Monday Morning Practice Pearls #66

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

The short answer is yes. There are several things that need to happen when conducting the informed consent discussion over the telephone or using audio- or video-conferencing or another web-based platform, also known as remote consenting. They include:

- Describing the specifics of the process in the protocol
- Confirming the identity of the patient and that they are in a private location during the discussion
- Obtaining signatures through an electronic platform.

Please see M2P2 #69 *What is iMedConsent™?* for information about using the iMED consent process.

What information needs to be in the protocol for remote consenting?

The process must be described in the protocol and approved by the IRB. If the protocol did not previously describe a remote process, or if there is a change in the process from telephone to another platform, the protocol must be amended. The consent section of the protocol should include:

- Whether the informed consent document (ICD) will be provided to the participant in advance of the consent discussion
- If the ICD will be provided electronically or in hard copy
- Where the participant will be located during the consent process
- How the privacy of the participant will be ensured during the consent process
- How much time the potential participant will have to consider their participation
- If the potential participant will be provided the opportunity to consult with others (family, friends, private physician) prior to providing consent
- What mode (e.g. telephone) or platform you intend to use for remote consent
- If using video-conferencing or another web-based platform, the platform must meet all NIH information security requirements.
- If participants will be coming to the NIH in order to participate in screening or research activities, the protocol should also include a justification for using a remote consent process.
- Be sure to include if the process will differ for initial consent vs. reconsent.

Note: Some IND/IDE sponsor 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.

How do I obtain signatures on the ICD?

You will need to use an electronic platform to collect the signatures, but the protocol must address how this will occur including:

- Name of the electronic platform you plan to use (e.g., iMed, Adobe, etc.), and if it is 21 CFR, Part 11 compliant.
- Description of how the signature of both the participant and the investigator will be obtained. You need to paint the picture of the process:
    - Will both be looking at the same screen?
    - Is the consent signature obtained synchronously or asynchronously?
    - Will a true electronic signature be used, or will the signature be obtained using a finger, stylus or mouse (not considered an electronic signature)?
    - For a "true" electronic signature, describe the process of how you will verify the identity of the participant prior to obtaining consent. Part 11 regulations require that an organization verify the identity of an individual before the organization sanctions an individual's electronic signature.

Note: A "true" electronic signature includes an electronically generated timestamp created at the time of signature. If the study is FDA regulated and you want to obtain true electronic signatures, the system MUST be 21CFR, Part 11 compliant.

Don't forget to confirm the identity of the patient

Whenever conducting a remote consent, it is important to ensure that you are speaking with the right individual. FDA requires 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, including telephone consent. 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 only via audio.

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

What are other factors to consider?

- The Clinical Center is using an electronic platform for obtaining required initials (e.g., embedded questions) and signatures on the consent (i.e., iMED).
- 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.