Policies and Procedures for the Protection of Human Research Subjects

100: Human Research Protection Program	
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Applicability
Authority
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State and Local Laws

Applicability

The Illinois State University (ISU) Human Research Protection Program (HRPP) oversees all research involving human subjects at ISU. The primary responsibility of the HRPP is to assure the protection of the rights and welfare of subjects participating in ISU research. Projects that do not meet the definitions of "research" or "human subjects" do not fall under the auspices of HRPP. Human subjects research conducted in collaboration with other entities is subject to ISU oversight if ISU is considered "engaged in the research" under Federal Regulations. Human subjects research occurring in countries other than the United States are subject to U.S. regulations and ISU policies and procedures, as well as any rules or regulations imposed by the country in which the research will take place.

Authority and Responsibilities

At ISU, the HRPP program has the full support of the upper levels of the administration including the Board of Trustees, the President, Vice President for Academic Affairs and Provost, and the Associate Vice President for Research and Graduate Studies.

The HRPP primarily consists of the Institutional Official (IO), the Research Ethics and Compliance Office (REC), the Institutional Review Board (IRB) Executive Committee (EC), and researchers conducting human subjects research. The President has designated the Associate Vice President for Research and Graduate Students as the IO for the HRPP. The IO is the institutional authority under which the IRB is established and empowered with independence to carry out its responsibilities. The IO sets institutional policies and ensures that resources and support are available for all components of the HRPP. The IO submits reports to OHRP and funding agencies. In representing the interests of the institution, the IO, under recommendation by and/or in consultation with REC or other researchers, may disapprove research that is approved by the IRB. The IO cannot approve research that has not been approved by the IRB.

The IO has supervisory responsibility over the Director, REC and joint supervisory responsibility over the IRB member. The Research Ethics and Compliance Office (REC) includes Director, Compliance Coordinator(s), IRB Specialist(s), and Graduate Assistant(s). The Director has supervisory responsibility over REC staff. The Director is responsible for ensuring that the IRB follows established policies and procedures. The Director investigates adverse events and noncompliance and enforces any sanctions resulting therefrom. REC is responsible for promoting excellence in the HRPP across the institution by: overseeing the daily operations and administrative support of the IRB; screening/pre-review of submissions; providing human subjects research education; seeking out and adopting best practices; and advising the IO. The IRB Executive Committee includes the Chair, the Vice Chair, full members and alternate members.

The ISU IRB is established in compliance with applicable federal regulations and state and local laws. The IRB has the authority to act independently of the institution in carrying out its responsibility to protect the rights and welfare of human research subjects. The IRB sets policies regarding review of research, reviews and approves research, and reviews adverse events and noncompliance matters.

Researchers include all individuals conducting or assisting with human subjects research. The individual identified as the Principal Investigator (PI) has supervisory responsibility over the other researchers associated with their research projects.

The HRPP is supplemented by ISU faculty, staff and students from all academic departments/units. Many other units on campus that contribute to the protection of subjects. Communication between these units may be necessary related to protocol review, program requirements, or other issues related to research compliance.

<u>Federalwide Assurance</u>

The Illinois State University Human Research Protection Plan complies with the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46; The Common Rule) for the Department of Health and Human Services (DHHS), as well as those of other applicable federal, state, and local agencies. ISU has an approved Federalwide Assurance (FWA) issued by the DHHS, Office for Human Research Protections (OHRP). FWA # 00000112 covers the ISU Institutional Review Board (IRB), IRB registration #00000116. The FWA indicates that ISU is guided by the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. The Nuremberg Code includes principles related to voluntary consent and sound research design, while the Declaration of Helsinki related to ethics in

medical research. The Belmont Report principles are applied by Illinois State in all human subjects research. These principles include:

> Respect 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.
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> 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. 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.
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> 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 FWA establishes additional responsibilities incorporated into the policies and procedures in this program.

In addition to federal regulations, there are additional state and local laws that may be applicable to human subjects research. Among these are:

> Illinois Mandated Reporters
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> Any personnel of higher education institutions who suspect child or elder abuse or neglect must report this to the Illinois Department of Children and Family Services (DCFS) or the Illinois Department of Aging, as appropriate. This applies to information obtained in the course of research as well.

Illinois Eavesdropping Law

Illinois law regarding recording requires that nor recording of private conversations may take place without the permission of all parties involved in the conversation.

Professional Ethics Codes

Investigators should also consult professional codes of ethics and regulations within their discipline when conducting their research, although the federal regulations take precedence over professional codes of ethics in the event of conflicting information.

American Anthropological Association (AAA)
American Association for State and Local History (AASLH)
American Historical Association (AHA)
American Psychological Association (APA)
American Sociological Association (ASA)
Association of Social Anthropologists (ASA)
National Association of Social Workers (NASW)
Oral History Society