



## Monday Morning Practice Pearls #47

### A potential study participant cannot come to the Clinical Center to sign the informed consent. Can I obtain informed consent via telephone?

- Review your protocol to ensure the protocol allows informed consent to be obtained via telephone.
- Treatment protocols typically only allow re-consent via telephone.
- Remember that telephone consent is NOT verbal consent – it is an IRB-approved alteration of written information consent. Verbal consent does not require an informed consent be signed. The IRB has not approved verbal consent for any NCI protocols.

### The protocol allows for consent/re-consent via telephone. Now what?

- Follow procedures outlined in CCR SOP PM-2 “Obtaining and Documenting the Informed Consent Process,” Step 11. Generally,
  - Send currently-approved informed consent document (ICD) to the patient and set up a time to review via the telephone
    - If a protocol amendment that changes the consent has been approved since you sent the ICD to the patient but before the telephone conversation, you must send the new ICD to the patient and use that version during the telephone conversation.
    - For telephone consent with a non-English-speaking patient, please refer to SOP PM-2 and M2P2 #24, #25, #26. Use of the interpreter line when a non-English speaking patient is at the Clinical Center is NOT telephone consent.
    - For telephone consent with a minor patient please refer to SOP PM-2.
  - Review ICD with patient and answer any questions.
  - 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 to hear them verbally agree to participate.
  - Ask the patient to return the entire signed document (via fax, mail or secure email).
    - If the patient faxes or emails the signed ICD, that becomes the “original” and the person obtaining consent signs that version.
  - The patient is considered “on study” once they sign and date the ICD. For example, once they sign the ICD, they can have blood drawn for screening as described in the consent document they just signed.
- Within 1 day of the telephone conversation during which the patient agrees to participate, document the conversation in the patient’s CRIS record using Documentation of Research Consent progress note.
  - The date of the telephone conversation during which a patient agrees to participate in the study is the date of consent.
  - Only include the relevant information in the note. You will write another note once you receive the signed ICD.

- Include in Additional Comments the fact that informed consent was obtained via telephone, that that patient agreed to participate, was instructed on signing the ICD and returning it, etc.

**Remember:** The informed consent is considered legally effective once the investigator receives the signed document. No research analysis should be performed until the signed informed consent document is received.

### **The patient returned the signed ICD. What do I do now?**

- Once the person who obtained consent receives the signed document, that person will sign the document and date their signature with the date the ICD is received. This signed document becomes the “original” informed consent document.
- Copy the fully-signed ICD and send copy to patient.
- Send the fully-signed original to the Clinical Center Health Information Management Department (HIMD) for scanning into CRIS as usual.
- Write a second note in CRIS which includes that the signed consent form was returned by the patient and a copy with both patient and investigator’s signatures was sent to the patient.
- Register the patient with the CRO within 24 hours of receiving the signed informed consent document.

### **Oops, I got the signed ICD and the patient and/or witness dated their signature incorrectly. Now what?**

- You should date your signature the date the ICD is received.
- Document the date discrepancy in your second CRIS note.

**IMPORTANT:** if you want to communicate with the patient via email, it must be done via a secure email system (SEFT: Secure File Transfer Service; Medical Secure Email; Secure Health Messaging)

### **What if I never get the signed informed consent document from the patient?**

- Do not perform any research analysis on any samples until you receive the signed document.
- If you do not receive the signed document in a reasonable period of time, contact the patient to find out when the document was sent.
- If the consent document is considered lost, you must obtain consent again.
  - Document in the original CRIS note that the signed document was not received at NIH.
  - Write another Documentation of Research Consent note if you need to obtain another consent.