The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Unexpected Incarceration of a Research Participant

1.0 PURPOSE

The purpose of this standard operating procedure is to describe regulatory and policy requirements that apply when a research participant becomes incarcerated while enrolled in a research study that was not designed to include prisoners at The Christ Hospital (TCH).

2.0 OVERVIEW

2.1 Prisoners are vulnerable participants in the context of participation in human subjects research. (Ref. Subpart C of 45 CFR part 46.)

2.2 A prisoner is a person who is involuntarily confined or detained 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.

3.0 POLICY

3.1 While The Christ Hospital does not engage in research involving incarcerated participants, it may happen that an individual becomes incarcerated while enrolled in a research study.

3.2 It is the policy of TCH that upon discovery of a participant's incarceration, the incarcerated subject must stop participating in the research which includes all research interactions, interventions and/or obtaining identifiable private information.

3.3 The principal investigator (PI), or designee, must provide written notification to the IRB regarding the incarceration. The notification should include an assessment of whether continuing in the study would be in the best interests of the prisoner-participant, and the PI's plans for either continuation or cessation of the intervention during the participant's incarceration.

3.4 As long as research activities are curtailed during the research participant's incarceration, meaning no interaction or intervention with, nor obtaining data from the participant while incarcerated, the participant does not have to be formally withdrawn as Subpart C is not invoked. Research activities may resume when the participant is no longer incarcerated.

3.5 If the investigator solicits or obtains information from the incarcerated participant's parents or spouse, rather than the incarcerated participant, for information regarding the participant's behavior and attitudes about the research project, such activity would constitute "obtaining identifiable private information about" the incarcerated participant, would invoke subpart C, and therefore require review and approval from the IRB.

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

4.0 RESPONSIBILITY

4.1 Principal Investigator

4.1.1 Notifies IRB: Upon discovery of a research participant's incarceration, the principal investigator (PI), or designee, must promptly provide written notification to the IRB regarding the incarceration. The notification should include a written assessment of whether it is in the best interests 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.

4.1.2 Notifies Department of Corrections, if Applicable: 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 appropriate Department of Corrections.

4.1.3 Submits Amendment to Request Temporary Continued Intervention: If the PI determines that temporary continued intervention is in the best interests of the incarcerated participant, the PI must promptly request an amendment to allow temporary continued intervention.

4.2 IRB

4.2.1 Reviews for Temporary Continued Intervention: If an investigator determines that temporary continued 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.

4.2.2 Submits Subpart C Certification Request to the Office for Human Research Protections (OHRP): If the research project in which the incarcerated participant is enrolled is supported by the U.S. Department of Health and Human Services (HHS), the institution must certify to the HHS 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. If OHRP determines that the research complies with Subpart C, they will issue an authorization letter. The amendment may only receive final IRB approval upon receipt of this authorization.

5.0 PROCEDURE

5.1 Principal Investigator or Authorized Designee

5.1.1 Written Notification to the IRB: The required notification should include a written assessment of whether it is in the best interests 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.

5.1.2 Considerations for Temporary Incarceration:

5.1.2.1 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.

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

5.1.3 Notifies the Department of Corrections: 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.

5.1.4 Submits an Amendment to Request Temporary Continued Intervention: If the PI determines that temporary continued intervention is in the best interests of the incarcerated participant, the PI must promptly create an amendment in Mentor IRB to request IRB approval to allow the involvement of the individual prisoner-participant to continue in the research. In the amendment, the PI must:

5.1.4.1 Outline modifications to the procedures to accommodate the prisoner-participant;

5.1.4.2 Provide documentation of permission from the penal institution where the prisoner-participant is incarcerated.

5.2 IRB Chair/Primary Reviewer

5.2.1 Assesses whether the protocol meets the criteria for research involving prisoners.

5.2.2 Reviews the amendment using the "IRB: Full Board Amendment Review Checklist" using the IRB Checklist to ensure the required information to satisfy research activities involving the vulnerable population is sufficiently detailed.

5.2.3 Contacts the PI and/or research coordinator with questions or needed clarification/documentation regarding the vulnerable population.

5.2.4 Assures that the IRB discusses additional safeguards according to the IRB checklist.

5.2.5 Reviews the IRB minutes to ensure that the following are sufficiently documented:

5.2.5.1 IRB discussion;

5.2.5.2 Any controverted issues;

5.2.5.3 Protocol-specific safeguards for the vulnerable population;

5.2.5.4 Any additional safeguards for the vulnerable population; and

5.2.5.5 IRB determinations.

5.3 IRB Staff

5.3.1 Ensures that the Amendment submission is complete and is available in its entirety in Mentor IRB for IRB Chair or designee review;

5.3.2 Assigns the IRB Chair or designee as reviewer assigning the "IRB: Full Board Amendment Review Checklist" checklist to the reviewer;

5.3.3 Documents discussion, any additional safeguards, and determinations of the IRB in the minutes; and

5.3.4 Communicates all IRB determinations through Mentor IRB in a notification letter sent to the Principal Investigator and any research coordinator(s) as outlined in SOP 1.04, "Conducting IRB Meetings / IRB Meeting Minutes"; and

5.3.5 Electronically submits a Subpart C Certification Form to OHRP if the research project is HHS-supported.

5.4 Convened IRB Review of Amendment

5.4.1 Reviews the amendment in accordance with the requirements of 45 CFR 46, Subpart C to ensure that the rights and wellbeing of the now-incarcerated subject are not in jeopardy.

5.4.2 Confirms 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.

5.4.3 Approves the amendment only if the following elements are found satisfactory:

5.4.3.1 The now-incarcerated participant can continue to consent to participate,

5.4.3.2 The participant is capable of meeting the research protocol requirements,

5.4.3.3 The terms of the now-incarcerated participant's confinement do not inhibit the ethical conduct of the research, and

5.4.3.4 There are other significant issues which would prevent the research involving human subjects from continuing as approved.

NOTE: Approval is limited to the individual subject and does not allow continued recruitment and enrollment of incarcerated participants into the research. If the elements are not found satisfactory, the incarcerated participant must be withdrawn from the research.

6.0 REFERENCES

6.1 United States Department of Health and Human Services (HHS)

6.1.1 Subpart C of 45 CFR part 46 - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

6.1.2 45 CFR 46.111 - Criteria for IRB approval of research

6.1.3 45 CFR 46.305 - Additional duties of the Institutional Review Boards where prisoners are involved

6.1.4 45 CFR 46.306 - Permitted research involving prisoners

6.1.5 The Belmont Report

6.1.6 HHS Office for Human Research Protections (OHRP)

6.1.6.1 Subpart C Certification Request to OHRP

6.1.6.2 Subpart C Certification Form

6.2 AAHRPP Domains and Elements: II.4.A