

Documentation and Recordkeeping Tips for Written Informed Consent

1. Assure that all personnel involved with recruitment and obtaining informed consent have completed training and have been approved by the IRB to participate in the protocol.
2. Provide a copy of the complete consent document to each participant.
3. Examine the executed document to ensure that all blanks are completed.
4. Confirm that the PI/designee signature line has been completed by the person who obtained the participant's consent.
5. Retain original, signed consent forms for at least three years after study termination. Note: Individual sponsors may have longer retention requirements.
6. Insert protocol specific information, including the IRB approval date and version, in the consent form header to ensure that the most recent, IRB-approved version is used to obtain informed consent (e.g., "1/25/11, Version 3," third version of the consent form approved by the IRB on 1/25/11).
7. Correct or update information on the consent form by submitting an amendment for IRB review and approval prior to use (i.e., do not cross through incorrect or outdated information).
8. Keep a limited number of consent form copies on hand (or print current version directly before starting the informed consent process) to avoid use of unapproved/outdated consent documents.
9. Use only blue or black ink when completing the consent document.