

Status **Active** PolicyStat ID **13321186**



**Boston
Children's
Hospital**

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Effective 1/1/2023
Next Review 8/29/2025

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Manager
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Applicability Boston Children's
Hospital- Policies
& Procedures

Informed Consent Decision Monitoring Program Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy describes the process by which a Decision Monitor may be appointed. It also provides the responsibilities of a Decision Monitor and procedures that may take place in the consent process.

Policy Statements

Informed consent is necessary to a subject's clear understanding of the risks and benefits of research. The informed consent process may be complicated by the inclusion of children and parents, where the authorized decision-maker is making a surrogate decision and the subject may have diminished capacity for assent/consent.

In order to maximize the parental permission/child assent process for protocols that present increased risk, the Institutional Review Board (IRB) may require after the permission/assent process is completed by the Principal Investigator (PI), that a Decision Monitor talk with each child/subject and parent to assess comprehension of the research and voluntariness for participation.

The IRB may require the use of a decision monitor as part of the approval process.

Protocols that May Require a Decision Monitor

The IRB may request that a decision monitor be designated for any protocol, including those that meet

the following criteria:

1. Greater than minimal risk
2. Protocols that are complicated and technical
3. Protocols where there is a concern that subjects may be less likely to differentiate research from clinical care

Decision Monitor Qualifications

A decision monitor:

1. Must not be directly involved in the study.
2. Is to be regarded as someone with whom families may confide their lack of understanding about issues or discuss any conflict, they may have with other health care providers when research is discussed.

IRB Chairs and members or others designated by the IRB may also serve this role.

Decision Monitoring Discussion Preparation

Preparation for the monitoring procedure:

1. The Decision Monitor will meet with the PI, the IRB Chair, and the Senior Director of Clinical Research Compliance to discuss the content and logistics for the decision monitoring process.
2. Each plan will be individualized to best suit the protocol.
3. The Decision Monitor and investigator will develop a form to document the monitoring process.
4. Each Decision Monitor will be provided with a copy of the protocol, the consent/assent forms, and the decision monitor forms.

The Decision Monitor is responsible for becoming familiar with the study so that they may discuss the study with the family and be able to determine from the family's responses that they have an acceptable understanding of the research.

Procedures

It is not anticipated that a subject/family will be unable to understand the issues of a study. The Decision Monitoring process is not to serve as a test. However, it is possible that subject/family may change their mind about the study. Also, if after appropriate efforts it is determined that a subject/family is unable to understand the issues, the investigator should not include the potential subject in the study.

1. **Determine Decision Monitoring Plan:** Once the protocol is approved by the IRB, the Principal Investigator (PI) will meet with the Decision Monitor, the IRB Chair, and the Senior Director of Clinical Research Compliance to:
 - a. Develop the decision monitoring plan and

- b. Identify the key information for which it will be important to verify that a subject/family understands.
2. **Parental Permission/assent obtained by investigator:** The investigator will inform the subject/family that involvement in a research protocol includes the receipt of a telephone call or a visit from a staff member of Boston Children's Hospital to ensure that each child and parent understands the study.
 - a. When possible, this contact will be scheduled 24 to 96 hours after the parental permission/assent forms are signed.
 - b. At a time when both the child and the parent will be available.
3. **The Decision Monitor speaks with both the subject and a parent**
 - a. Again, if possible this is scheduled between 24 and 96 hours after permission/assent is obtained.
 - b. The Decision Monitor will use a written document of the key components that will be discussed.
4. **Documentation:** The Decision Monitor documents the discussion.
5. **Comprehension.**
 - a. If the subject/family understands the study then:
 - i. A copy of the decision monitoring report will be given to the investigator
 - ii. A copy of the decision monitoring report will be placed in the subject's research record
 - iii. And the investigator is informed that they may proceed.
 - b. If the subject/family **does not** understand (comprehension is not attained), then the Decision Monitor will inform the PI and request that:
 - i. The PI meet with the subject/family to:
 1. Discuss the misunderstandings with the subject/family
 2. Confirm the subject/family's corrected understanding
 3. Document that the conversation has taken place.or
 - ii. The PI meet with the Decision Monitor and the family. At this time, they will:
 1. Review the study.
 2. Confirm the subject/family's corrected understanding
 3. Document that that this has taken place or
 - iii. The PI and Decision Monitor meet with the family to:
 1. Review the study.
 2. After the PI addresses the issues, the Decision Monitor will again ask the subject/family the same questions from the Decision Monitor Form.

- 3. The DM will document that the issues have been explained again and that the child and parent appear to understand the issues **or**
- iv. Other remedies may be appropriate to resolve misunderstanding and assure the subject/family understand the research. Documentation of this process should be included in the research subject records.

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures

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