



Monday Morning Practice Pearls #66

Is there anything special that needs to be done when conducting remote consenting?

The short answer is yes. Before conducting the consent discussion remotely (e.g., over the telephone or using audio or video-conferencing/telehealth visit), please confirm:

- The IRB-approved protocol contains specifics of the remote consenting process (e.g., using the NIH-approved telehealth platform ThinkAndor), including obtaining signatures via electronic platform (e.g., iMed).
- That participant can access the electronic platform to obtain signatures. See below *How do I obtain signatures remotely on the ICD?*

Note: For non-English speaking participants, ensure that an interpreter is available and if short form process is to be used, a bilingual witness is available. Please review M2P2s #24, #25 and #26 about enrollment of non-English speaking participants.

What am I looking for in the protocol to allow for remote consenting?

- Statement that allows for initial consenting and re-consenting to be conducted in-person or remotely.
- Statement about how required signatures will be obtained (e.g., iMed or Adobe)

Note: Some IND/IDE sponsors may not allow the use of an electronic signature platform so your protocol may not include this information. Paper consent will need to be obtained for these protocols.

I'm ready to consent the participant remotely – anything else to remember?

YES – don't forget to confirm that you are speaking with the right individual. FDA requires the identity to be verified for FDA-regulated research using electronic signature and to document this verification as part of the consent process but does not dictate how it is done. CCR recommends verification of identify as a best practice whenever consent is obtained remotely. Suggestions include:

- Audio only: Ask the individual's DOB as indicated on a government-issued document, or other PII or health-related information.
- Video + Audio: Ask the individual to show/provide some form of official identification, such as a government-issued document. Examples of government-issued documents include a birth certificate, passport, or a driver's license.

IMPORTANT: For patients being consented outside of the U. S., video can't be used due to other countries' privacy regulations; therefore, conduct the consent process only via audio.

Also, ask the patient if they are in a private location to be able to have the informed consent discussion.

Remember that remote consent is NOT verbal consent – it is an IRB-approved alteration of written informed consent. Verbal consent does not require an informed consent document (ICD) to be signed. The IRB has not approved verbal consent process for any NCI protocols.

How do I obtain signatures remotely on the ICD?

iMed consent signature process: This is the preferred method to obtain signatures whenever possible. See M2P2 #69 *What is iMedConsent?* for more information.

iMed is not available or cannot be used: If the iMed system is not functioning or otherwise cannot be used (e.g., the participant cannot access or the sponsor does not allow the use of iMed) the consent will need to be sent to the participant via secure method as a pdf. Note that if using the NIH Off Site informed consent to enroll participant that are not coming to or using NIH Clinical Center (CC) resources, you will not be able to use iMed as the participant doesn't have a CC Medical Record Number. The references to CRIS below do not pertain to participants that sign an off-site informed consent.

Signatures can be obtained one of two ways:

1. Via Adobe signature function – see *Guidelines for Adobe Signature Function* under this M2P2.
2. Printing and signing paper copy
 - If patient agrees to participate, ask the patient to sign the ICD and date the signature that day.
 - If the patient “needs to think about it,” you must set up a time to speak with them again, so you hear them verbally agree to participate.
 - Ask the patient to return the entire signed document via secure method.
 - If the patient faxes or emails the signed ICD, that becomes the “original” and the investigator signs that version using the date when the ICD was received.
 - Once the investigator who obtained consent receives the signed document, that person will sign the document and date their signature with the date the ICD is received.
 - Copy the fully signed ICD and send copy to patient via secure method. Maintain a copy for your records until the scanned version is verified in CRIS.
 - Send the fully signed original to Medical Records for scanning into CRIS as usual.

REMEMBER: DO NOT perform any research procedures, including lab work, until the signed ICD is received from the patient. Informed consent is not valid without the signed ICD.

Another factor to consider:

If there is an external reviewing IRB, consider any additional IRB requirements. For example: NCI CIRB requires that a witness be present during remote consent and that this be documented in the consent note; however, the witness is not required to sign the consent.

Related M2P2s:

- #24: *You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's preferred language for healthcare. What do you do? Part 1: Seeking IRB Approval & Securing Translator.*
- #25: *You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's preferred language for healthcare. What do you do? Part 2: Consent Discussion and Documentation.*
- #26: *You learn that your patient doesn't speak English BUT you have an IRB-approved protocol consent in the patient's preferred language for healthcare (i.e., the full English version translated). How does the consenting process differ when not using the short-form consenting process?*
- #72: *What do I need to know about ThinkAndor®?*