University of Illinois Rockford

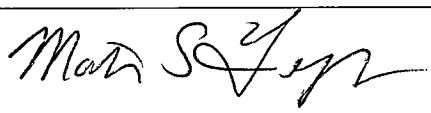
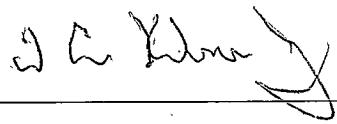
A UIC Health Science Campus

Institutional Review Board

1601 Parkview Avenue

Rockford, IL 61107

POLICY & PROCEDURE MANUAL

University of Illinois Rockford Institutional Review Board	Version # 4
Approved By: Martin Lipsky, M.D., Regional Dean	
Approved By: Thornton Kline, Jr., M.D., IRB Chair	

University of Illinois Rockford (UIR)

Institutional Review Board (IRB)

Policy & Procedure Manual

For Faculty, Staff, and Students

Section 1: Introduction

1.1. Purpose and Scope

This policy and procedure manual, and any other relevant standard operating procedures, govern the University of Illinois Rockford (UIR) Human Subject Protections Program (HSPP), including the Institutional Review Board (IRB), in human subject's research. This manual includes the policy and operating procedures required under the terms of the Federal Wide Assurance (FWA) FWA00005607, which is granted by the Office for Human Research Protections (OHRP).

1.2. Mission Statement

The mission of the UIR HSPP is to ensure that there are adequate mechanisms developed and maintained to maximize the protection of the rights and welfare of all human subjects involved in research. The IRB works with the institution investigators, research staff, students, and the UIR IRB members as equal stakeholders in fulfilling the mandate to uphold the public's trust to respect and protect people who participate as subjects of human research.

1.3. UIR HSPP

1.3.1. Jurisdiction

Policy

The UIR HSPP is responsible for the oversight of all *research* that involves *human subjects* (as defined by HHS and FDA regulations) that is conducted by employees or agents of the University of Illinois Rockford regardless of the location of the research or its sources of financial support. In addition, the UIR HSPP has included in its jurisdiction any review of UICOM-R patient records for research purposes.

In exercising that oversight, the UIR HSPP will permit such research to be conducted on UIR premises only if the principal investigator (PI) is an employee or student sponsored by UIR faculty

Research that is conducted by UIR employees or agents in locations not owned or operated by UIR may still be considered the responsibility of UIR HSPP. In such instances, the investigator must inform his/her Department Head about such activities. It is the responsibility of the Chair/Department Head to assure that research is conducted with adequate protection of human subjects and this may include oversight by the UIR HSPP and IRB.

It should also be noted that in accordance with the federal regulations, outside locations may need to apply for an assurance of compliance with OHRP if the location is "engaged" in human subject research and there is no IRB available at the site and the project is federally funded.

Procedures

University of Illinois Rockford employees or agents who conduct human subject research in their roles of members of the medical staff/students or research staff under the auspices of UIR, whether at UIR or at any other organization or location owned or controlled by University of Illinois Rockford, must inform his/her Department Head about such activities. It is the responsibility of the Department Head to assure that research is conducted with adequate protection of human subjects and this may include oversight by the UIR HSPP or the establishment of an IRB authorization agreement with an IRB of another institution. Department Heads are encouraged to contact RSS for guidance when these situations arise.

Human subject research conducted by an employee or agent usually falls under the jurisdiction of the UIR IRB. This includes research conducted at schools, institutions, community groups, or other hospitals not owned or controlled by UIR. If a determination is made that the activity falls under the purview of UIR HSPP, UIR IRB may choose to rely on another IRB for review through the use of an IRB authorization agreement.

UIR recognizes that collaborative research programs may originate or be conducted at other institutions, or be conducted at multiple institutions. Investigators are expected to consult with their Department Head regarding these activities. The RSS office is also available to offer the investigator and Department Head advice such as:

- Whether review by UIR IRB may be necessary in accordance with the federal regulations,
- Whether review by multiple institutions may be necessary,
- Whether an activity constitutes engagement in human subject research,
- Whether an IRB authorization agreement between institutions may be considered, and
- Whether a collaborating institution requires an assurance of compliance when they are engaged in research and receive federal funding.

Research protocols may be submitted for IRB review only by individuals who are employees or agents of University of Illinois Rockford. The records of the Registrar and Human Resources Department will be considered determinative in establishing the existence and scope of that appointment. Individuals who do not hold such an appointment may participate in the conduct of clinical investigations only when an individual who holds a staff appointment is designated as PI, and is a sufficiently active collaborator in the research to assume full responsibility for the ethical and scientific conduct of the investigation.

The University of Illinois Rockford has a registered reciprocal agreement with the University of Illinois at Chicago which allows either IRB to be the IRB of record when:

1. Performing collaborative protocols, or when,
2. Employees or agents affiliated with one campus perform research on human subjects that are located at the campus.

If it is determined that an employee or agent of UIR will use UIC's IRB as the IRB of record, the employee or agent must submit a summary of the research and the approval letter in IRBNet.

Note: The PI proposing the research cannot make the decision on which IRB will be the IRB of record.

1.3.2. Support

Research Support Services (RSS)

Policy

UIR maintains an administrative office to oversee the Human Subject Protection Program (HSPP), and to provide administrative support to the UIR IRB and to investigators. The Research Support Specialist reports to the Associate Dean of Academic Affairs. It is the responsibility of the Research Support Services Specialist to identify the immediate and long-term resource requirements of the Human Research Protection Program. The Research Support Services Specialist is also responsible for managing submissions received through IRBNet, providing guidance and advice to all key research personnel, pre-reviewing all types of research protocol submissions, maintaining records, and performing any other duties assigned.

Procedures

The Research Support Services Specialist is responsible for day-to-day operations of the HSPP. The Research Support Services Specialist will ensure that the following responsibilities are performed:

- Maintenance of correspondence, training records (CITI, HSPP105 HIPAA, other), and protocols through the use of IRBNet.

- Reviews of protocols before submission to IRB reviewer(s).
- Notification of upcoming expiring protocols and documentation of expired or lapsed IRB approval.
- Preparation of agenda, minutes, and other documents needed for convened meetings.
- Notification to investigators of approval of protocol, modifications, etc.
- Preparation and updating of Policy and Procedures.
- Documentation of Training Records.
- Ensuring new IRB members receive appropriate training.

1.4. Ethical Principles and Regulations

Ethical Principles

UIR adheres to the ethical principles and guidelines for the protection of human subjects in research as described in the Belmont Report. These principles and guidelines include respect for persons, beneficence, and justice.

- **Autonomy**
  - Individuals are to be treated as autonomous agents, and persons with diminished autonomy are entitled to protection. The principle of respect for persons encompasses two moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
- **Beneficence**
  - Individuals are to be treated in an ethical manner by respecting their decisions, protecting them from harm, and striving to secure their well-being. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules are complementary expressions of beneficent actions: (1) do no harm, and (2) maximize possible benefits and minimize possible harms.
- **Justice**
  - The benefits and burdens of research are to be shared fairly. An injustice occurs when some benefits to which a person is entitled are denied without good reason or are imposed unduly. There are several widely accepted formulations for the just distribution of burdens and benefits. Each formulation embraces a basis for the distribution of burdens and benefits. 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.

UIR has elected to not extend OHRP's authority to all human subjects research conducted at UIR; however, the aforementioned principles of the Belmont Report and the Common Rule (45 CFR 46), or comparable protections in certain cases, will be applied to all research reviewed and approved by UIR within the framework of applicable federal, state, and local laws. If research is being conducted in another state, then the laws of that state take precedence.

Department of Health and Human Services Regulations (DHHS 45 CFR 46)

UIR holds a federal wide assurance (FWA00005607) from the Office of Human Research Protection. UIR operates in full compliance with all applicable federal, state, and local laws and regulations, and with the Federal Wide Assurance (FWA) and incorporated "Terms of the Federal Wide Assurance." The regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the structural basis for the review and approval of all research at UIR regardless of funding. UIR requires all research that involves human subjects, that is conducted by UIR employees and students on its premises or under its sponsorship, whether or not supported by external funding, to be reviewed and approved by the UIR IRB. This policy also applies to UIR employees and students who conduct research at other hospitals, schools, institutions, community groups, or other places external to UIR. Individuals who are not affiliated with UIR, but who participate in research as Key Personnel, must also abide by these policies and procedures.

Food and Drug Administration Regulations

UIR also agrees to apply the U.S. Food and Drug Administration (FDA) Human Subject Regulations including but not limited to 21 CFR 50 (Informed Consent), 56 (IRB Regulations), 312 (Investigational New Drug Applications, IND), 600 (Biological Products), and 812 (Investigational Device Exemptions) when research falls under the jurisdiction of the FDA.

Other Federal Funding Agencies and Federal Laws

Other Federal Agency regulations are applicable to the extent required if they provide research funding at UIR. This includes:

- The Health Insurance Portability and Accountability Act (HIPAA) of 1996 45 CFR 160 and 164
- Department of Education 34 CFR 97, 98, 99
- Department of Defense 32 CFR 219
- Department of Justice 28 CFR 46
- The Energy Reorganization Act of 1974
- The Emergency Medical Treatment and Active Labor Act

- The Federal Food, Drug, and Cosmetic Act (21 USC§355; 371)
- The Food and Drug Administration Modifications Act of 2007
- The 'No Child Left Behind' Act
- The Privacy Act of 1974 (5 USC 552 (a))
- The Public Health Service Act (42USC§262 (generally))
- The Public Health Service Act, Licensing of Biological Products and Clinical Laboratories, Biological Products
- Protection of Pupils Rights Amendment
- Research on Transplantation of Fetal Tissue (PL 103-43)
- Bayh-Dole Act (PL 96-517, Patent and Trademark Act Amendments of 1980)

State of Illinois

UIR complies with the following Illinois State Laws:

- The AIDS Confidentiality Act (410 ILCS 305)
- The Abused and Neglected Child Report Act (325 ILCS 5/1)
- The Consent by Minors to Medical Procedures Act (410 ILCS 210)
- The Control of Communicable Diseases Code (77 Ill. Adm. Code 690)
- The Elder Abuse and Neglect Act (Public Act 90-0025)
- The Genetic Information Privacy Act (410 ILCS 513)
- The Illinois Anatomical Gift Act (755 ILCS 40)
- The Illinois Department of Public Health Laboratory (Infectious Disease) Reporting Requirements
- The Illinois Health Care Surrogate Act (755 ILCS 40)
- The Illinois Medical School Experiments (Public Act 110; ILCS 305/20)
- The Illinois Medical Patients Rights Act (410 ILCS 50/3.1)
- The Illinois Power of Attorney Act (755 ILCS 45/1-1)
- The Illinois Probate Act (755 ILCS 5)
- The Juvenile Court Act (705 ILCS 405/1.1)
- The Mental Health Treatment Preference Declaration Act (755 ILCS 43)
- The Personal Information Protection Act (815 ILCS 530)
- The University of Illinois Act (110 ILCS 305)
- Illinois Freedom of Information Act (5 ILCS140)
- Illinois Court of Claims Act (705 ILCS 505)

International Research

Any research activities conducted outside of the U.S. under the auspices of UIR must be conducted consistent with the ethical principles set forth by the UIR IRB. Both investigators and the UIR IRB must take into consideration local laws and cultural context and make sure the

research complies with the local regulations. When research is conducted internationally, documentation of the IRB or equivalent ethics committee review at the local site will be required. Additionally, the UIR IRB may request the use of local consultants or rely on one of its members with personal knowledge of local context.

The UIR IRB, investigators, and research staff is urged to refer to the OHRP website that provides links to key regulatory and ethical guidance for countries outside the U.S. This site may be found at http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html.