

Advocate Health Care IRB Consenting Tips

Who can consent

- The principal investigator.
- Sub-investigators and study personnel formally delegated by the principal investigator as per the Advocate Health Care IRB application, Section XIII.
- People authorized to consent must have completed human subject training, have to be knowledgeable about the study and able to answer questions.

Consent process and documentation

- **Ensure that you are using the most recent version of the AHC IRB-approved consent document.**
- Initiate the consenting process by explaining the study and what it entails to a potential subject.
- Give the potential subject a copy of consent form and any other study information, and a copy of HIPAA Authorization to take home to review and discuss with family, friends and doctors.
- Review with the potential subject the HIPAA Authorization and **each page** of the consent document on the return visit. Continue the discussion, answer questions, and provide additional information.
- The presence and signature of a witness **is required** during the entire consent discussion for greater than minimal risk studies. The presence and signature of a witness **is not required** during the entire consent discussion for minimal risk studies, unless the subject or subject's legally authorized representative is unable to read.
- Obtain agreement to participate in the study documented by a signature and date on the HIPAA Authorization form and consent document.
- Ensure that all pages of the consent document are initialed by the subject or subject's legally authorized representative, if the consent has designated spaces on each page for subject's initials.
- The consent document must be signed and dated by the subject **or** subject's legally authorized representative, study representative obtaining consent and witness. The only signatures on the consent document can be those on the designated signature lines.
- Ensure that the dates of signatures on the consent document and HIPAA Authorization properly correspond to the calendar dates when the documents are signed.
- If the study has **additional consent(s)** (e.g. for tissue collection), these have to be reviewed and signed by the subject or subject's legally authorized representative.
- Give the subject copies of signed and dated written consent document(s) and HIPAA Authorization.
- Place originals of signed and dated written consent document(s) and HIPAA Authorization in the subject's research record. Note: whether these documents are placed in the subject's medical record depends upon a policy of individual institutions and investigators.
- Document in the subject's chart that the consent was obtained prior to participation in the study and that the subject was given copies of signed and dated written consent document(s) and HIPAA Authorization.

Note

- As a study representative obtaining consent on a particular study, you **cannot** serve as a witness on that study.
- Do not make any notes on the IRB-approved consent document. If you do so, that particular consent ceases to be the IRB-approved consent.