Frequently Asked Questions – Informed Consent (IC)

Telephone consent:

1. *Q:* What is a "telephone consent?"

   A: The IRB can approve "alterations" in the informed consent document and process; obtaining consent via telephone is an alteration of the in-person written IC process. A patient signature is still required on the IC document prior to any research procedures being performed.

2. *Q:* Is telephone consent the same as verbal consent?

   A: No, telephone consent IS NOT verbal consent; it is an oral agreement to participate in a research protocol prior to the signed IC document being received by the research team. If the IRB were to approve a verbal consent process, a signature on the IC document would not be required.

3. *Q:* The patient returned the signed English IC document and a witness also signed the document. What should I do?

   A: A witness signature is only required for the short for consent process. If you receive an IC document with a witness signature, please document in your CRIS note that you realize a witness signature is present but that the signature is not required since the short form consent process was not used.

4. *Q:* I spoke with the patient about the research study and reviewed the consent with him. He wants to talk with his wife about the study before he decides to participate. What should I do?

   A: You must schedule a time to speak with the patient again after he has had time to talk with his wife so you can hear him agree (or not) to take part in the research.

5. *Q:* I reviewed the IC document with the patient and he agreed to take part in the tissue study. The patient was instructed to sign and date the IC document for that date (i.e., the date of the conversation and signature) and return to the research team. When the IC document was returned three days later, the patient had dated his signature for a later date, not the date of the telephone conversation. What should I do?

   A: In your CRIS note, indicate the date of consent as the date of the telephone conversation during which the patient agreed to participate. Then in the "Comments" section, specify that, even though the patient was instructed to sign and date the consent the day of the telephone conversation, when the signed document was returned, the patient had not followed these instructions. This will document the fact that you realize the patient signed with the incorrect date even though he/she had been instructed otherwise. TIP: If the patient is ready to consent after your conversation, have them sign and date the IC document before you finish your phone call.

6. *Q:* It has been two weeks and I still haven't received the IC document signed by the patient. The patient said she faxed it over last week and confirmed the correct fax number. What should I do?

   A: No research procedures can be performed until the IC signed by the patient is received at NIH. You may need to send a FedEx envelope to the patient, consent the patient again and have her send the signed consent back via FedEx.

Short form consent process:

1. *Q:* I am consenting a non-English speaking patient using a short form in the patient's preferred language and the English long form. The English long form contains embedded questions about future use of samples and data but the short form does not have these questions. What should I do?

   A: The investigator obtaining consent askes the patient the embedded questions then indicates the patient's answer using the investigator's initials on the long form. The patient DOES NOT initial the English long form. The CRIS note should explain the discussion of the embedded questions. See OHSR guidance at their FAQ website

2. *Q:* Why do I need a witness signature on both the short form and the English long form?

   A: It is a federal regulation that a witness be present during the short form consent process and sign both the short form and long form (called "written summary" in the regulations). See 45 CFR 46.117(b)(2)

3. *Q:* I see two different versions of short forms on the IRBO website – which do I use?

   A: It depends when the protocol was originally approved by the IRB. For all protocols originally approved on or before January 21, 2019, use the versions under "Common Rule English Consent Short Form." So, if you have a study that begins with "18C," use this version. For studies originally approved after January 21, 2019, use the short form versions under "Revised Common Rule Short Form Consents." The short form website is very clear – please select carefully.

Other issues with informed consent document:

1. *Q:* I forgot to get the patient to initial the embedded questions in the IC document. What should I do?

   A: DO NOT perform any of the procedures described in the embedded questions as no response is considered a negative answer to the question. Re-consent the patient when able with a new consent document and ensure that the embedded questions are answered. TIP: "Flag" pages with embedded questions so they are not missed.

2. *Q:* I sent the fully signed IC document to HIMD but it still isn't uploaded into CRIS – what is the problem?

   A: Check to make sure the patient isn't in "Pre-Admit" status in CRIS – HIMD will not upload documents if the patient is in this status. The admission process must be complete prior to signing the patient onto a research study.

Issues with CRIS note:

1. *Q:* I am consenting a 16-year-old patient onto a research protocol via telephone and her father will be signing the IC document. How should this be documented?

   A: The new CRIS Documentation of Research Consent note allows for several types of consent processes: telephone consent, use of a legally authorized representative (LAR)/parent, use of assent, use of short form and use of an interpreter. Select all of the appropriate processes. For the example, you would select telephone consent, use of LAR/parent and use of assent.

2. *Q:* How and when does the informed consent process need to be documented in CRIS?

   A: According to CCR SOP PM-2, the IC process should be documented in CRIS within one business day of the consent being signed or of the telephone conversation during which the patient agreed to participate. When using the telephone consent process, DO NOT wait to receive the signed IC document to write the note – just complete the information in CRIS as appropriate then write an addendum to the note when you receive the signed consent.