**The Christ Hospital IRB** **Number:** 3.19
**Submitted By:** Erica Jones, CIP **Effective Date:** 3/27/09
**Approved By:** Steve Roberts, MD **Revised/Reviewed Date:** 10/24
(II.1.A, II.4.A)

**STANDARD OPERATING PROCEDURE**

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

## 1. POLICY

**1.1.** The Christ Hospital requires 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 to be designed to include additional protections against coercion or undue influence.

**1.2.** The IRB will review 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 and approve only research which satisfies the applicable conditions as set out below. All research meeting this classification, regardless of funding source, will be reviewed and approved in accordance with 45 CFR Part 46, Subpart B and Subpart C, as applicable.

## 2. OVERVIEW

**2.1.** 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:
- **2.1.1.** that individuals should be treated as autonomous agents, and
- **2.1.2.** that persons with diminished autonomy are entitled to protection.

**2.2.** Those groups of individuals who are recognized under federal law as having diminished autonomy entitled them to additional protection include:
- **2.2.1.** minors
- **2.2.2.** pregnant women, fetuses and neonates (see SOP 3.17 *Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research*).
- **2.2.3.** prisoners (The Christ Hospital does not engage in research involving incarcerated subjects),
  - **2.2.3.1.** While TCH does not engage in research involving incarcerated subjects, it may happen that an individual becomes incarcerated while enrolled in a research study. Procedures for the unexpected incarceration of a research participant are outlined under PROCEDURE.

**2.3.** 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).

**2.4.** 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.

## 3. RESPONSIBILITY

**3.1.** Researchers and the IRB must identify research participants who may be susceptible to coercion or undue influence and provide additional protections in the research protocol for these groups or individuals.

## 4. PROCEDURE

### 4.1. Investigator

#### 4.1.1. General Considerations for Vulnerable Populations

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.

#### 4.1.2. Considerations for the Unexpected Incarceration of a Research Participant

Upon discovery of a participant's incarceration, the principal investigator (PI), or designee, must promptly notify the IRB in writing of the incarceration**.** This notification should include a written assessment of whether it is in the best interest of the prisoner-participant to continue in the study, and the PI's plans for continuation or cessation of the intervention during the participant's incarceration. If the participant were enrolled in a clinical trial involving therapeutic treatment, or investigational drugs or devices, and immediate cessation of the research intervention could imperil the imprisoned participant's health, the PI must also promptly notify the Department of Corrections.

*Considerations for Temporary Incarceration*: If a participant is incarcerated temporarily while enrolled in a study and the temporary incarceration has no effect on the study, the PI may keep the participant enrolled if research activities, including the collection of identifiable information from the incarcerated participant, are curtailed during the participant's incarceration.

If a participant is incarcerated temporarily while enrolled in a study and the temporary incarceration may affect the participant's health or safety, the PI must assess risks to the incarcerated participant resulting from cessation of the research intervention during the temporary incarceration. The PI may consider requesting temporary continuation of the intervention.

*Immediate Cessation of the Intervention*: Where an incarcerated participant may be safely withdrawn from research interventions, or for research that does not involve interventions, the PI must immediately cease all research activities

involving the prisoner-participant and the incarcerated participant will be immediately withdrawn from the study. The PI may retain and use data collected from or about the participant up to the point of incarceration.

*Temporary Continuation of the Intervention:* If the PI determines that immediate cessation of a study intervention may harm the incarcerated participant or withdrawal from the study presents significant risks to the patient and as such that continuation of the intervention is in the best interests of the incarcerated participant, the PI must provide the following information to the IRB:

- Determination of the minimum intervention necessary to protect the incarcerated participant.
- Plan for monitoring the incarcerated participant's health and safety during discontinuation of the medication (including tapering if warranted) or removal of the device; or for continued dosing or placement of the device.
- Description of standard care the participant was receiving while in the research study (if applicable);
- Timeline for safely withdrawing the incarcerated participant from the intervention;
- Specification of either:
    1. following safe cessation of the intervention, the incarcerated participant will be permanently withdrawn from the study; or
    2. via an IRB-approved amendment, the incarcerated participant will be kept on the study intervention.

In preparing the request for temporary continuation, the PI may wish to consult with the IRB, TCH Risk Management, and/or a qualified representative from the Ohio Department of Rehabilitation and Corrections Office of Holistic Services to confirm the plan for continuation is compliant and feasible.

## 4.2. IRB

### 4.2.1. General Considerations for Vulnerable Populations

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.

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.

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.

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.

### 4.2.2. Considerations for the Unexpected Incarceration of a Research Participant

In the event that an Investigator wishes that continuation of the intervention is in the best interests of the incarcerated participant, the convened IRB, in consultation with a legal representative from the hospital's Risk Management Department, will review the submitted amendment in accordance with the requirements of 45 CFR 46, subpart C, to ensure that the rights and wellbeing of the now-incarcerated participant are not in jeopardy.

The convened IRB should evaluate if the now-incarcerated participant can:

- Continue to consent to participate,
- Capable of meeting the research protocol requirements,
- The terms of the now-incarcerated participant's confinement do not inhibit the ethical conduct of the research, and
- There are no other significant issues preventing the research involving human subjects from continuing as approved.

If these elements are found satisfactory, the convened IRB may approve the amendment to allow the incarcerated participant to continue to participate in the research. The approval would be limited to the individual subject and would not allow continued recruitment and enrollment of incarcerated participants into the research. The these elements are not found satisfactory, the incarcerated participant must be withdrawn from the research.

*Additional IRB Considerations for Subpart C:*

If the Investigator solicits or obtains information from the parents or spouse, rather than the incarcerated subject, for information about the incarcerated subject's behavior and attitudes for the research project, this activity would constitute "obtaining identifiable private information about" the incarcerated subject, and would invoke subpart C and would be require review and approval from the IRB.

During detention, the incarcerated subject does not have to be formally withdrawn; as long as there is no interaction, intervention or obtaining data with the subject while incarcerated, meaning subpart C is not invoked. Therefore, there is no need to withdraw and re-enroll. If the investigator can wait until the person is no longer incarcerated, subpart C is never an issue.

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.

*Subpart C Certification Request to OHRP*
If the research project is in which the incarcerated participant is HHS-supported research, the institution must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2). The institution must electronically submit a Subpart C Certification Form to OHRP and wait for a letter of authorization in reply.

## 5. REFERENCES

### 5.1. HHS Policies

**5.1.1.** 45 CFR 46.111 – Criteria for IRB approval of research.

**5.1.2.** 45 CFR 46.305 – Additional duties of the Institutional Review Boards where prisoners are involved.

**5.1.3.** 45 CFR 46.306 – Permitted research involving prisoners

### 5.2. OHRP Webpage –Subpart C Certification Request to OHRP