BCM Office of Clinical Research: OCR-P-10-01

Obtaining and Documenting Informed Consent

Introduction

This procedure describes the process f outline procedures for obtaining and documenting informed consent.

This procedure applies to all clinical research studies conducted at Baylor College of Medicine or affiliates requiring informed consent.

PI responsibilities

The Principal Investigator (PI) is responsible for ensuring that informed consent is obtained in accordance with federal, sponsor and local guidelines prior to performing any research-related screening or procedures:

- The PI may designate an appropriately trained and credentialed individual to obtain informed consent on the study Delegation of Authority Log, as applicable.
- The PI is responsible for ensuring that the delegated person has received appropriate training to perform this function and is sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects, and about the ethical basis of the informed consent process and protocol.
- The PI is responsible for ensuring that appropriate revisions to the consent form are made when important new information becomes available that may impact a subject's willingness to participate in the trial and in accordance with the IRB of record guidelines.
  - Revised consent forms must receive approval from IRB of record, the sponsor, BCM Reliance, if applicable and applicable regulatory agencies prior to use.
  - PI or designee is responsible for re-consenting subjects following IRB approval of revised consent, if required.

Informed consent process

The PI or designee fully informs subject or subject's legally authorized representative (LAR), as defined by the IRB of Record and applicable regulatory guidance, of all pertinent aspects of the study, including review of currently IRB-approved informed consent form document and other pertinent study-related information:

- The informed consent process must be conducted in the subject's preferred language.
- Ample time and opportunity for subject or subject's LAR to inquire about the details of the clinical study, and to decide whether or not to participate in the study as well as to consider other available options, will be provided.
- All questions about the trial should be answered to the satisfaction of subject or subject's LAR.
- Signature of subject or subject's LAR is obtained on informed consent document and consent process is documented by the individual obtaining informed consent.

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Translations

Informed consent discussions must include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent:

- The consent form is translated in the subject's primary language and approved by the IRB of record, is signed and dated by subject and investigator or designee to document informed consent. Signing the informed consent document indicates that the subject and investigator or designee understands the document they are signing.
- Alternatively, if allowed by sponsor and Policy of IRB of record, an IRB-approved short form in the participant's language can be used:
  - An impartial witness, unaffiliated with the conduct of the research, process is required when a short form is used.
  - The witness must understand both the subject's language and English, and may not be a member of the study team.
  - The translator can serve as the witness if s/he is not a member of the study team.
- It is preferred that a family member not serve as translator or witness. For studies conducted at affiliate locations, ensure affiliate requirements for whom may serve as a translator or witness are followed.

Child assent

If subject is a child, assent is obtained and documented in accordance with requirements of sponsor and Policy of IRB of record:

- A child is capable of providing assent based on age, maturity, and psychological state. Where assent is to be obtained, the amount and complexity of the information provided to the child depends upon the child's level of cognitive and emotional maturation.
- Any document used for assent must be approved by the IRB.
- Assent is documented using either an age appropriate assent form or a paragraph in the adult consent form per requirements of sponsor and Policy of IRB of record.
- Children enrolled in a study must be re-consented for continuation of study participation at the time they reach 18 (the age of majority established by the state).
- The individual obtaining assent documents assent process.

Remote consent

If consent is obtained remotely, informed consent process follows protocol specific procedures approved by the IRB of record, BCM Reliance, and affiliates, if applicable.

Recruiting and consent material

Recruiting and consent material given to subjects must be IRB approved, BCM Reliance, and affiliates, if applicable.

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Obtaining and Documenting Informed Consent, Continued

Documenting informed consent	Informed consent is documented using the current consent form approved by the IRB of Record, BCM Reliance, and affiliates, if applicable: • Participant name, identifiers, signatures, time of consent, and dates are obtained as required by sponsor and IRB of record. At a minimum, signature of subject or subject's LAR and investigator or designee and dates are required. • Investigator or designee provides a copy of signed and dated consent form to the subject or subject's LAR at the time of consent. • Completed consent form is filed in subject binder. An additional copy may be filed in the subject's medical record per study site requirements. • Process for obtaining informed consent is documented in subject study binder. This process may alternatively be documented in the subject's medical record if required per study site policy.
Reference	BCM Human Research Protections Manual

VERSION/REVISION HISTORY:

Approval Date	Version	Owner	Approver	Revision Summary
11/9/2021	1	OCR	Catherine Simmons (CS), Jose Rodriguez (JR)	