Remote Consent

When the IRB approves a phone consent process that requires the subject’s signature on the consent document, the following steps should be taken:

1. The study team confirms the potential subject’s interest in learning more about the study and verifies the mailing address.
2. A blank consent form is mailed, along with a cover letter that introduces the study and explains when the phone conversation will occur. A stamped, self-addressed envelope is provided so the subject can return the signed consent document to the study team.
3. After the potential subject has received the document, a member of the study team calls the subject and walks through the entire document over the phone, answering questions and making notes about the subject’s questions. Time and date of the conversation should be recorded.
4. Once all questions are answered, the subject signs the consent form if they are willing to participate. S/he returns the consent form by mail in the provided self-addressed envelope.
5. Once received, the study team member who conducted the consent conversation should sign the consent form and date with today’s date. To explain the discrepancy, this individual should also write a note on the consent form stating that the subject’s consent was obtained by phone on xx date (the date the subject signed.)
6. The subject should receive back a full-signed copy of the consent form for their records.