Stony Brook University

FAR BEYOND

IRB Meeting - Discussion

Research with Human Subjects

Review Criteria

Each IRB member should participate in the criteria for IRB approval of research

- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117

Code of Federal Regulations 45 CFR 46.117

Research with Human Subjects

Review Criteria

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

Code of Federal Regulations 45 CFR 46.117

Research with Human Subjects

The consent form is either:

- A written consent document that embodies the elements of informed consent required by 45 CFR 46.116.

Code of Federal Regulations 45 CFR 46.117

Research with Human Subjects

Or:

- A short form written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative (when this method is used there needs to be a witness to the oral presentation)

Code of Federal Regulations 45 CFR 46.117

Research with Human Subjects

Review Criteria

The IRB approves only those studies where this requirement is satisfied. If the criteria is not satisfied, the study must be deferred

Bankert and Amdur, 2006