INFORMED CONSENT
Reference: 45cfr46.116

“No investigator may involve a human being as a subject in research... unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.”

ELEMENTS OF INFORMED CONSENT
Reference: 45cfr46.116(a)

Please refer to the IN THE KNOW Bulletin #4 for the basic and additional elements of informed consent.

INFORMED CONSENT AS A PROCESS

Obtaining informed consent is a process; it is not merely a form that requires a signature. Researchers can be creative about the process to optimize effectiveness. For example, minors could be provided with a quiz to check understanding. It is however necessary to document the informed consent process, and to provide a copy of the documentation to the participant.

Reference: 45CFR46.117(a)

“Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.”

DEFINING TERMS
Informed Consent, Assent and Permission

Informed Consent:
Required from participants (or legal representative) aged 18 or above.

Assent and Permission:
Minor Assent is required from participants aged 7-17.
In addition, Parental or Legal Guardian Permission is required for participants aged 7-17.
IN THE KNOW
Bulletin of the Tufts SBER IRB Medford Campus

DOCUMENTATION OF INFORMED CONSENT
Reference: 45cfr46.117

There are two approved ways to document Informed Consent, Assent and Permission (Standard Written and Short Form), and one approved way to waive the documentation requirement.

Standard Written
(for literate persons)

Process:
- Consent document is read to, or read by the participant and parent or legal guardian (if applicable) and the parties sign the Consent document or Assent and Permission documents.

Short Form - Witness to Consent
(for illiterate or learning disabled persons)

Process:
- Consent script is read to participant and parent or guardian (if applicable) in the presence of a witness.
- Both the PI and the witness must sign a copy of the script.
- The witness must sign a copy of the short form document, and if the participant, parent or guardian wish to write their name, make a mark or a finger print they should be given the opportunity to do so. (Note: this must be culturally appropriate).

Waiver of Documentation of Informed Consent
(for cultural reasons and/or safety & confidentiality concerns).

Process:
- The PI needs to apply by submitting a Request for Waiver of Documentation of Informed Consent with the application.
- A consent document is read to, or read by, the participant and parent or legal guardian (if applicable).
- The document is signed only by the investigator.
- An information sheet is given to the participant.

The information for this Bulletin was taken from the website for the United States Department of Health and Human Services (DHHS), Office of Human Research Protections. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html This website is an invaluable source of information regarding the regulations that govern human subject research.