Status Active PolicyStat ID 17413810

Where the world comes for answers

Effective 3/1/2025
Next Review 2/29/2028

Owner Susan Kornetsky: Manager
Department Research
Applicability Boston Children's Hospital- Policies & Procedures

General Information: Informed Consent and Parental Permission Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Written Informed Consent Form: The written consent form is a formalization of the agreement to participate, and it is used to document a process.

Key information: A Department of Health & Human Services (HHS), Office of Human Research Protections (OHRP) term. A concise and focused presentation of information, at the beginning of informed consent 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.

Legally Authorized Representative: An individual, or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." 45CFR.46.102(c) and 21CFR50.3(l).

Witness: A third party present during the oral presentation of the consent form and the consent interview. The IRB may require a witness to the consent process based on the nature and risks of

research

Policy Statements

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

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:

1. The research
2. What they are being asked to do
3. The associated risks and benefits of the research for which they are providing consent

Procedures

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:

1. **Information** is critical for a person to make an informed choice as to whether they, or their child, should participate in research.
    a. The Belmont Report suggests providing information that the "reasonable volunteer" will want to know.
    b. It is important that families understand the difference between what is necessary for their care and what is being proposed specifically for research.
    c. 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.
2. **Comprehension** will vary subject to subject and family to family.
    a. 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.
    b. Comprehension may require that time be provided to allow subjects to think about participation and to ask questions.
3. **Voluntariness** requires conditions free of undue influence and/or coercion including conditions under which an individual or family may agree or disagree without any fear of repercussions.

General Requirements of Informed Consent

The Department of Health and Human Services (HHS) and the U.S. Food & Drug Administration (FDA)

regulations outline the basic general requirements of informed consent.

1. Informed consent be obtained for the subject or legally authorized representative.
2. 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.
3. The prospective subject or the legally authorized representative must be provided with information that:
    a. A reasonable person would want to have in order to make an informed decision about whether to participate;
    b. Is in language that is understandable; and
    c. An opportunity to discuss that information.
4. 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.
5. Informed consent must be obtained before the initiation of any screening processes performed solely for the purpose of research.
6. 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. 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

Required Elements of Informed Consent

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

1. A statement that the study involves research
2. An explanation of the purposes of the research
3. The expected duration of the subject's participation
4. A description of the procedures to be followed
5. Identification of any procedures that are experimental
6. A description of any reasonably foreseeable risks or discomforts to the subject
7. A description of any benefits to the subject or to others that may reasonably be expected from the research
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
10. 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
11. 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
12. 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
13. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens;
    a. *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
    b. *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.*

Additional Elements That May Be Required as Appropriate

1. 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
2. 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
3. Any additional costs to the subject that may result from participation in the research
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5. 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
6. The approximate number of subjects involved in the study
7. 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
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
9. For research involving biospecimens, whether the research will (if known) or might include

whole genome

10. 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.
11. Any conflict of interest (COI) 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.
12. Risk of discovery of unreported sexual abuse, neglect or suicidality or other mandated reporting
13. Requirement for pregnancy testing

Timing of Informed Consent

1. 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.
2. 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 undue influence or coercion.
3. 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
4. The amount of time required will vary with protocols and individuals.
5. When possible, potential subjects are not to be presented with all the information at once or at the last minute.
6. The informed consent process may occur over multiple discussions as appropriate.

Obtaining Informed Consent

1. Investigators are responsible, on a per protocol basis, for designating appropriate individuals to obtain consent for a protocol. It is also the investigator's responsibility to train, oversee, and monitor all individuals who obtain consent on his or her protocol.
2. 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.
3. 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.
4. 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.

5. 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.
6. Often the investigator provides information, and a research nurse is made available to follow-up and provide additional information.
7. 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?

Documentation of Informed Consent

1. The IRB requires the signature of the subject or legally authorized representatives
2. During the review process, the IRB determines the signatures required and incorporates these requirements in the final approved consent/assent forms.
3. All consent documents must contain the date signed by the participant or the participant's legally authorized representative.
4. 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.
5. The IRB requires the signature of the individual responsible and the date of the signature for obtaining informed consent must be included on all consent documents.
6. The individual who obtains consent is not required to be present to witness the family/subject sign the consent.
7. Only after a subject sign the consent is the individual who obtained consent to sign the document.
8. 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.

Special Considerations

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. 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.

a. The informed consent is to be read to the subject/family, and the subject/family is to be encouraged to ask questions.

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

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

i. Sign and date the consent document

ii. 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.
- 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.

Requirement for Witness

At the bottom of the consent form document, the witness 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 voluntarily. A witness signature is required only in the following circumstances:

1. 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
2. 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.
3. 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.

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.

1. The consent document cannot give the subject the option of having data removed.
2. 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:

   a. 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,
   b. Address the maintenance of privacy and confidentiality of the subject's information.

3. 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).
4. The IRB must approve the consent document.
   i. 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.

Related Content

- Department of Health and Human Services Regulations HHS 45 CFR:
  - §46.116(a)(5)(i): General requirements for informed consent
- The Belmont Report
- IRB Policies:
  - Informed Consent with Non-English-Speaking Subjects (For additional information on the process required in order to use a short form)
  - Parent Permission and Child Assent (For additional information on legally authorized representatives)
  - Waivers and Alterations of Informed Consent/Parent Permission Child Assent (For additional information on waiving elements of informed consent)
- IRB Forms:
  - Short Form Translations

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025

Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

Boston Children's Hospital- Policies & Procedures