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| <b>IRB Policy #:</b>  | <b>200</b>                                     |
| <b>Policy Title:</b>  | <b><i>Scope and General Review Process</i></b> |
| <b>Date Approved:</b> |  |
| <b>Date Reviewed:</b> |  |

**Purpose:** Specify scope and ethical principles of research oversight.

**Definitions:**

**Policy:**

IRB review and approval shall be required for any research involving human subjects that is conducted by or under the direction of SIUC faculty, staff, or students in connection with the fulfillment of institutional responsibilities or academic requirements; or is performed with, or involves the use of, University records, facilities or equipment belonging to the University.

In accordance with 45 CFR 46.109, The IRB chair or designee shall determine whether a given activity can be considered human subjects research.

Certain categories of research involving minimal risk to subjects and meeting one of the Federal categories for expedited review need not be reviewed and approved by the full IRB, but rather by the IRB chair or a duly authorized designee through expedited review procedures.

The three basic ethical principles – Respect for Persons, Beneficence, and Justice – set forth in the Common Rule and *The Belmont Report*, shall guide the IRB in its review.

*Respect for Persons:*

Where appropriate, the IRB shall require adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

In accordance with 45 CFR 46.111(b), when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, students, or economically or educationally disadvantaged persons, the IRB shall determine whether additional safeguards have been included in the research to protect the rights and welfare of these subjects.

The investigator shall seek informed consent from each prospective subject or the subject’s legally authorized representative in accordance with and to the extent required by 45 CFR 46.116, and such consent shall be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and retained as a matter of record.

When research involves more than minimal risk or substantial stress or discomfort, such

risk, stress or discomfort shall be carefully explained to the subject before his or her participation and justified by the expected benefits of the research.

A subject shall have the right to withdraw from a research project at any time or to refuse to participate without loss of benefits to which the individual would otherwise be entitled. In addition, a subject shall have the right to appropriate professional care, to privacy and confidentiality in the use of personal information, and to freedom from undue embarrassment, discomfort, anxiety and harassment.

*Beneficence:*

Direct or potential benefits to the subject or the importance of knowledge to be gained shall not preclude consideration of the inherent risks to the individual.

The IRB will consider the qualifications of the investigator, his or her professional development, and experience when assessing the degree of risk to subjects in the research project. Protocols which require skill levels beyond those held by the PI will be disapproved or modified. The PI may also be required to include additional qualified personnel in the project. These considerations apply to research that may fall within all categories of IRB review.

Where appropriate, research plans shall make adequate provision for monitoring the data collected to ensure the safety of subjects.

Risks to subjects shall be minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risks, and whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to subjects shall be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if they were not participating in the research). The IRB shall not consider the long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibilities.

*Justice:*

Selection of subjects shall be equitable. When appropriate, every effort will be made to include subjects of diverse age, race, gender, and ethnicity.

The IRB shall ensure that compensation or inducement offered for participation in a study is made appropriately, with subjects fairly recruited and adequately informed rather than unduly influenced by promised compensation. Financial remuneration or other inducements should not be so great as to be coercive to potential subjects and

should constitute reasonable compensation for the inconvenience of participating. Compensation or inducement information shall be included in the Informed Consent.

No recruitment or involvement of human subjects in research shall be permitted until the IRB has reviewed and approved the research application, and informed consent has been obtained. It shall be the investigator's responsibility to obtain approval from the IRB prior to the initiation of any research, including pilot or pre-test studies, involving the use of human subjects. Non-affiliated researchers seeking to recruit on the SIUC campus shall submit a brief description of the proposed study and a copy of the study's approval letter from their institution's IRB.

The investigator should ensure that consent for participation is sought only under circumstances that minimize the possibility of coercion or undue influence.

When using students as subjects, the investigator should ensure that the consent for participation is sought only under circumstances that minimize the possibility of coercion or undue influence. If participation in the research is in partial fulfillment of a course requirement, the research option must be included in the original course syllabus and genuine equivalent alternatives to participation must be available (e.g., term papers, literature review, attendance at colloquia or research seminars). Participation must be voluntary so the student can withdraw at any time without penalty and still receive appropriate credit to the level of his or her participation. When a research project requires attendance in multiple sessions, a subject may withdraw from the study at any time and receive credit for the sessions he or she has attended.