

Ethical Standards and Legal Principles

310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

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POLICY:

- I. The UIC HSPP is compliant with applicable federal regulations and directives and state and local laws that apply to human subjects research as set forth in the UIC FWA with OHRP.

PROCEDURE:

Ethical Principles.

- I. OPRS staff and investigators, and research personnel conducting research under the oversight of the UIC IRB must read *The Belmont Report* and understand their ethical responsibilities in conducting human subjects research. *The Belmont Report* is available at the OPRS website at: <http://www.research.uic.edu/protocolreview/irb/index.shtml>. The core principles of *The Belmont Report* are the following:
 - A. Respect for persons;
 - B. Beneficence, and
 - C. Justice.
- II. In its FWA, UIC has elected to not extend OHRP's authority to all human subjects research conducted at UIC; however, the 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 at UIC within the framework of applicable federal regulations and directives and state and local laws. (See UIC HSPP *Institutional Authority and Oversight* policy for more information).
- III. UIC investigators conducting research in Illinois must apply Illinois state law when applicable. If the research is being conducted in another state, then the laws of that state take precedence. (See UIC HSPP policies *Local Research Context* and *International Research* for more information).
- IV. Investigators conducting research in another jurisdiction must consider state law including, but not limited to, child abuse and elder abuse reporting, HIV testing and reporting, infectious and/or communicable disease testing and reporting, informed consent requirements, age of consent matters, payment issues, recruitment matters, cancer registries, birth defect reporting, cognitive impairment, and other state laws

that are applicable to human subjects research. (See UIC HSPP policies *Local Research Context* and *International Research* for more information).

- V. If more than one law exists which applies in the same situation, the more stringent of the two must be applied.

Legal Principles.

I. Definitions:

- A. **CHILD/CHILDREN/MINORS:** The federal research regulations define children as individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the State or local law of the jurisdiction in which the research will be conducted. In Illinois, individuals under the age of 18 are considered minors with the exceptions noted in the UIC HSPP policy *Research Involving Children*.
- B. **CLOSE FRIEND:** In Illinois, "Any person 18 years of age or older who has exhibited special care and concern for the patient and who presents an affidavit to the attending physician stating that he or she (i) is a close friend of the patient, (ii) is willing and able to become involved in the patient's health care, and (iii) has maintained such regular contact with the patient as to be familiar with the patient's activities, health, and religious and moral beliefs. The affidavit must also state facts and circumstances that demonstrate that familiarity." (755 ILCS 40/10).
- C. **COGNITIVELY IMPAIRED:** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993)
- D. **COMPETENCE:** Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See terms *Incompetence*, *Incapacity*.) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (e.g., writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993).

- E. **DECISIONAL CAPACITY:** In Illinois, “the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or forgoing life-sustaining treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician.” (755 ILCS 40/10).
- F. **DISABLED PERSON:** In Illinois, a person 18 years or older who: 1) because of mental deterioration or physical incapacity is not fully able to manage his or her person or estate, or 2) is a person with mental illness or developmental disability and who because of mental illness or developmental disability is not fully able to manage his or her person or estate, or 3) because of gambling, idleness, debauchery or excessive use of intoxicants or drugs, so spends or wastes his or her estate as to expose the person with disability or dependents to want or suffering. (Section 11a-2).
- G. **GUARDIAN:** DHHS and the FDA define a guardian as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Illinois, the term Guardian “means a court appointed guardian of the person who serves as a representative of a minor or as a representative of a person under legal disability.” In Illinois, a variety of guardianship appointments exist and the investigator should take care to document that the guardian’s representation of the ward is within the scope of their authority: limited guardianship, plenary guardianship, guardian of the person, guardian of the estate, and temporary guardianship. (Health Care Surrogate Act, 755 ILCS 40).
- H. **INCAPACITY:** Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993)
- I. **INCOMPETENT:** A legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.
- J. **INSTITUTION:** A residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential schools for the mentally or physically handicapped; and homes for dependent and neglected children.
- K. **LEGALLY AUTHORIZED REPRESENTATIVES (LARs):** DHHS and the FDA define a legally authorized representative as “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.” (46.102(c); 21 CFR 50.3).
- L. **MATURE MINOR:** In Illinois, individuals under the age of 18 are considered mature minors if they are emancipated by court order or have been adjudicated to be an adult for the purpose of criminal prosecution.
- M. **PERSONAL INFORMED PROTECTION ACT (PIPA):** The PIPA is an Illinois State Law that creates specific requirements for public universities and other

data collectors to notify individuals when their personal information, such as their social security number, may have been improperly accessed. For more information as to PIPA, please refer to:

<http://www.cio.illinois.edu/policies/pipa/index.html>

- N. PRISONER: Any “individual involuntarily confined or detailed in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.” (45 CFR Part 46.303(c)).
- O. SURROGATE: “Surrogate decision maker” means an adult individual or individuals who (i) have decisional capacity, (ii) are available upon reasonable inquiry, (iii) are willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity, and (iv) are identified by the attending physician in accordance with the provisions of [the Illinois Health Care Surrogate Act] as the person or persons who are to make those decisions in accordance with the provisions of [the Illinois Health Care Surrogate Act]. (755 ILCS 40/10).

Requirements for Other Disclosures to Subjects.

- I. Illinois state law and VHA Handbook 1605.1 may require possible additional disclosure to subjects within the informed consent form as to the possibility that certain information may be required to be reported to state or federal agencies. If the finding of a reportable event is anticipated as part of the research and the reportable event is not incidental to the research, the principal investigator should inform subjects during the informed consent process about the possibility of disclosure of the event if it occurs. In addition, if applicable, VA Handbook 1605.1 on Privacy and Release of Information requires that subjects be informed to of special disclosure requirements as part of the informed consent process:
 - A. Abused and Neglected Child Report Act (325 ILCS 5/1);
 - B. The Elder Abuse and Neglect Act (Public Act 90-0025); and
 - C. The Illinois Department of Public Health Laboratory (Infectious Disease) Reporting Requirements, list of reportable diseases available at: <http://www.idph.state.il.us/health/infect/LabReportingRequirements2008.pdf>;
 - D. AIDS Confidentiality Act or the Control of Communicable Diseases Code (77 Ill. Adm. Code 690);
 - E. VHA Handbook 1605.1, Privacy and Release of Information, pp. 59; 62.
 - 1. The VA has special reporting requirements for VA Research subject HIV notification to the spouse or friend: “Before any patient gives authorization to being tested for the HIV, as part of pre-test counseling, the patient must be informed fully about this notification provision.” (p. 59).
 - 2. VHA “may disclose individually-identifiable information, excluding 38 U.S.C. 7332- protected information, to Federal, State, and/or local public health authorities charged with the protection of the public health or safety pursuant to a standing request or other applicable legal

authority (see subpar. 27a for disclosing 38 U.S.C. 7332-protected HIV information). Standing requests are valid for three years, at which time they must be reissued. Examples of public health reporting requiring a standing request or letter include: (a) Communicable diseases (e.g., hepatitis, tuberculosis, sexually transmitted diseases, etc.); (b) Vital statistics (e.g., deaths, etc.); and (c) Other State reporting requirements (e.g., animal bites)." (VHA Handbook 1605.1, p. 62).

3. The VA also may disclose the information to cancer registries. (VHA Handbook 1605.1, p. 62).

Illinois Law and HIV Testing and Results.

- I. In Illinois, "the subject of the test or the subject's legally authorized representative must be notified by personal contact whenever possible of the confirmed positive result of an HIV test. When the subject or the subject's legally authorized representative is notified of a confirmed positive test result, the health care provider or professional shall provide the subject or the subject's legally authorized representative with a referral to counseling in connection with the confirmed positive test result and a referral to an appropriate medical facility for the treatment and management of HIV. A health care provider shall not be in violation of this Section when an attempt to contact the test subject or the subject's legally authorized representative at the address or telephone number provided by the test subject or the test subject's legally authorized representative does not result in contact and notification or where an attempt to deliver results by personal contact has not been successful. (410 ILCS 305/9.5)"
- II. In Illinois, "no person may disclose or be compelled to disclose the identity of any person upon whom a test (*Note: Test refers to tests designed to reveal a condition indicative of Human Immunodeficiency Virus (HIV) infection*) is performed, or the results of such a test in a manner which permits identification of the subject of the test" except to the individuals and institutions listed in 410 ILCS 305/9.
- III. The informed consent process should inform potential research subjects about the possibility of disclosure of the HIV test results as required by these statutes.

Laws that apply to research at UIC.

The following is a list of the laws that apply to research at UIC, including national, state, and local law, as applicable. Regulations, directives, or guidance that apply to research at UIC are provided in the UIC OVCR policies and procedures. As noted, the laws below may not necessarily apply to all research protocols and neither is the list below conclusive. This list does not include laws applicable to clinical research trials billing.

Federal Laws:

Confidentiality of Drug Abuse, Alcoholism, and Alcohol Abuse, Infection with Human HIPAA

Immunodeficiency Virus (HIV) and Sickle Cell Anemia Medical Records (38 USC 7332)

Confidentiality of Healthcare Quality Assurance Review Records (38 USC 5705)

Department of Defense: Limitation on Use of Humans as Experimental Subjects (10 USC §980)

The Energy Reorganization Act of 1974

The Emergency Medical Treatment and Active Labor Act
The Family Education Rights and Privacy Act (Department of Education)
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, 42 USC §262 (generally)
The Public Health Service Act, Licensing of Biological Products and Clinical Laboratories, Biological Products
Protection of Pupils Rights Amendment (Department of Education)
Research on Transplantation of Fetal Tissue (PL 103-43)
Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980)
VA Claims Confidentiality Statute (38 USC 5701)

Illinois 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 50)
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 ILCS 140/)
Illinois Court of Claims Act (705 ILCS 505/)