Policies and Procedures for the Protection of Human Research Subjects

102: Investigator Responsibilities	
Version: 1	**Effective Date: 2/8/2018**

POLICY:

Illinois State University (ISU) designates investigator responsibilities and requires reporting in accordance with federal regulations.

RESPONSIBILITY:

It is the responsibility of the research investigators, the IRB Chair and the Director, Research Ethics and Compliance Office (REC) to ensure compliance with this policy.

PROCEDURE:

Investigator Responsibilities

Investigators are responsible for:

1. Determining what activities meet the definitions of research involving human subjects according to HHS regulations and relevant guidance.

2. Obtaining IRB approval before beginning any human subjects research, including recruitment or consenting of subjects.

3. Providing the IRB with sufficient information and related materials about the research (e.g., grant applications, research protocols, consent documents) so that the IRB can fulfill its regulatory obligations.

4. Following institutional policies and procedures established for facilitating IRB review.

5. Carrying out sound ethical research consistent with research plans approved by an IRB.

6. Refrain from proposing research in which the investigators hold a dual role, unless the IRB has determined whether there are sufficient protections in place to ensure that subjects will not feel coerced to participate. Dual roles are typically encountered when the investigators are the subjects' instructor, therapist, social worker, corrections officer, etc.

7. Ensuring that all study personnel are fully trained, including mandatory CITI training, University policies and procedures, and training on study-specific procedures.

8. Overseeing all aspects of student-led research in which the investigator acts as advisor.

9. Meeting ongoing requirements in the conduct of approved research that include:
    a. Obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB.
    b. Giving a copy of the informed consent document to each research subject (or the subject's legally authorized representative), and keep the signed original or a copy of it for their records, unless documentation of informed consent has been waived by the IRB. If the documentation of informed consent requirement is waived, the IRB may require investigators to provide subjects with a written statement regarding the research.
    c. Obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects.
    d. Promptly reporting to the IRB when the research is modified in order to eliminate apparent immediate hazards to subjects without prior IRB approval.

10. Ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with established policies and procedures of the IRB. Investigators shall submit sufficient materials and information for the IRB to meet its regulatory obligations, and with sufficient time for the IRB to carry out review prior to the expiration date of the current IRB approval.
    a. Continuing review of research and approval of research studies is required for Expedited Review and Full Board Review studies until research-related interactions and interventions with human subjects or the obtaining and analysis of identifiable private information described in the IRB-approved research plan have been completed. When a human subjects research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the IRB, although investigators must continue to honor any confidentiality protections of the data. Investigators also must honor any other commitments that were agreed to as part of the approved research, such as providing information about the study results to research subjects or providing compensation to research subjects for research participation.
    b. Closing inactive or completed research studies in accordance with IRB Policy 110: Closure.

11. Ceasing all research activities involving human subjects related to that study If IRB approval of that study expires before continuing review and approval occur, except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB. If the IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

12. Providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others.

13. Providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB.

14. Keeping certain records related to conducted research for at least three years after completion of the study.
    a. Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are considered research records included in this responsibility.
    b. HIPAA data must be retained for a minimum of six years after the subject signs the authorization.
    c. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS or the IRB at reasonable times and in a reasonable manner.
    d. Investigators that leave ISU shall identify the successor responsible for maintaining the research records at ISU for the required period of time.

15. Complying with other applicable federal regulations, state and local law, and University policies, such as:

    a. FERPA – applies to educational records
    b. HIPAA – applies to protected health information
    c. Mandated Reporter laws and policies – researchers are obligated to report child abuse or neglect as well as certain crimes
    d. Financial Conflicts of Interest – significant financial interests must be disclosed to the University and potentially to prospective participants
    e. Minors Activity Compliance Committee – approval from the MACC is required for projects involving children
    f. Export Controls – applies to sharing of restricted data as well as international travel
    g. Risk Management – applies to international travel