Remote Consent: Process and Documentation

Purpose

This policy is to ensure adequate documentation of prospective informed consent for research when a parent/legal guardian is not present

This policy is not intended to describe the process for obtaining an e-signature that is expected to meet all criteria to be legally recognized in accordance with regulatory requirements. i.e. e-consent for FDA regulated research.

Investigators who seek to use electronic signatures, intending to meet the same standards as an in person written consent, should first contact the IRB office. This will likely require reviews by other institutional departments such as General Counsel, Research IT, HIPPA and IT Security.

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/ in person communication. For example, an investigator may discuss the study over the phone or a HIPPA compliant method for video conferencing method, but 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.

Note: 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 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 IRB Policy: ***Waivers and Alterations in Informed Consent/Parental Permission/Assent Children.***

Procedures

The guidelines 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.

Examples

- 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.
- 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. Mail / email / fax two copies of the informed consent form for each participant with instructions to contact the Principle Investigator (PI)I/research staff when consents are received.
   a. Use secure methods to transmit information according to BCH 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. 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.
   a. If assent is required, the PI/Authorized staff must have a discussion with both parent/legal guardians and a child participant.
   b. 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 feel confident that each participant/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 consent form.
   c. 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.
   d. Subjects should be instructed to retain one signed copy of the consent form for their own records.
4. Once received, the PI/research staff should sign the appropriate signature line with the 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.

    a. Sample language documentation: *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.

    a. 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.

    b. 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.

8. To help investigators document the informed consent process, BCH's EQuiP has a modifiable ***Informed Consent Checklist***.

Related Content

IRB Form

Informed Consent Checklist

Document Attributes

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