The Christ Hospital IRB **Number:** 3.19
Submitted By: Erica Jones, CIP **Effective Date:** 3/27/09
Reviewed By: Steve Roberts, MD **Revised/Reviewed Date:** 09/22
Approved By: Steve Roberts, MD
(II.1.A, II.4.A)

STANDARD OPERATING PROCEDURE

Additional Safeguards for Vulnerable Populations Other Than Decisionally Impaired, or Pregnant Women, Fetuses or Neonates

POLICY:

Research involving participants who may be subject to coercion or undue influence and not able to make an independent choice about whether to participate in research must be designed to include additional protections against coercion or undue influence. Research with human participants requires researchers to incorporate ethical principles into all research proposals. The principle requiring respect for persons means that research proposals should incorporate two convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. Those groups of individuals who are recognized under federal law as having diminished autonomy entitled them to additional protection include:

- minors
- prisoners (The Christ Hospital does not do research on prisoners*),
- pregnant women, fetuses and neonates (see SOP 3.17 Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research).

*See NOTE below.

The IRB requires additional protections for participants who may be capable of giving consent to research but who may be vulnerable to coercion because they are decisionally impaired (see SOP 3.18 Additional Safeguards for Decisionally Impaired Adults in Research).

There may be other groups or individuals who may be susceptible to coercion or undue influence because of circumstances, illness, or incapacitation and may not be fully capable of deliberation and the ability to express opinions or choices. Students, for example, may be influenced by a teacher to participate in research because they fear that their grade may be determined by their choice not to participate in the teacher's research and so may need additional protection from coercion or undue influence of the researcher. This policy requires researchers and the IRB to identify research participants who may be susceptible to coercion or undue influence and to provide additional protections in the research protocol for these groups or individuals.

NOTE: When Subjects Become Prisoners During a Research Protocol: The Christ Hospital does not conduct research on prisoners. If a subject becomes a prisoner after enrollment in research, the Principal Investigator is responsible for reporting this in writing to the IRB immediately. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease, ***and the subject must be withdrawn from the study***. In special circumstances in which the PI asserts that is it in the best interests of the subject to remain in the research study while incarcerated, or

feels that withdrawal from the study presents significant risks to the patient, the IRB Chair may determine that the subject may continue to participate in the research until the requirements of HHS regulations at 45 CFR part 46, subpart C "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects" are satisfied.

At the earliest opportunity after receiving the Principal Investigator's recommendation to allow the subject to remain in the study, the IRB should review the protocol again with a legal representative from the hospital's Risk Management Department. The Committee should take special consideration of the conditions of being a prisoner as set forth in 45 CFR 46, subpart C. Upon this review, the IRB can either a) approve the involvement of the prisoner-subject in the research in accordance with this policy or b) determine that this subject must be withdrawn from the research. Additionally, the IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject's participation by the investigator without regard to the subject's consent.

PROCEDURE

Investigator:
Research proposals submitted to the IRB for review and approval will describe the population from which research participants are to be recruited and will list additional protections if those populations include individuals or groups who may be subject to coercion or undue influence.

IRB Members:
When the IRB reviews research which include participants who are vulnerable, the IRB Chair will ensure that one or more individuals who are knowledgeable about or experienced in working with such participants are present at the meeting.

1. The IRB will determine whether the populations from which research participants are to be recruited or individuals who may be recruited are fully able to make an independent choice about whether to participate. Factors to consider include:

    - Whether economic factors may induce individuals to take undue risk. For example, uninsured individuals may choose to participate in research with more than minimal risk in order to have health exams or health care.
    - Whether severe illness may induce individuals to take undue risk. Individuals with terminal illnesses may believe that a research protocol may cure their disease.
    - Whether participants' ability to understand the research will impact their ability to make an independent decision. For example, individuals who do not have the equivalent of a high school education or whose first language is not English may have difficulty understanding the research and the consent process.
    - Whether an individual's primary care physician is conducting the research. Individuals who are accustomed to thinking of a physician as a health care giver may not fully comprehend that same physician's role as a researcher.
    - Whether cultural differences may prevent full understanding of the researcher. Individuals whose values are shaped by a culture other than the researcher's may make decisions on assumptions that are not valid.

- Whether there are any other factors which may unduly influence an individual to participate in research.

2. If there are groups of individuals who may be subject to coercion or undue influence, the IRB will evaluate whether the additional protections in the research protocol are sufficient. Protections should enhance a potential participant's ability to understand the research and make a reasoned decision about whether to participate. Nothing in this policy should be construed to prevent a class or group of individuals from having the opportunity to participate in research.

3. The following are additional protections researchers should consider and the IRB should evaluate in protocol involving participants who could be subject to coercion or undue influence:
    - For research involving participants who may have difficulty comprehending the research, the IRB may require an appropriate method of assessing the decision-making capacity of potential participants.
    - For research involving participants whose ability to comprehend may fluctuate, the IRB may require that participants involve family members or caregivers in the consent process and may require periodic re-consent.
    - Third party consent monitors may be required during the recruitment and consenting process.
    - Waiting periods between the consent process and signing the consent document may be required for some populations who may be vulnerable to allow more time for participants to consider the information that has been presented.
    - Repeated consent sessions with groups of participants, audiovisual presentations, or informed consent comprehension tools may be required.
    - Other measures might include an independent monitor to observe the consent process or videotaping or audio-taping the consent process, requiring an opinion of the participant's primary care physician, or involvement of a family member or friend in the disclosure and decision-making process.
    - More frequent than annual review of research involving vulnerable populations and greater than minimal risks.
    - Inviting a consultant to the IRB to assess vulnerabilities of the participant population and make recommendations on additional protections.
    - If the researcher is also the primary care physician, requiring that another physician advise the participants or provide primary care.
    - Any other additional protections the IRB may determine need to be included in the research to protect vulnerable participants.

Ref: 45 CFR 46.111(a)(3)