



## Obtaining Informed Consent/Assent Remotely: Process and Documentation

### Policy

- Boston Children's Hospital Institutional Review Board 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 communication (for example an investigator discusses the study over the phone/skype but still requires 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. The following are procedures to follow to ensure adequate documentation of prospective informed consent process for research.

Note: Federal regulatory agencies do not regard verbal telephone consent as constituting the documentation of signed informed consent that is required by federal regulations. The process described below should not be confused with the IRB finding that a protocol meets the criteria for a waiver or alteration of the consent document /process. Please see *Waivers and Alterations in Informed Consent/Parental Permission/Assent Children*).

### Procedures

The guidelines below are provided to assist investigators 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. An example may be family members of a patient with a rare genetic trait that live in another state and will contribute research samples to a disease registry, or when a newborn is transferred to the Boston Children's Hospital NICU while the parents remain at the birth hospital, and enrollment in the study is required within the first 12 hours of life.

When obtaining informed consent in these situations:

1. Mail / email / fax two copies of the informed consent form for each participant with instructions to contact PI/research staff when consents are received. Use secure methods to transmit information according to BCH data security policies.
2. Once each participant has a copy of the consent in front of them, PI/research staff must review the study and consent document with each participant, asking questions to gauge comprehension, and answering subject's questions and concerns. This can be done by phone or videoconference.

If assent is required, the PI/Authorized staff must have a discussion with both parent/legal guardian and child participant.

PI/PI Authorized staff should document the entire informed consent/assent process for each person in a memo or related study document.

3. After all questions are answered and the PI/research staff feels confident each participant/parent/guardian understands the study, have each person sign and date consent form (recommended to flag or highlight the correct signature line), and return the signed consent form. If there is a separate assent form, ensure the child participant signs, dates and returns the assent form with the signed consent form. Whenever possible, the signed consent/assent should be returned to the researcher before a research procedure takes place. A consent /assent could be returned by emailing back a scanned PDF or by fax. If this is not possible, a signed copy may be returned by mail at a later date. Subjects should be instructed to retain one signed copy of the consent form for their own records.
4. Once received, the PI/research staff that explained the study should sign the appropriate signature line with current date (not the date they spoke with participant/parent/guardian). The PI/PI Authorized signor should specify to whom the study was explained within the PI/PI authorized signor section.

Boston Children's 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."*

5. Ensure all signatures and dates are accurately documented. Any errors should be noted in a note or memo.
6. It is recommended to document in a separate note to file/progress note, or with a note under the PI signature line on the consent form, that consent was obtained over phone/by videoconference with actual date and mailed/emailed/faxed back. E.g. *"Discussed with [person] via telephone/videoconference on [insert date], and received sign consent form on [insert date]."*
7. If the subject is expected to mail back the signed consent all attempts need to be made to receive the signed version. If the signed copy is not returned, the investigator may need to follow up with the family or ask the family to bring the signed consent to the hospital at the time of the next visit. If an investigator does not receive a signed copy they will not have the informed consent documentation. However, 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.

*A template Informed Consent Checklist that may help investigators document this process can be found at the BCH Education and Quality Improvement Program (EQuIP) website at <http://www.childrenshospital.org/research-and-innovation/research/research-administration/equip/study-tools-and-templates>.*

## Related Content

## Document Attributes

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