



General Information: Informed Consent and Parental Permission

For research involving children, also read *“Special Considerations: Assent and Parental Permission”* for regulation and guidance specific to parental permission and minor assent.

Policy

- A key requirement of human subject protection is voluntary participation. The informed consent process must assure that the potential subject fully understands the research, understands what they are being asked to do, and understands the associated risks and benefits of the research for which they are providing consent.
- It is the policy of Boston Children's Hospital to comply with all federal and state regulations that pertain to informed consent.

Definitions

Informed Consent	<p>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.</p> <p>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 anytime, and to remind them of that fact.</p>
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Process of Informed Consent

1. What are the 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, comprehension, and voluntariness.

- **Information** is critical for a person to make an informed choice as to whether he or she, or his or her 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 more 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 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. Some considerations include:

- The technicality of the details of the protocol, and who can best explain them.
- Who is best able to answer the questions that may come up?
- It may be possible 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.
- Who is able to 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. Who Should Provide Consent? General Requirements Consent

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. 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 and all questions have been answered to the best of the investigator's ability.

4. What is the 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. When possible, potential subjects are not to be presented with all of the information at once, or at the last minute. The amount of time required will vary with protocols and individuals.

5. Are there Special Informed Consent Considerations for Research Data Retention for FDA Regulated Research?

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 Researcher 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 researcher 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, under the informed consent process, 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 IRB recommendations are to be implemented if, when asked to provide permission, a research subject or family member is determined to be illiterate. There are two possibilities for obtaining consent:

One: Reading the full consent:

- If illiterate (in whatever the language of the consent process) 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.

Two: Use of the Short Form Method of Consent:

Investigators could consider using the short form method of consent. This 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 policy "Consent with Non-English Speaking Subjects" provides further details on the process required in order to use a short form. An English version of the short form is located on the IRB website in the same location as the translated versions.

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 and identify any that are experimental.
- A description of drugs or devices, if applicable, state whether any are investigational.
- Description of study design.
- A description of any potential risks or discomforts to the subject.
- A description of any direct or potential 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. Indicate if none.
- A statement that describes how confidentiality will be protected and maintained and who has access to the data.
- For research that involves more than minimal risk, explanations as to whether any compensation and any medical treatments are available if injury occurs and, if so, what this consists of, or where further information may be obtained or who to call
- An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights.
- An explanation of whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled.
- Compensation or study reimbursement for participants.
- The number of subjects in the trial.
- Description as to where research data and consent documents will be stored.
- A phone number to call:
 - If participants had questions regarding the research.
 - If participants wanted to voice concerns or complaints to the research staff, investigator or IRB office.
 - If participants feel their rights or welfare as a research subject have been violated.

3. Additional Elements that May be Required as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject that is currently unforeseeable. The **statements** should be included for all research involving investigational drugs and medical devices, and for all research in which the risk profile of the research interventions in the participant population are not well known.
- The possibility that participation would be terminated including by the investigator without regard to the subject's consent and plans for discontinuation. This statement should be included whenever there are anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subjects' consent. (i.e sponsor may stop trial before completion).
- Any additional costs to the subject that may result from participation in the research. This should be disclosed when there is a possibility the study will add additional costs.

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- A statement that any significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject. This should be disclosed in all studies.
- The consequences of a subject's decision to withdraw from the research, and the procedures for orderly termination of participation by the subject. This should be disclosed whenever a subject's decision to withdraw from the research may result in adverse consequences.
- Statement that treatment or procedure may involve risks to the embryo or fetus if the subject is or becomes pregnant. This statement should be included for all research that included pregnant women or women of child bearing potential in which the risk profile of the research interventions on the embryo and fetuses are not well known.
- 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.
- Requirement for pregnancy testing.

No informed consent, whether oral or written, may include exculpatory language whereby a subject or representative is made to waive or appear to waive any of his or her rights, or to release or appear to release the investigator, sponsor, institution, or its agents from liability or negligence.

4. Signatures

A. Subject or Legally Authorized Representative

The IRB requires the signature of the subject or legally authorized representatives (see separate IRB policy titled "Special Considerations: Assent and Parental Permission") on informed consent documents unless a waiver or alteration of consent is approved (see separate IRB policy titled "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 for obtaining informed consent must be included on all consent documents, along with the date of the signature. 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 signs 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 committee 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. See separate guidance titled "Informed Consent with Non-English Speakers" for details about short form method.
- When the subject cannot read and the consent document must be read to him or her.
- 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 the witness signature confirms that the information in the consent form and other written documents was 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:

"Special Considerations: Assent and Parental Permission"

"Informed Consent with Non-English Speakers"

Document Attributes

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