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**Boston
Children's
Hospital**

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Effective 1/1/2023
Next Review 1/1/2026

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

Remote Consent: Process and Documentation Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the policy also applies to foundation practices leasing space at hospital-licensed locations.

Policy Statements

Boston Children's Hospital's Institutional Review Board (IRB) policy and federal regulations state that informed consent must be obtained prior to obtaining any study information, and that the entire consent process should be accurately documented.

When the IRB requires a written consent form, the discussion or process may take place by a means other than a face-to-face/in person communication. For example, an investigator may discuss the study over the phone or a use another HIPPA compliant method of video conferencing method. However, both methods still require the parent to sign a written consent document. When this occurs, additional steps are necessary to accurately document the consent process, especially if the consent cannot be immediately returned to the investigator.

This guidance is to ensure adequate documentation of prospective informed consent for research when

a parent/legal guardian is not present. It is not intended to describe the process for obtaining an e-signature (electronic signature) that is expected to meet all criteria to be legally recognized in accordance with regulatory requirements (i.e. e-consent for U.S. Food & Drug Administration regulated research).

- Federal regulatory agencies do not regard verbal telephone consent as constituting the documentation of signed informed consent that is required by the federal regulations.
- There are times when the IRB can approve a method other than written consent that allows a subject the ability to check a box electronically to provide consent. The guidelines provided should not be confused with the IRB finding that a protocol meets the criteria for a waiver or alteration of consent.

Procedures

The examples provided are to assist Principal Investigators (PIs) in obtaining and accurately documenting informed consent when the subject/parent is not present to sign the informed consent document within a time frame specified by a research protocol.

Two Example Situations:

1. Enrollment in a study is required within the first 12 hours of life and newborn is transferred to the Boston Children's Hospital NICU while the parents remain at the birth hospital.
2. Family members of a patient with a rare genetic trait live in another state and are willing to contribute research samples to a disease repository.

When obtaining informed consent in these situations:

1. **Providing the consent forms to the subject/family:** The PI/research staff should mail/email/fax two copies of the informed consent form for each participant with instructions to contact the Principle Investigator (PI)/research staff when consents are received.
 - a. Use secure methods to transmit information according to Boston Children's Hospital data security policies.
 - b. There may also be situations when consent forms that need to be signed are posted on websites and families may be instructed how to access them.
2. **Reviewing the consent form with the subject/family:** Once the participant has a copy of the consent form in front of them, the PI/research staff must review the study and consent document with each participant.
 - a. This should include asking questions to gauge comprehension, and answering a subject's questions and concerns.
 - b. This can be done by phone or videoconference.
 - c. If assent is required, the PI/research staff must have a discussion with both parent/legal guardians **and** the child participant.
3. **Obtaining subject/family signatures:** After all questions are answered and the PI/research

staff feel confident that each subject/parent/guardian understands the study, then each person needs to sign and date the consent form.

- a. It is recommended to flag or highlight the correct signature line.
- b. If there is a separate assent form, ensure the child participant signs, dates, and returns the assent form with the signed parental permission/consent form.

4. Instructions for subjects/families returning the signed consent form to the research team:

- a. Subjects/families should be instructed to retain one signed copy of the consent form for their own records.
- b. Whenever possible, the signed consent/assent should be returned to the researcher before a research procedure takes place.
 - i. A consent/assent could be returned by emailing back a scanned PDF or by fax.
 - ii. If this is not possible, a signed copy may be returned by mail at a later date.

5. When subjects/family return the consent/assent form:

- a. **If the PI/research team receives the consent/assent:** Once received by the research team, the PI/research staff should:
 - i. Sign the appropriate signature line
 - ii. Provide the current date of signature (not the date they spoke with participant/parent/guardian).
- b. **If the PI/research team does not receive the consent/assent:** If the subject is expected to mail back the signed consent, all attempts need to be made to receive the signed version.
 - i. If the signed copy is not returned, the investigator may need to follow up with the family. The PI/research staff may need to ask the family to bring the signed consent to the hospital at the time of the next visit.
 - ii. If an investigator does not receive a signed copy, they will not have the informed consent documentation. The research records should clearly document the process and discussion with the family. It is for this reason all attempts must be made to receive a scanned or faxed version before initiating the research and to not rely on families remembering to send it back.

6. Review of all signatures and dates: The PI/research team should ensure all signatures and dates are accurately documented.

- a. Any errors should be noted in a note or memo.

7. Documentation of the consent process: PI/research staff should document the entire informed consent/assent process for each subject in a memo or related study document.

- a. **Date of PI/research team signature:** The PI/research team should specify to whom the study was explained within the PI/research team signor section. Boston

Children's Hospital policy further states: "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."

- b. That consent was obtained over phone/by videoconference with date of subject/family's consent and when mailed/emailed/faxed back.
 - i. Sample language documentation: *Discussed with [name of person] via telephone/videoconference on [insert date], and received sign consent form on [insert date].*

Related Content

- IRB Policy: Waiver and Alternations of Informed Consnet/Parental Permission/Child Assent
- EQiP template: Informed Consent Checklist

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures