proposal will be held in the “Chairpersons Review” file awaiting final review and sign-off by the IRB chair.

Proposals eligible for an expedited review that have been received from a DERP with a completed *Proposal Review and Comment Form* from at least two members of that DERP will be held in the “Chairperson’s review” file awaiting final review and sign-off by the IRB Chairperson.

4. The department/school/unit representative has indicated that the proposal should be classified as requiring a full review - Two reviewers in addition to the department/school/unit representative must read proposals requiring a full review. The secretary will send a copy of the proposal, together with a cover letter and a *Proposal Review & Comment Form*, to two members of the IRB Executive Committee selected through a continuing rotation process. The original proposal is held in a “full proposals in review” file until both additional reviewers' comments are received. All members of the IRB Executive Committee will receive a copy of the protocol prior to the meeting at which the protocol will be considered.

D. IRB Member Review of Expedited and Full Proposals

IRB Executive Committee members serve, on a rotating basis, as reviewers for proposals requiring expedited or full reviews. The members are asked to read the proposal under consideration, consider both the “Proposal Submission Guidelines” and the “Criteria for Approval,” then to indicate a recommendation to the IRB as a whole for that research proposal. The member’s recommendation can be one of the following:

Approve the project as proposed,

Withhold approval of the project pending some minor revisions, or

Deny approval for the project with recommendations for major revision.

Space is allowed on the “Proposal Review and Comment Form” for the members to write short narratives explaining the reasons for the recommendation s/he makes. Except when recommending approval, members must state their reasons for withhold or deny as clearly and directly as possible.

In general, IRB members are allowed five to ten working days to complete reviews of expedited and full proposals and return their reviews to RECO. Once each week the secretary will examine the proposals in the “in review” file to insure that each is being processed expeditiously.

E. IRB Committee Meetings for Full Proposals

Research proposals that require a full review must come before the entire IRB Executive Committee at a regular or special meeting. Prior to that meeting, two IRB members and the IRB Chairperson will have read and considered the proposal. During the time allotted at the meeting, the chair will ask both of these members to briefly summarize the proposal, state their recommendations (approve, withhold, or deny), and briefly explain their reasons for their recommendations. A discussion will then be held and, as necessary, experts in the area may be consulted for their opinions. It is also not unusual to have questions of the Principal Investigator, who may elect to attend the meeting for this purpose. After discussion is concluded, a motion will be made by one (or both) of the reviewers and a vote will be held. As in all business before the IRB, a majority vote is required before any action might be taken.

F. Review Outcomes: Approval, Withheld Pending, and Denial

All research proposals brought before the IRB, whether exempt from further review or requiring an expedited or full review, must either be approved as submitted, withheld pending minor revisions, or denied with recommendations for major revisions. The IRB Chairperson is empowered, on behalf of the IRB committee, to approve all exempt and expedited proposals that have received satisfactory reviews from the appropriate combination of department/school/unit representatives and IRB members. The IRB Chairperson is also empowered to withhold approval from a proposal pending minor revisions one time only. Proposals that, in the opinion of the Chairperson, are still substantially deficient after a Principal Investigator’s response to a request for minor revisions must be brought before the IRB committee for consideration. Only the IRB Executive Committee may approve a proposal requiring a full review, or deny approval to any proposal.

Exempt proposals having been read and recommended by a department/school/unit representative, and expedited proposals having been read and recommended by both a department/school/unit representative and an IRB member, will be held by the secretary in the “Chairperson’s review” file. Such proposals will be assumed to not require additional review or modification and, as such, are ready for IRB approval. At

least once each week the IRB Chairperson will read each of the proposals in the “Chairperson’s review” file. If the Chairperson concurs with the approval recommendations given by the department/school/unit representative and IRB member (for expedited reviews), the Chairperson will give IRB approval to the research proposal. A signed approval letter will then be sent to the Principal Investigator. A copy of this letter is also sent to the department/school/unit representative.

On occasion, a proposal in the “Chairperson’s review” will have been misclassified and will require additional review. In this circumstance, the IRB Chairperson will destroy the approval letter and return the proposal to the secretary for routing as either an expedited or full review.

On other occasions, the Chairperson may disagree with the approval recommendations of the department/school/unit representative and IRB member (for expedited reviews) and will determine that approval of the proposal as submitted is not warranted. In this case, the Chairperson 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 RECO. In certain cases, the Chairperson might also elect to contact the Principal Investigator directly, to insure that the needed revisions are understood or to discuss ways the Principal Investigator might meet the requirements of IRB. If the Principal Investigator responds to the issues raised in this letter to the satisfaction of the Chairperson, the Chairperson may approve the proposal as revised. If no revisions are made, or the revisions are not satisfactory to the Chairperson, 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 on the approval letter. Full and expedited protocols will not be approved for a period greater than one year

G. Questions and Appeals

Any person may request an appointment with the IRB Chairperson, or an opportunity to address the IRB Executive Committee at a regular or special meeting, for any purpose related to the business of the IRB. 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. As necessary, the Chairperson will be available for personal meetings; discussions with research teams or laboratories; and presentation meetings before departments, schools and units.

Principal Investigators are encouraged to use their department/school/unit representatives as their first points of contact for IRB related issues. Questions or concerns that cannot be resolved by the department/school/unit representative should be brought to the IRB Chairperson. If resolution cannot be reached with the Chairperson, the Principal Investigator may be scheduled to present the case before the IRB Executive Committee at the next regular meeting or at a special meeting called by the Chairperson (if the situation warrants). The decision of the IRB Executive Committee, however, is final.

H. Continuation Reviews

It is not unusual for a research study to require additional time beyond what was originally planned. The Principal Investigator must request a continuation review when additional time is needed beyond the approval period stated in the approval letter. Such a request must be in writing and may be in the form of a simple letter detailing the reasons for the continuation and the new anticipated date of completion. This letter and any supporting documents (if necessary) should be sent directly to the Research Ethics and Compliance Office.

Federal regulations require that continuation reviews occur at the same, or higher, level as the initial review. For this reason, the IRB Chairperson is empowered to approve requests for continuation when the original proposal was reviewed and approved under either an exempt or expedited process. Proposals that required a full initial review must be brought before the IRB committee for continuation consideration. For this reason, Principal Investigators are urged to allow sufficient time for the continuation review process to be accomplished before the expiration of the current approval.

Research protocols may be approved for continuation for a maximum of three years from the original date of approval in periods not to exceed one year. Shorter approval periods may be required depending on the circumstances of the research, reporting requirements to internal or outside agencies, and the risks to the human subjects. Research protocols having had three years of approval must be resubmitted and reviewed as new proposals.

I. 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 Research Ethics and Compliance 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, 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 (expedited review or full review) as the initial proposal. This modification review may involve department/school/unit representatives, IRB members or the IRB Executive Committee, as appropriate. As with an initial review, the requested modification may be approved, withheld pending minor revisions, or denied. If approved, the revised protocol will carry the same approval period as the original approval unless a continuation has also been requested by the Principal Investigator (see the prior section for continuation review procedures).

IV. 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 insures this responsibility by investigating complaints of subjects suffering adverse reactions to a research process or of Principal Investigators (or co-investigators) not following their approved research protocols. Principal Investigators are required, under this policy, to follow the research protocols they have submitted to, and 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 at the RECO. The Chairperson, in consultation with the institutional representative to the IRB and any other IRB members as may be required, conducts the initial investigation. The purpose of the initial investigation is to determine two points as quickly as possible. 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 may 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 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/her department chairperson, school director or unit supervisor, 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 Executive Committee will then decide whether further investigation is needed or whether sufficient information is available to determine that an adverse reaction or non-compliance indeed has occurred. The IRB Executive Committee will also decide whether 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 of, 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.

Certain agencies, both within and outside the university, 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 Community Rights and Responsibilities Office, the Ethics and Grievance Committee, department chairpersons, school directors or unit supervisors; Deans; and/or the Provost, as well as outside funding and governmental bodies).

V. Policy on Submitting Group Research Projects (Batching)

Each semester the IRB processes numerous protocols coming from instructors teaching research-oriented courses. In many cases, these protocols represent student research projects, with each student doing essentially the same activity. Creating these separate,

yet nearly identical, protocols takes a lot of instructor time, not to mention the amount of time and effort needed for separate IRB reviews. While such work is necessary if each protocol were to describe a substantively different or unique research activity, it seems to represent unnecessary duplication for these mostly similar protocols.

To aid in the processing of these essentially identical, class-originated research protocols the IRB suggests a "batching" of the protocols together. There would be one, single protocol submission for all of the essentially identical projects. The instructor would complete one IRB Protocol Submission Form together with one protocol narrative. Following the standard format, this narrative would describe: a brief background and description of the research project; a description of the intended research subjects (who they are and how they will be recruited); what the research activities will be asking the subjects to do; a description of any instruments or apparatuses that will be used; what data will be collected; the risks to the subjects; and any benefits that might accrue to them as a result of his/her participation in the research activity. The instructor will also submit one informed consent document and/or script that will be used by all of the students doing the research. This document and/or script will contain, at a minimum: a brief description of the research activity; a statement of the subject's desired role and the nature of their participation; a description of the data to be collected, and whether that data will be anonymous, confidential, or neither; a description of both the risks and benefits associated with participation in the research; a statement that participation by the subject is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue participation at any time without penalty or loss of benefits; and the name(s) and telephone number(s) of appropriate contacts (e.g., the course instructor, the IRB office) should the subject have any questions about the research or research participants rights.

The instructor would then attach to this basic protocol submission two additional elements. The first element would include descriptions of the particular variation(s) each student, or group of students, will take on the project. This typically will include: a listing of the questions to be asked (for interview-type research activities) or instrument to be administered (for survey-type research activities); a more detailed specification of the characteristics of the subjects to be recruited for that particular activity, if appropriate; and any additional conditions or design elements that will be used exclusively for that activity. For example, students in a class learning to do survey research might each develop their own ten question instruments targeted towards particular audiences. The instructor's cover submission would describe an overall project of surveying adult subjects drawn as a convenience sample from university students walking across the quad. Each individual student's additional page(s) would provide the actual survey questions that student intended to use along with any specifics for implementation (e.g., "Since my survey is directed towards sports appreciation, I will be recruiting only subjects wearing a sports-oriented t-shirt"). The second additional item would be a listing of the names of the students participating in this class project. Student names should be clearly identified with the survey, interview, or other research activity they will be engaging in. If several students are working together collaboratively on a common activity this should also be clearly indicated.

The entire batch packet would then be reviewed by the IRB as a single protocol, reducing the amount of time and paperwork needed for review and providing much faster feedback to the instructor.

VI. Policy on Internet Research

Using the Internet for data collection from living human subjects presents a new and exciting opportunity for researchers from many fields. This new medium, however, requires a certain degree of computer technical competence. It demands that investigators carefully consider the interaction between their technical choices and their ability to safeguard data collected from subjects, including whether such can even be kept anonymous or confidential. Special considerations must also be made when informed consent is necessary, especially from minors and other special populations.

Current technology provides e-mail as the most straightforward, easiest, and fastest means for exchanging information over the Internet. Current e-mail systems, however, use a "store and forward" scheme to pass e-mail from the originating computer, through intermediary computers, to the recipient's computer. These in-between machines may, as a routine part of e-mail processing, make duplicate or back-up copies of all e-mail passed through them. Unless the e-mail is encrypted (a secure, yet seldom used, procedure), the text of the message could be read by any number of potential individuals. Furthermore, all e-mail carries several components identifying the identity of the sender. For these reasons, e-mail data cannot usually be described as either anonymous, or even confidential, unless special steps are taken.

Data posted to a web form, on the other hand, is transmitted directly from the user's web browser to the hosting computer. These transmissions are not stored on any intermediary machines, although they could be intercepted while in transit. Secure server software (e.g., SSL technologies) can easily and automatically encrypt all transmissions between a subject's web browser and the researcher's server making such interceptions meaningless. Furthermore, a web form survey could be constructed so as to not ask any identifying questions of the subject. The only identifying information obtainable would be the IP address of the subject's computer, directly identifying only computers that are hard-wired onto the Internet. This would not be a problem for dial-up computers and laboratory computers not assigned to a particular person, since many users would be making use of the same IP numbers rendering exact user identification difficult, if not outright impossible. Thus, web form collected data could be anonymous if special steps are taken. Unfortunately the design, testing, and use of a web form on a secure server require a higher level of technical expertise on the part of the researcher.

Research studies requiring a complete informed consent procedure and form present a special challenge. In an e-mail situation the researcher may elect to e-mail a consent form to a potential subject, having that subject print, then sign and return (either by U.S. Mail or FAX) the completed form. Once the researcher received back the signed consent form he or she could then e-mail the data collection instrument to the subjects for e-mail, U.S.

Mail, or FAX return. In a web form situation, the researcher may have the consent form on an entry page to the web site. The subject would have to read the form, and then click on a button at the bottom of the page signifying consent before being brought to the main data collection page. This kind of abbreviated (or "waived") informed consent process, common in regular U.S. Mail surveys, implies that people who click on the entry button, then complete and submit the survey, have consented to the low-risk instrument. Certain data collection instruments might require additional security with a subject needing to possess a special login and/or password to gain to the web form. Such a login and/or password, perhaps to an unpublished URL, would be obtained from the researcher only after receipt of the properly completed informed consent document. Such data collection could be anonymous (for example, if all subjects shared the same password and no identifying questions were asked) or merely confidential (if individual passwords were used or identifying questions asked). The IRB requires researchers to completely describe, and perhaps demonstrate, the proposed methodology to gain approval.

Beyond the guidance and policies for gaining approval described above, researchers coming through the IRB process are also expected to adhere to the Illinois State University policies for Campus Mass Electronic Communication. These policies can be found on the ISU Policies website Section 8.2.14.

http://www.policy.ilstu.edu/fiscal/mass_electronic.html

VII. Policy on School Based Research with Minors

A. Final Arbiters

School administrators/committees themselves remain the final arbiters as to whether research can be conducted in their facilities.

B. High Standards

The IRB strongly believes it has the responsibility, nonetheless, to hold protocols written by ISU faculty and staff as principal investigators to the highest standards. Those standards include the application of Family Educational Rights and Privacy Act (FERPA) and Health Insurance Portability and Accountability Act (informally known as HIPAA Privacy Act), as well as those federal regulations set by the Office of Human Research Protections (OHRP) for the protection of human subjects.

C. Special Populations

Of particular concern is research in schools with special populations. Those special populations are defined as students with ADHD, autism, learning disabilities, or another characteristic, which if revealed, would place the students at risk.

The IRB recognizes that recruiting special populations in schools has been/is dependent on working relationships with nurses, principals, directors of special education, etc. The IRB also acknowledges that there is a risk of loss of privacy and/or confidentiality in having those persons use their knowledge of students' file information to serve as

intermediaries in the recruitment of school populations. As noted above [in General IRB Policies], the IRB will make individual decisions on a case-by-case basis which will weigh benefits and risks to individual participants. But the IRB will consider approving protocols outlining the use of nurses, principals, directors of special education, etc., under the following stipulations:

1. The school contacts will not release any information to the ISU researchers without specific, prior parental consent. That consent must be in writing.
2. The PIs or Co-PIs cannot redisclose that information (participants' names, conditions, classifications, responses, etc.). The PI can ask that a new Co-PI be allowed access through a request for a modification to the original approved protocol. Preferably information shared with an investigator not named in the original protocol has been stripped of identifiers.
3. Recruitment letters (sent in mailings, as bookbag handouts, etc.) must include disclaimers that say that no one at ISU will be able to identify their children as members of a special population until the parents contact the ISU investigators. In other words, the school contacts should not give investigators names, addresses, etc., as a first step in recruitment.

VIII. Policy on Classroom Research

A. Definition of Research and Human Subjects

Research is defined as “a systematic investigation including research development, testing, & evaluation designed to develop or contribute to generalizable knowledge.” A “human subject” is “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.” (Section 46.101 - Definitions of CRF Title 45, Part 46, Dept. of Health and Human Services policy for Protection of Human Research Subjects).

B. Student Policy Stated

All student research is subject to IRB review following guidelines outlined in Illinois State University Policy for the Protection of Human Research Subjects. Class research projects (including independent studies) require review by the IRB only if they are intended for generalization (e.g., publishing, presenting, or archiving), contain more than minimal risk encountered everyday, or involve a protected class of citizens (e.g., mentally incapacitated persons, children, prisoners, pregnant women, or economically or educationally disadvantaged persons).

C. Policy Qualified

1. Faculty are responsible for determining whether a student research project has reached a threshold for review and are not relieved of their responsibility to use human subjects in an ethical manner.
2. All student class research must have a faculty advisor as the principal investigator (PI).
3. The departmental/school/unit IRB representative will be responsible on a yearly basis for informing faculty of the student research policy and will be available for interpretation of the policy.
4. Class-only projects that may be disseminated in the future must be reviewed (e.g., student research symposiums). IRB review must occur prior to any data collection.
5. Class projects designed to “practice” systematic investigation techniques need not be reviewed when they involve supervised training of new members of a profession. Examples include teacher trainees practicing evaluation, clinical interns practicing assessment or diagnosis, and student journalism reporters practicing interviewing, etc. These activities should still communicate applicable or reasonable elements of informed consent (e.g., institutional affiliation, purpose of investigation, risks, benefits, voluntary participation, permission to withdraw, etc.).
6. A student engaged to work on an already approved research project where a portion of the data will be used for a course assignment, independent study, honors project, symposium/conference presentation, etc. must have his/her name submitted by the PI as a modification to the original proposal.
7. Theses and dissertations are generalizable research and must be reviewed when they involve research with human subjects.