Guideline (2): Documentation of Informed Consent.

The following documentation must be provided to the IRB:

1) Except as provided in paragraph (c) of this section, informed consent will be documented via 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 and a copy retained in the study’s records.

2) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
   - A written consent document that embodies the required elements of informed consent. The consent may be read to the subject or the subject’s legally authorized representative, but must be read before it is signed; or
   - A short form written consent document containing the required elements of informed consent that is presented orally to the subject or the subject’s legally authorized representative. Those who elect this method must ensure that a witness is present for the oral presentation. The IRB will approve a written summary of what is to be said to the subject or the representative. Only the short form itself will be signed by the subject or the representative. The witness will sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. Copies of each signed document shall be kept in project files.

3) An IRB may waive the requirement for a signed consent form for some or all subjects if:
   - The only record linking the subject and the research is the consent document and the principal risk is potential harm from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking his/her with the research—the subject’s wishes will govern; or
   - The research presents minimal risk of harm to subjects and involves no procedures necessitating written consent
   - If the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.