

Institutional Review Board (IRB) Policies & Procedures Manual



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General Information: Informed Consent and Parental Permission

Purpose

This policy provides general reference and guidance concerning the informed consent process and parental permission.

Policy

It is the policy of Boston Children's Hospital to comply with all federal and state regulations that pertain to informed consent.

A key requirement of human subject protection is voluntary participation. Furthermore, the informed consent process must assure that the potential subject fully understands:

- the research,
- what they are being asked to do, and
- the associated risks and benefits of the research for which they are providing consent.

For research involving children and the regulation and guidance specific to parental permission and minor assent, see the IRB policy: ***Special Considerations: Assent and Parental Permission***.

Procedure

Informed Consent: Informed consent is not merely a signature on a form, but a process of mutual communication. The process starts before any form is signed and continues throughout the entire study. The process begins by meeting with the patient. In pediatrics, this must be a family centered activity that involves the child/adolescent, the parent/guardian, and, sometimes, other caregivers.

The written consent form is a formalization of the agreement to participate, and it is used to document a process. Investigators must explain the research in terms that the potential subject can understand. Informed consent is not the mere disclosure of information; it is an interactive process. Subjects must be able to describe what they are consenting to do. Because informed consent continues throughout the entire research activity, subjects must be kept apprised of new information regarding the study. They must have the opportunity to ask, and be encouraged to ask, ongoing questions. Subjects are kept up to date through verbal discussions, written materials, and, when necessary, by having a subject re-sign a written informed consent document that contains additional information. It is important to keep in mind that subjects retain the right to withdraw at any time, and to remind them of that fact.

Process of Informed Consent

1. Principles of Informed Consent

The Belmont Report informs us that respect for persons requires that subjects “to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them”. A subject’s choice incorporates three elements:

- **Information** is critical for a person to make an informed choice as to whether they, or their child, should participate in research.

The Belmont Report suggests providing information that the “reasonable volunteer” will want to know. It is important that families understand the difference between what is necessary for their care and what is being proposed specifically for research. It is also important to recognize that some families will want more information than others, and investigators must be prepared to provide what a reasonable person would want to know and additional information, if requested.

- **Comprehension** will vary subject to subject and family to family.

The manner in which information is provided may impact comprehension. It must be recognized that individuals may need to be presented information in a variety of ways in order to comprehend the information. Comprehension may require that time be provided to allow subjects to think about participation and to ask questions.

- **Voluntariness** requires conditions free of coercion and/or undue influence, including conditions under which an individual or family may agree or disagree without any fear of repercussions.

2. Who Should Obtain Informed Consent?

Investigators are responsible, on a per protocol basis, for designating appropriate individuals to obtain consent for a protocol. Only members of the research team who have experience in all elements of the study may provide a complete and accurate description of the research, and answer questions and concerns.

Even when responsibilities for obtaining informed consent are delegated, the investigator always remains responsible for assuring an adequate process to obtain informed consent. Special considerations include:

- The technicality of the details of the protocol, and who can best explain them. For example, research that involves the use of an investigational drug will likely require that a physician member of the research team obtain informed consent
- Who is best able to answer the questions that may come up? It may be advantageous to have two individuals involved in the consent process. Often the investigator provides information, and a research nurse is made available to follow-up and provide additional information.
- If an individual other than the investigator is obtaining consent, is the investigator available if questions arise?
- Who can spend as much time with the families as they require?
- If an investigator is also the family’s physician, can the family distinguish the different roles?

3. General Requirements

Both HHS and FDA regulations require that informed consent be obtained for the subject or legally authorized representative.

Informed consent must be documented on a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative unless the IRB has approved a waiver of consent, the required elements or approved another method of obtaining consent as specified in the regulations.

Informed consent must be obtained before the initiation of any screening processes performed solely for the purpose of research.

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

The information that is given to the subject or the legally authorized representative should be in language understandable to the subject or the legally authorized representative

No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

HHS and Key Information

HHS regulations require that informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

In general Boston Children's Hospital will apply the key information summary requirement to all consent documents. If research is not under the jurisdiction, exceptions can be made on a case-by-case basis to not require a summary of key information.

Signature and Distribution

The study investigator or designee is also required to sign the consent document to attest to the fact that all the elements of informed consent have been explained to the subject/legally authorized representative and all questions have been answered to the best of the investigator's ability.

A copy of the informed consent is to be given to the person signing the form. Unless otherwise approved by the IRB, a copy of the signed consent form is to be placed in the medical record if the study involves medical interventions, to ensure the safety of the patients who participate in research.

4. Appropriate Timing for Informed Consent

Special consideration is to be given to the timing and location of all communications concerning informed consent, including when and where informed consent is given.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

It is recognized that for minimal risk research and in some time sensitive circumstances the consent process may need to occur quickly and at the time of an initial encounter. The amount of time required will vary with protocols and individuals. When possible, potential subjects are not to be presented with all the information at once or at the last minute. The informed consent process may occur over multiple discussions as appropriate.

5. Research Data Retention for FDA Regulated Research: Special Considerations

When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

The investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject must distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through chart review, and address the maintenance of privacy and confidentiality of the subject's information.

The investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). The IRB must approve the consent document.

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study, the subject's medical record or other confidential records requiring the subject's consent. However, a researcher may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

6. Subjects who cannot read, write or have some impairment that hampers consent process or documentation

Before asking a subject to review and sign an informed consent form, every investigator is responsible for ensuring that potential research subjects are capable of reading the form.

Investigators are not to assume that subjects are able to read and, when appropriate, are to inquire in a sensitive way as to whether the subjects are able to do so. If not, investigators are to make special arrangements without causing embarrassment to the subjects.

Illiterate subjects are not to be excluded from the research because they are unable to read unless there is an overriding scientific or safety concern.

The following recommendations are to be implemented when a research subject or family member is determined to be illiterate. Two possibilities include:

1. Reading the full consent:

If illiterate (in any language) but cognitively competent, the consent process proceeds as usual. The informed consent is to be read to the subject/family, and the subject/family is to be encouraged to ask questions.

This process must be conducted with a witness present. In this case, the witness is to observe the entire process, not just the signature.

If able, the subject/family is to affix a signature to or make an "X" on the consent document.

The witness is to sign and date the consent document, and is to document, in writing, that the process took place and that the subject voluntarily consents to participate.

2. Use of the Short Form Method of Consent:

Investigators could consider using the short form method of consent. The short form method permits a detailed discussion of the research described in the consent form. However, the subject/legally authorized representative is asked to sign a short form which attests to the fact that the elements of consent were verbally described.

The IRB policy: **Consent with Non-English-Speaking Subjects** provides further details on the process required in order to use a short form. An English version and translated versions of the short form are located on the IRB website.

Documentation of Informed Consent

1. General

Informed consent must be documented on a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.

A copy is to be given to the person signing the form.

Unless otherwise approved by the IRB, a copy of the signed consent form is to be placed in the medical record if the study involves medical interventions, to ensure the safety of the patients who participate in research. Informed consent must be obtained before the initiation of any screening processes performed solely for the purpose of research.

The study investigator or designee is also required to sign the consent document to attest to the fact that all the elements of informed consent have been explained to the subject/legally authorized representative (parent/guardian) and all questions have been answered to the best of the investigator's ability.

2. Required Elements

The following elements are required in all informed consent/parental permission documents:

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures that are experimental

- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - *A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or*
 - *A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

3. Additional Elements that May be Required as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject

- The approximate number of subjects involved in the study
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

For research involving biospecimens, whether the research will (if known) or might include whole genome

- FDA may inspect the records for any research that involves any drug or device that is either being administered as part of the research study or is not approved for marketing. This statement should be included in all consents for research that will be submitted to or held for inspection by the FDA in support of a marketing application. All uses of drugs and devices are subject to this unless it is the use of a marketed drug or device in the practice of medicine. Investigational drug or device, or is under their jurisdiction.
- Any conflict of interest disclosure. This should be included in any protocol that the IRB determines it is necessary to disclose a real or potential COI for the investigator or institution.
- Risk of determining unreported sexual abuse, neglect or suicidality or other mandated reporting
- Requirement for pregnancy testing

4. Signatures

a. Subject or Legally Authorized Representative

The IRB requires the signature of the subject or legally authorized representatives

For information on legally authorized representatives see IRB policy: **Special Considerations: Assent and Parental Permission** on informed consent documents unless a waiver or alteration of consent is approved, see IRB policy: **Waivers and Alterations of Informed Consent/Parental Permission/Assent Children**.

During the review process, the IRB determines the signatures required and incorporates these requirements in the final approved consent/assent forms.

All consent documents must contain the date signed by the participant, or the participant's legally authorized representative.

If the IRB reviews research that is conducted in another state or country, the determination as to who may sign the consent and who is a legally authorized representative must be determined by the locality where the research takes place.

b. Signature of Individual Obtaining Informed consent

The signature of the individual responsible and the date of the signature for obtaining informed consent must be included on all consent documents.

Individuals other than the investigator may obtain consent; however, any individual who obtains consent must be listed on the protocol application as having this role. It is also the investigator's

responsibility to train, oversee, and monitor all individuals who obtain consent on his or her protocol.

The individual who obtains consent is not required to be present to witness the family/subject sign the consent. Only after a subject sign the consent is the individual who obtained consent to sign the document.

The signature of the person who obtains consent is not to be "back dated" to coincide with the date of the research subject's signature.

c. Witness Signature

A witness signature is required only in the following circumstances:

- If the IRB approves the use of the "short form method of consent." In this situation the witness signature only attests to the fact that the information was explained in the subject's native language and the subject/family had opportunities to ask questions. For further details about the short form method, see the IRB policy: **Informed Consent with Non-English Speakers**.
- When the subject cannot read, and the consent document must be read to them.
- When communication impairments limit a subject's ability to unambiguously register consent. In such cases, it is important that there be an independent observer of the communication.
- When given the nature of the research and the anticipated condition of a subject, the IRB is concerned that questions may arise as to whether consent/assent is being given knowingly and voluntarily. In these situations, verification of the consent may help to protect subjects, who may be temporarily sick or too upset to provide meaningful consent/assent under the anticipated circumstances.

In the last three bullets of the consent document, the witness signature confirms that the information in the consent form and other written documents were accurately explained to and ostensibly understood by, the subject or the subject's legally authorized representative, and that the informed consent was given freely.

Related Content

IRB Policies:

Informed Consent with Non-English Speakers

Special Considerations: Assent and Parental Permission

Waivers and Alterations of Informed Consent/Parental Permission/Assent Children.

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