Human Research Protection Policy

UNIVERSITY OF
ILLINOIS
SPRINGFIELD

Policy name: Human Research Protection Policy

Policy statement: This policy governs the Human Research Protection program at UIS. The Human Research Protection program includes the operations of the UIS Institutional Review Board for the Protection of Human Subjects of Research.

I. Purpose

To protect the rights and welfare of human subjects in research, to establish Institutional Review Board (IRB) oversight of research involving human subjects, and to comply with the Federal Policy for the Protection of Human Subjects and applicable federal laws and regulations.

II. Scope

This policy applies to all members of the campus community, including but not limited to university faculty, staff, students, adjunct and clinical faculty, visiting faculty, postdoctoral appointees, visiting scholars, and visiting scientists engaged in university-sponsored research conducted in campus facilities or at off-campus locations irrespective of the risks, project scope, funding, or location of the research.

Individuals engaged in university-sponsored research activities involving human subjects, human tissues, or medical records of human subjects must comply with:

1. The Federal Policy for the Protection of Human Subjects and federal agency regulations and guidance for the protection of human subjects;
2. Food and Drug Administration regulations for drugs, biological products, and medical devices;
3. Requirements approved by an IRB; and
4. Policies and procedures approved by the Vice Chancellor for Academic Affairs and Institutional Official.

III. Definitions and Principles

The VCAA is the Institutional Official responsible for compliance with federal and state laws and is responsible for the effective functioning of the human research protection program. The Chancellor appoints members to one or more IRBs, upon recommendation by the VCAA, consistent with the requirements of federal regulations.

The IRBs are committees that perform ethical review of proposed research. The Human Subjects Review Officer serves as the Chair of the IRB. Only an IRB has the authority to approve proposed research activities involving human subjects or medical records for human subjects. The IRBs, Associate Vice Chancellor for Research and Institutional Effectiveness (AVCRIE), or staff of the Office of Research and Sponsored Programs (ORSP) have authority to require modifications to proposed activities before approval. Research involving human tissues may require approval by an IRB, the Institutional Biosafety Committee (IBC) or both committees.

Principal Investigators must submit proposed research to the ORSP that manages the IRB review process. Investigators are responsible for providing all information necessary for IRB review. No research activities subject to this policy may begin before IRB approval.

The IRBs may establish additional policies and requirements as necessary for compliance with laws and regulations pertaining to the use of human subjects or medical records for human subjects in research. The ORSP, a unit reporting to the AVCRIE, provides administrative support for the review of research by the IRBs. The ORSP may establish standards and procedures necessary for implementation of IRB policies or requirements and for business operations of the human subjects' research protection program. Such policies and procedures must be approved by the Institutional Official (VCAA).

Principal Investigators are responsible for reporting to the IRB unanticipated problems or adverse events during research activities. The IRB and ORSP report concerns about human protection and non-compliance to the AVCRIE. The AVCRIE and the IRBs have authority to apply additional requirements in the case of unanticipated problems or adverse events and have authority to suspend or terminate approval of research activities that are not being conducted in accordance with IRB policies or requirements, campus policies and standards, or that have been associated with unexpected harm to subjects. The AVCRIE or IRB, as applicable, will report any suspension or termination of approval promptly to the Principal Investigator, the VCAA, and the funding department or agency head.

IV. References

Office of Research and Sponsored Programs (www.uis.edu/research).

UIS IRB Policies and Procedures (https://www.uis.edu/research/research-integrity/irb/policy/)

Date approved by Chancellor's Cabinet: February 19, 2019

Approved by Chancellor:

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Effective date: February 19, 2019