CHICKEN SOUP FOR THE BUSY COORDINATOR

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Informed Consent: When is an Impartial Witness Needed?

During the informed consent process of a new research study, Sue, who is a new CRC, is unsure whether an impartial witness is needed. Thus, she consulted the opinions of a senior CRC on this and the senior CRC advised on the following:

DEFINITION of Impartial witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legal representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

N.B: The impartial witness should not be a member of the study team.

Impartial witness is needed when:

Short Consent Form is Used (For Non-English Speaking Subjects who are Literate in Another Local Language)

If the fully translated ICF in the language understandable by the subject is not available and the Short Consent Form is used to consent subjects, an impartial witness is required during the informed consent process. The impartial witness should be fluent in both English and the language understandable by the subject.

The subject / subject's legal representative, the study team member obtaining consent and the impartial witness must sign on both the DSRB-approved English language Informed Consent Form (ICF) and the short consent form.

Consenting Subjects who are Unable to Read (Illiterate or Unable to Read Due to Visual Impairment)

When a subject / subject's legal representative (LR) is **unable to read** (i.e. illiterate or unable to read due to visual impairment), an impartial witness should be present during the entire informed consent discussion.

Informed consent for these subjects should be performed in the following manner:
a. The person conducting the consent discussion should read and explain the consent form to the subject or the LR.
b. The subject or subject's legal representative must provide verbal consent to the subject's participation in the study.
c. If capable of doing so, the subject or subject's legal representative should personally sign and date the ICF.
d. The impartial witness should also personally sign and date the ICF.

Subjects Who Are Incapable of Personally Signing and Dating the Consent Form

Situations may be encountered in which mentally competent subjects are unable to personally sign and date the ICF such as subjects with physical disabilities that prevent them from being able to write.

Documentation of informed consent for these subjects should be performed in the following manner:
a. The subject should affix his / her thumbprint on the ICF;
b. An impartial witness will be required to attend the consent discussion, as well as sign and date on the ICF;
c. The impartial witness may also write the subject's name and the date of consent on the ICF, on the subject's behalf.

For both the scenarios above:

- The study team member conducting the consent discussion should personally sign and date the ICF.
- A complete copy of the signed ICF should be given to the subject or his / her legal representative.
- Finally, the person taking consent should document and clearly describe the informed consent process in the source documents.

References:

1. NHG investigator manual 3rd Edition Sept 2017 Chapter 5.4 Documentation of Informed Consent & chapter 5.5 Subjects who are Unable to Read Page 133-137
2. NHG PCR SOP 501-C01 Informed Consent Form and Process
3. NHG PCR SOP 501-A02 Responsibilities of the Research Team

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