Informed Consent Decision Monitoring Program

Purpose

This policy describes the process by which a decision monitor may be appointed and provides the responsibilities of a decision monitor.

Policy

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.

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 (DM) talk with each child and parent to assess their comprehension of the research and voluntariness for participation.

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:

- Greater than minimal risk
- Protocols that are complicated and technical
- Protocols about which there is concern that subjects may be less likely to differentiate research from clinical care
- The IRB may require the use of a decision monitor as part of the approval process.

Decision Monitor Qualifications

A decision monitor must not be directly involved in the study and 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

In preparing for the monitoring procedure, the DM will meet with the investigator, the IRB chair and the Director of Clinical Research Compliance to discuss the content and logistics for the decision monitoring process.

Each plan will be individualized to best suit the protocol.

The DM and investigator will develop a form to document the monitoring process.

Each DM will be provided with a copy of the protocol, the consent/assent forms**,** and the decision monitor forms.

The DM is responsible for becoming familiar with the study so that he or she may discuss it with the family and be able to determine from their responses that they have an acceptable understanding of the research.

Procedure

Decision Monitor Procedure

1. **Determine Decision Monitoring Plan**
   Once the protocol is approved the investigator will meet with the DM, the Director of Clinical Research Compliance, and the IRB Chair to develop the decision monitoring plan and identify the key information for which it will be important to verify that a subject /family to understand.

2. **Permission/assent obtained by investigator**
   The investigator will inform each child and parent 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.
   When possible, this contact will be scheduled 24 to 96 hours after the permission/assent forms are signed**,** 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** (if possible, between 24 and 96 hours) after permission/assent is obtained**.**
   The DM will use a written document of the key components that will be discussed.
   The DM documents the discussion.

4. **Comprehension.**
   a. If the subject and parent understand the issues, a copy of the Decision Monitor report will be given to the investigator and placed in the subject's research record and the investigator is informed that he or she may proceed.
   b. **Comprehension not attained.** If the subject or parent do not seem to understand any of the issues, The DM will inform the investigator, so that they may continue the consent process and may request that:
      i. The PI discuss the misunderstandings with the subject, confirm their corrected understanding and document that his has taken place or
      ii. The PI and DM meet with the family. At this time, they will review the study and confirm their corrected understanding and document that that this has taken place or
      iii. The PI and DM meet with the family and review the study. After the PI addresses the issues, the DM will again ask the child and parent the same questions from the Decision Monitor Form.
      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 family/subject understand the research. Documentation of this process should be included in the research subject records.

It is not anticipated that a subject and parent will be unable to understand the issues (e.g., this is not to serve as a test). However, it is possible that subject or parent may change their mind about the study. Also, if after appropriate efforts, it is determined that a subject or parent is unable to understand the issues, the investigator should not include the potential subject in the study.

Related Content

None Identified

Document Attributes

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