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HOW SHOULD CONSENT BE OBTAINED FOR SUBJECTS WHO ARE UNABLE TO READ?

Scenario 1:

During his admission, Mr Han, 75, expressed his interest to participate in a clinical research study. He is illiterate but offers to give thumbprint as he did for his medical consent forms.

How should consent be taken from Mr Han?

Firstly, the study team member obtaining consent from Mr Han should ascertain that he demonstrates mental competence and is able to understand the informed consent discussion. He should be able to indicate approval or disapproval to participate in the study to qualify for enrolment.

Secondly, the study team member should ensure that an impartial witness is present throughout the consent discussion. Mr Han should affix his thumbprint onto the informed consent form (ICF). The impartial witness must personally sign and date on the ICF. He / she may also write Mr Han's name and date the ICF on the latter's behalf. The entire informed consent process should be clearly documented in Mr Han's medical records.

Scenario 2:

Madam Shanti attends her medical appointment at the clinic together with her daughter. Dr. Bean speaks to them about a research study which he thinks might benefit Madam Shanti. As Madam Shanti and her daughter are not able to read and understand English properly, they prefer to converse in Tamil.

How should informed consent be obtained from Madam Shanti and her daughter?

The preferred method of obtaining consent from non-English speaking subjects is to provide a ICF written in a language understandable to them. Ideally, a certified translation of the DSRB-approved English ICF is preferred. If a fully translated ICF is not available, the DSRB-approved English ICF and DSRB short consent form (written in the language understandable by the subject) should be used.

The consent discussion should be conducted in the subject's preferred language, i.e. Tamil. A translator should be present to translate the English ICF for Madam Shanti. An impartial witness should also be present; the impartial witness can be the translator. Madam Shanti, the study team member obtaining consent and the impartial witness must personally sign and date on both the DSRB-approved English ICF and the short consent form. A copy of the set of signed English ICF and short consent form must be provided to the Madam Shanti. The informed consent process should be clearly described and documented in Madam Shanti's medical records by the study team member obtaining consent.

References
NHG Investigator's Manual (2nd Ed) Chapter 5.4: Documentation of Informed Consent
NHG Addendum to the NHG Investigator's Manual Chapter 5.6: Non-English Speaking Subjects
GCP Section 4.8 (Informed Consent of Trial Subjects)
NHG PCR SOP 501-C01 Informed Consent Form and Process

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