
STANDARD OPERATING PROCEDURE

Additional Safeguards for Vulnerable Populations Susceptible to Coercion or Undue Influence Other Than Decisionally Impaired, Children, or Pregnant Women, Fetuses and Neonates

1.0 PURPOSE

While specific regulations pertaining to additional protections for specific vulnerable populations involved in human research are specified in 45 CFR 46, Subparts [B](#), [C](#), and [D](#), and [IRB SOPs 3.17](#), 3.18, 3.22, and 3.23 (i.e., pregnant women, fetuses, and neonates; decisionally impaired individuals; children; and incarcerated participants of research), there are other groups who may be vulnerable and susceptible to coercion or undue influence. The purpose of this standard operating procedure is to describe regulatory and policy requirements that apply when The Christ Hospital (TCH) Institutional Review Board (IRB) is reviewing research involving these other groups of vulnerable populations who may be susceptible to coercion or undue influence and address additional protections for these groups.

2.0 OVERVIEW

2.1 Respect for Persons

Research involving 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.

(Refer to the [Belmont Report](#).)

2.2 Diminished Autonomy

Groups recognized under federal law as having diminished autonomy entitle them to additional protection including:

- 2.2.1 Pregnant women, fetuses and neonates (ref. [IRB SOP 3.17](#), “Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research”);

- 2.2.2 Minors (ref. [IRB SOP 3.22](#), “Additional Protections for Children Involved as Subjects in Research”); and
- 2.2.3 Prisoners. Note: While TCH does not engage in research involving incarcerated participants, it may happen that an individual becomes incarcerated while enrolled in a research study (ref. [SOP 3.23](#), “Unexpected Incarceration of a Research Participant”).

2.3 Decisional Impairment

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 (ref. [IRB SOP 3.18](#), “Additional Safeguards for Decisionally Impaired Adults in Research”).

2.4 Others

There may be other groups who may be susceptible to coercion or undue influence because of circumstances, illness, or incapacitation, and who may not be fully capable of deliberation and the ability to express opinions or choices. For example, students may be influenced by a teacher to participate in research because they fear that their grade may be determined by their choice to either participate or not participate in the teacher’s research, and so may need additional protection from coercion or undue influence of the researcher.

2.5 Nature of the Research

Risks may vary for particular groups depending on the nature of the research being conducted. So, a researcher should consider what protections or additional steps may be needed to minimize risk for their specific study population, such as outlining procedures for consenting individuals with diminished decision-making capacity, or specifying a plan to address incidental findings from the research.

Note: Additional protections should not discourage research with vulnerable populations nor those requiring special considerations.

3.0 POLICY

The Christ Hospital requires that 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 be designed to include additional protections against coercion or undue influence. Research proposals submitted to the IRB for review and approval must describe the population(s) from which research participants are to be recruited and list additional protections if those population(s) include groups who may be subject to coercion or undue influence.

The IRB will review research involving vulnerable participants, regardless of funding source, and approve only research which provides adequate protections for these groups or individuals. Protections should enhance a potential participant’s ability to understand the research and make a

reasoned decision about whether or not to participate. Nothing in this policy should be construed to prevent a class or group from having the opportunity to participate in research.

4.0 RESPONSIBILITY

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 and individuals.

4.1 Researchers

Researchers should consider the following and include additional protections in protocols involving participants who could be subject to coercion or undue influence.

4.1.1 Comprehension Assessment

4.1.1.1 For research involving participants who may have difficulty understanding the research, the IRB may require an appropriate method of assessing the decision-making capacity of potential participants.

4.1.1.2 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. Such participants may also require periodic re-consent.

4.1.2 Waiting Period

Waiting periods between the consent process and signing the consent document may be required for some groups or individuals who may be vulnerable, to allow more time for these participants to consider the information that has been presented.

4.1.3 Additional Tools

Other tools may be utilized, such as:

4.1.3.1 Informed consent comprehension tools;

4.1.3.2 Repeated consent sessions with the vulnerable participants;

4.1.3.3 Audiovisual presentations; video/audiotaping the consent process;

4.1.3.4 Requiring an opinion of the participant's primary care physician in the disclosure and decision-making process.

4.1.4 Uninvolved Physician

If the researcher is also the participant's primary care physician, requiring that another physician advise or provide primary care for the participant.

4.2 IRB

The IRB should evaluate the following in protocols involving participants who could be subject to coercion or undue influence.

4.2.1 Reviewer Expertise

The IRB Chair will ensure that one or more board members or consultants knowledgeable about or experienced in working with the vulnerable population are present at the meeting.

4.2.2 Independent Choice

The IRB will determine whether the population(s) from which research participants are, or who may, be recruited are each fully able to make an independent choice about whether to participate. Factors to consider include the following.

- 4.2.2.1 Economic Factors: 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 obtain health exams or health care.
- 4.2.2.2 Severe Illness: Severe illness may induce individuals to take undue risk. For example, individuals suffering from terminal illnesses may believe that a research protocol may cure their disease.
- 4.2.2.3 Ability to Understand: A participant's ability to understand the research impacts 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.
- 4.2.2.4 Primary Care Physician as Researcher: When a research participant's primary care physician is conducting the research, the participant who is accustomed to thinking of a physician as a health care giver may not fully comprehend that same physician's role as a researcher.
- 4.2.2.5 Cultural Differences: Cultural differences between the research participant and the researcher may influence the research. That is, participants whose values are shaped by a culture other than the researcher's may make decisions on assumptions that are not valid.
- 4.2.2.6 Other Factors: Other factors may unduly influence an individual to participate in research.

The IRB may require additional protections in protocols involving participants who could be subject to coercion or undue influence, including but not limited to the following.

4.2.3 Comprehension Assessment

- 4.2.3.1 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.
- 4.2.3.2 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. Participants may also require periodic re-consent.

4.2.4 Informed Consent Monitoring

It be appropriate to acquire an independent monitor to observe the consent process.

4.2.5 Waiting Period

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.

- 4.2.6 Additional Tools
Other tools may be utilized/required, such as:
 - 4.2.6.1 Repeated consent sessions with groups of participants;
 - 4.2.6.2 Audiovisual presentations; video/audiotaping the consent process;
 - 4.2.6.3 Informed consent comprehension tools;
 - 4.2.6.4 Requiring an opinion of the participant’s primary care physician in the disclosure and decision-making process.
- 4.2.7 More Frequent Review
More frequent than annual review of the research involving vulnerable populations and greater than minimal risks may be necessary.
- 4.2.8 Uninvolved Physician
If the researcher is also the primary care physician, requiring that another physician advise the participants or provide primary care.
- 4.2.9 Additional Otherwise Unspecified Protections
The IRB may require other additional protections to be included in the research to protect vulnerable participants at their discretion.

5.0 PROCEDURE

5.1 Principal Investigator or Authorized Designee

- 5.1.1 Creates a new protocol application through the web-based IRB submission system, [Mentor IRB](#), and selects the appropriate category under Vulnerable Participants field indicating this will be the target population for the research activities (ref. [SOP 2.01](#), “Guidelines for New Protocol Submission” for submission guidelines);
- 5.1.2 Addresses the process of obtaining informed consent and selection of participants with particular attention to preventing undue influence or coercion.

5.2 IRB Chair/Primary Reviewer

- 5.2.1 Assesses whether the protocol meets the criteria for research involving the vulnerable population.
- 5.2.2 Reviews the protocol using the IRB checklist to ensure that 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
 - 5.2.5.5 IRB determinations

5.3 IRB Staff

- 5.3.1 Ensures that the submission is complete and is available in its entirety in Mentor IRB for IRB chair or designee review (ref. [SOP 2.01](#), “Guidelines for Protocol Submission” for document requirements);
- 5.3.2 Assigns the IRB chair or designee as reviewer including the “IRB: New Protocol Reviewer Checklist” checklist to the reviewer;
- 5.3.3 Documents discussion, protocol-specific safeguards, 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”.

5.4 Convened IRB

- 5.4.1 Reserves the right to invite a consultant with understanding and expertise in the participant population to the IRB meeting to assess vulnerabilities of the population and make recommendations on additional protections may be needed;
- 5.4.2 Reviews the proposed research, informed consent process, assent process, and other applicable documents to determine whether the study meets criteria at [45 CFR 46.111](#) and [21 CFR 56.111](#), if applicable, for approval by the convened IRB;
- 5.4.3 Assures that there are protocol-specific safeguards for the vulnerable population;
- 5.4.4 Discusses the proposed research including outlining any necessary additional safeguards for the vulnerable population; and
- 5.4.5 Approves the research only if the IRB determines the following:
 - 5.4.5.1 That the research is conducted in accordance with sound ethical principles, and
 - 5.4.5.2 Informed consent will be obtained in accordance with [45 CFR 46.116](#) and all applicable additional subparts.

6.0 REFERENCES

6.1 [IRB Standard Operating Procedures](#)

- 6.1.1 SOP 1.04 - Conducting IRB Meetings / IRB Meeting Minutes
- 6.1.2 SOP 2.01 - Guidelines for New Protocol Submission
- 6.1.3 IRB SOP 3.17 - Additional Safeguards for Pregnant Women and Fetuses and Neonates in Research
- 6.1.4 IRB SOP 3.18 - Additional Safeguards for Individuals Without Decision-making Capacity
- 6.1.5 IRB SOP 3.22 - Additional Protections for Children Involved as Subjects in Research
- 6.1.6 IRB SOP 3.23 - Unexpected Incarceration of a Research Participant

6.2 Code of Federal Regulations

- 6.2.1 United State Department of Health and Human Services (HHS)
 - 6.2.1.1 [45 CFR 46, Subpart B](#) - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- 6.2.1.2 [45 CFR 46, Subpart C](#) - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- 6.2.1.3 [45 CFR 46, Subpart D](#) - Additional Protections for Children Involved as Subjects in Research
- 6.2.1.4 [45 CFR 46.111](#) - Criteria for IRB approval of research
- 6.2.1.5 [45 CFR 46.116](#) - General requirements for informed consent

- 6.2.1.6 United States Food and Drug Administration
[21 CFR 56.111](#) - Criteria for IRB approval of research.
- 6.2.2 [The Belmont Report](#)

6.3 AAHRPP Domains and Elements

- 6.3.1 [II.1.A](#)
- 6.3.2 [II.4.A](#)