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Research Involving Non-English Speaking Subjects

Scenario

Mr. Osman went to the clinic for his diabetes follow-up appointment, accompanied by his son, Amin. After the consultation, Mr. Osman agreed to be referred by his attending doctor to Lily a Clinical Research Coordinator (CRC) to discuss about a study involving an interviewer-administered survey. Mr. Osman was interested to participate in the survey, but he was only able to read and speak Malay, while Lily was not literate in Malay. The DSRB-approved study documents available were the English informed consent form, Chinese and Malay short consent forms and English questionnaire. Amin proposed to provide consent and the answers to the questionnaire on Mr. Osman's behalf as he is fluent in both English and Malay.

What should Lily do?

- Lily should advice Amin to be the translator and impartial witness for Mr. Osman during the informed consent process instead. The intention is to protect Mr Osman's autonomy and to ensure that his participation in the study is voluntary.
- If Mr Osman agree to participate, he should sign off as the participant, Amin to sign off as the translator and impartial witness, and Lily as the person administering the consent, on the English informed consent form and Malay short consent form.
- Lily should provide Mr. Osman a copy of the English informed consent form and the Malay short consent form and also document the informed consent process in the source documents.
- Next, Lily should provide an oral presentation of the English questionnaire to Amin for verbal translation to Mr. Osman, whom should provide the answers personally. Lily should be present throughout the process to provide further clarifications if necessary.
- Alternatively, Lily could seek help from a Malay-speaking clinic staff to be the translator and impartial witness, instead of Amin.

What could be done in future?

- Lily could assist the Principal Investigator (PI)/the study team to arrange for a full Malay translation of the informed consent form and questionnaire by an individual who is competent in English and Malay.
- The qualifications of the translator should be documented in the NHG DSRB Certification of Translation template. (DSRB must approve the Malay informed consent form and questionnaire before use.)
- By administering a Malay questionnaire, it would save time as the survey questions could be administered directly to the participant without having it to be translated on the spot.
- A CRC who is fluent (able to read and speak) in the Malay language could also be included in the study team so as to ensure that the method of administering the questionnaire to each Malay-speaking participant is consistent.

References

1. NHG PCR SOP 501-C01: Informed Consent Form and Process
2. NHG Investigator's Manual 2nd Edition & Addendum to Investigator's Manual: Chapter 5.4 Documentation of Informed Consent & Chapter 5.6 Non-English Speaking Subjects

**Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*

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