Process for Obtaining Informed Consent Documentation

Generally, the IRB requires consent to be documented by a written consent form that includes all the required elements, and all appropriate optional elements, approved by the IRB prior to use. An IRB approved consent document will contain the date of IRB approval. Unless the need for consent is waived by the IRB, the written consent form must be reviewed with the participant (or the participant’s representative), and signed and dated by the participant or the participant’s representative before any research procedures (including screening) or research data collection can begin. The consent form should also be signed and dated by the individual who obtains the participant’s consent.

Oral Consent Process (Waiver of Documentation)

Oral consent must meet the regulatory requirements of DHHS (45 CFR 46.117) and FDA (21 CFR 56.109). An investigator may request that the IRB waive the requirement for written informed consent and approve instead an oral consent process for some or all potential research participants. The investigator should submit this request for oral consent with the e-IRB application and the investigator must include a script that the consent designee will use with participants. This script must include all the required consent elements and the elements required for HIPAA privacy authorization (when PHI is to be collected). If oral consent is obtained, the details about that consent (time, date, identity of consent designee) should be recorded in the study record by the consent designee. If the project involves clinical care, these details about the consent should be added to the clinical record.

The IRB may approve a request for oral consent for non-FDA regulated studies under two circumstances:

1. The only record linking the participant to the research would be the consent document and, the principal risk to the participant would be potential harm resulting from a breach of confidentiality. In this case, each participant will be asked if he/she wants documentation linking him/her to the research and the participant’s wishes will govern; or

2. The research presents no more than minimal risk to the participants and involves no procedures for which written consent is normally required outside of the research context.

For FDA-regulated studies, waiver of documentation is only permitted if the study presents no more than minimal risk (second bullet above). If the IRB approves an oral consent process, the IRB may require the investigator to provide participants with a written statement regarding the research. Such a document requires IRB approval.