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101: University and IRB Responsibilities

The intent of this Standard Operating Procedure (SOP) is to describe the responsibilities of both the University and the Institutional Review Board (IRB) as it relates to human subjects research conducted at Illinois State University (ISU). It is the responsibility of the Institutional Official (IO, Director, Research Ethics and Compliance Office (REC), and the IRB Chair to ensure compliance with this SOP.

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1. University Responsibilities

Illinois State university ("ISU", "the university", "the institution") will establish and maintain a Human Research Protection Program (HRPP) in accordance with federal and relevant guidance, as well as state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects

The university establishes research activities involving human subjects that are subject to the review and approval of the IRB. This includes research activities involving human subjects that are:

- Sponsored by the university; or
- Conducted by or under the direction of any employee or agent of the university, including students, in connection with his or her university responsibilities; or
- Conducted by or under the direction of any employee or agent of the university using the property or facilities of the university.

Projects being conducted using the property or facilities of the university, but not under the direction of any employee or agent of the university, do not require review by the ISU IRB. Such projects are reviewed by the Director of Research Ethics and Compliance (REC) under the "courtesy approval" procedures.

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;
- Provide adequate meeting space for the IRB;
- Provide appropriate training opportunities for REC staff, IRB members, investigators, and the campus;
- Review and determination of research activities involving human subjects that are considered to be exempt form IRB review;
- Secure and maintain a Federalwide assurance and IRB registration with OHRP.

2. Institutional Review Board (IRB) Responsibilities

The IRB will comply with federal, state, and local laws as they might relate to the activities covered by this policy. The IRB will review all research involving human subjects that has not been determined by the university to be exempt from IRB review, and will approve those research protocols that comply with its requirements. The IRB will develop and maintain written procedures and will maintain records as required.

Written Procedures

Written procedures for the IRB will include:

- Initial and continuing review of research projects, including the level of review applied (i.e. expedited or full board);
- Such procedures will include the reporting of IRB findings to investigators and the institution.
- Determining which projects require review more than annually.
- Review of proposed modifications to approved research protocols, including the level of review applied;
- Such procedures will ensure that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.
- Determining which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
- Ensuring prompt reporting of unanticipated problems involving risk to subjects or other (UPs) and instances of serious or continuing noncompliance with the approved research project or with the requirements of the IRB by investigators.

Such procedures will include prompt reporting to the Institutional Official and, if appropriate, the federal Office of Human Research Protections (OHRP) or other state or federal office(s), all instances of UPs, serious or continuing noncompliance and suspension or termination of IRB approval.

Review

The IRB is responsible for determining whether nonexempt research involving human subjects meets the following approval criteria:

1. Risks to the subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic of treatment purpose;
2. Risks to subjects are reasonable in relation to the anticipated benefits, if any;
3. Selection of the subjects is equitable;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, except where the IRB has determined that the waiver or alteration of informed consent is approvable;
5. Informed consent will be documented, except where the IRB has determined that the waiver of documentation of informed consent is approvable;
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and

8. Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Additional IRB Review Responsibilities

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 shortened periods of approval. 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 and investigation of potential harm to human subjects.

The IRB will, at its discretion and for any reason whatsoever, investigate any activity, persons, or records covered by this policy. Investigations may include interviewing a principal investigator, co-principal investigator(s), subject or any other person connected with research involving human subjects; observe the process for obtaining informed consent from subjects, where applicable; examination of the research records involving human subjects, including informed consent documents and collected data; and inspection of any facilities, laboratories, equipment, or supplies used in human subjects research.

3. Records

The IRB will prepare and maintain adequate records of its activities. This includes, but is not limited to:

- Copies of all documents related to research projects that are reviewed by the IRB.
- Minutes of convened IRB meetings which will be in sufficient detail to show:
  - Attendance at the meetings;
  - Actions taken by the IRB;
  - The number of members voting for, against, and abstaining for the actions taken by the IRB;
  - The basis for requiring changes in or disapproving research; and
  - Discussion of controverted issues and their resolution.
  - Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- A current list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholding, paid or unpaid consultant.

The IRB records required by this policy 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 university, OHRP or other state or federal office(s) at reasonable times and in a reasonable manner.

4. Institutional Review Board (IRB) Membership

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 to promote a complete and adequate review of research activities commonly conducted by the university. The IRB members will be sufficiently qualified thought he 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. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision0-makign capacity, or economically or educationally disadvantaged persons, considerations shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The membership of the IRB will include:

- One member who will serve as the Chair.
- One member who will serve as the Vice Chair.
- At least one member whose primary concerns are in scientific areas,
- 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
- One member who will serve as an ex officio (voting or non-voting) member.

The membership of the IRB may include:

Two members (in addition to the Chair or Vice Chair) 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.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Members will be appointed for a term of three (3) years. At the discretion of the IO, chronic in attendance, repeated delay in completing reviews or failure to follow established policies and procedures, etc. may result in the members removal from the IRB Executive Committee. Consecutive terms may be served with the approval of the IO. 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.

5. Meetings

Regular scheduled meetings of the EC will be held monthly, or as needed, to conduct the timely review of proposed human subjects research. A special meeting of the EC may be called by the Chair or the Chair's designee to consider any urgent matter related to the protection of the rights and welfare of human research subjects. All EC meetings will be conducted in accordance with Robert's Rules of Order.

A quorum is required for the review of proposed research at convened EC meetings. A quorum is established when a majority of the EC members are in attendance, including at least one member whose primary concerns are in nonscientific areas. EC members may attend meetings via telephone conference call (teleconference) so long as the members have received all pertinent materials prior to the meeting and can actively and equally participate in all discussions and votes.

The Human Subjects Research Specialist (HSRS) for REC attends the meetings and records the minutes. They are not a member of the EC and cannot vote. The IO can attend as well, but is not a member of the EC and cannot vote.

The Principal Investigator and researchers are encouraged to attend the meeting to discuss any potential issues with their protocol. Researchers are invited into the meeting room to answer questions the EC may have regarding their study after discussion at the meeting. Researchers are then excused from the meeting prior to a motion.

Actions of the EC will be directed by a majority of those voting members present at the meeting. No EC member may participate in the initial or continuing review of any project in which the member has a conflicting interest. When conflicts of interest are present, the member may provide information requested by the EC, but will recuse themselves from the meeting for any deliberation or vote. The EC member must physically leave the meeting room (or hang up from the teleconference line) in order to be considered recused from the meeting. IRB meetings are not subject to the Open Meetings Act.