

## 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 or email address.
  - If the consent form will be sent by postal mail, the 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.
  - Alternatively, if the subject agrees to email communication, the consent form is sent by secure email.
2. 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.
3. 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.
  - Alternatively, the consent form should be scanned by the subject and returned to the study team by email.
  - The subject signs the document electronically, using DocuSign or Velos for FDA-regulated research or REDCap for research not under FDA regulations.
4. Once the signed version is returned, the study team member who conducted the consent conversation should sign the consent form and date with **today's** date. If postal mail is used, explain the discrepancy in dates. The study team member should 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.)
5. The subject should receive back a full-signed copy of the consent form for their records.

\*The above guidance applies when the IRB has required the subject's signature on a paper consent form. For minimal risk studies, REDCap can be used to obtain and document informed consent. If not previously approved, the IRB must approve the new electronic consent process as a study modification. Please see the guidance document entitled "[Electronic Consent Processes for Minimal Risk Research](#)" for more details.