OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Office for the Protection of Research Subjects (OPRS)
Institutional Review Board
FWA# 00000083

201 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-1711
Fax: 312 413-2929

http://research.uic.edu/human-subjects-irbs/

Approval Criteria: Additional Protections for Vulnerable Populations

Version: 1.2; Date: 02/21/2017
Approved by: Human Protections Administrator, Director of OPRS, and Executive IRB Chair
AAHRPP REF#: 192
AAHRPP Elements: II.4.A., II.4.B., III.1.C., III.1.F..

POLICY:

I. The UIC IRB ensures that additional safeguards are included in the research design to protect the rights and welfare of research participants who have limited autonomy and are at risk for coercion and undue influence.

II. In addition to the populations covered by subparts B (pregnant women, human fetuses and neonates), C (prisoners) and D (children), UIC policy also requires the IRB to consider the need for additional protections when reviewing research involving other groups who may be subject to coercion or undue influence temporarily or permanently. These other potentially vulnerable populations include subjects who:
    A. are susceptible to coercion or undue influence (e.g., the homeless, prisoners, UIC employees or students involved in research in an educational setting, and economically or educationally disadvantaged subjects, terminally ill, patients with limited or no treatment options, socially and economically disadvantaged);.
    B. lack comprehension of the research and its potential risks (e.g., educationally disadvantaged, dementia, schizophrenia, depression);
    C. have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault); and
    D. are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status)

PROCEDURES :

I. The Investigator must submit the materials specified in the protocol application for the IRB to obtain information in sufficient detail to make the determinations required by the Federal regulations for approval for conducting the research in the applicable vulnerable population.

II. Specific appendices describing research activities and additional protections are

submitted when the protocol involves children, prisoners, pregnant women (and human fetuses and neonates) and the decisionally impaired. For other potentially vulnerable populations where no appendix is available, the application asks the investigator to provide a rationale for inclusion of the population and describe any additional safeguards or protections.

III. The IRB determines whether the research involves participants vulnerable to coercion or undue influence or subjects with diminished capacity to consent due to environmental, medical, mental or social circumstances, such as participants who are educationally or economically disadvantaged, terminally ill, alcohol or substance abusers, or pre- or post an invasive medical procedure. The protocol is examined for inclusion of additional safeguards to protect the rights and welfare of these subjects, and the adequacy of these safeguards by reviewing the protocol, IRB application, appendices and consent documents to ascertain whether the applicable criteria for approval (e.g., DHHS, FDA) are met.
    A. In making their determination, the IRB considers protocol specific issues, including the context of the research, purpose, relevance of research to possible vulnerable population, eligibility criteria, study design, relationship between investigator and subject, risks, measures to minimize risks, additional protections, benefits, compensation and alternatives to participation.
    B. Additional protections may include, but are not limited to: assessment of understanding of consent process and ability to provide informed consent, use of witnesses, requiring consultants/advocates, formally renewing consent at specified stages, reassessing subject's ability to provide voluntary consent, inclusion of additional language in consent document, limiting scope of protocol, or more frequent monitoring of research.

IV. The IRB documents their review and determinations regarding the provision of additional safeguards for individuals who are vulnerable to coercion or undue influence in the meeting minutes or, when review occurs under expedited conditions, review guides.

V. For international research or research funded by the Department of Education, Department of Defense, Department of Justice, or the Department of Veteran's Affairs, the IRB follows any additional protections described in the relevant authorities' or agencies' regulations or laws.

REFERENCES:

45 CFR 46. 111(b) plus subparts B, C, and D
21 CFR 50.3

UIC HSPP policy *Ethical Standards and Legal Principles*

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 4/30/12	1.0, 2/11/09	Updated to reflect new approval date and individuals; updated description for gathering material on participation of vulnerable populations and additional safeguards from investigators and IRB determination.
1.2, 02/21/17	1.1, 4/30/12	Editorial revisions.