§ 26.1117  Documentation of informed consent.

(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.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §26.1116. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §26.1116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall 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.

§§ 26.1118–26.1122 [Reserved]

§ 26.1123  Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.