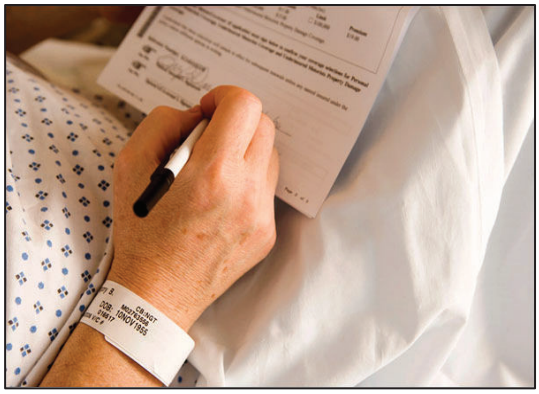
Frequently Asked Questions (FAQs)
on Informed Consent Process and Documentation

1. What should I do if the Subject cannot read nor understand English, but I have only an English version of the Patient Information Sheet & Consent Form (PIS/CF)?



Answer:
If the subject / legally acceptable representative (LAR) is unable to read, an **impartial witness**, who is not a member of the study team, should be present during the entire informed consent discussion. If a translator is being used, this person can serve as a witness. The written informed consent document should be read and explained to the subject / LAR. The subject / LAR must orally consent to the subject's participation in the study.

The subject / LAR should sign and personally date the informed consent document, followed by the impartial witness doing similarly. By signing the consent document, the witness attests that the information in the consent document was accurately explained to, and apparently understood by the subject / LAR, and that consent was freely given by the subject / LAR. The person conducting the consent discussion (e.g. PI) should then sign and personally date the consent document. A copy of the signed consent document should be given to the subject / LAR.

Investigators are encouraged to make use of the DSRB Short Form Template 207-005/6/7 for Chinese, Malay and Tamil speaking subjects. Please see below.

2. What is a Short Form?

Answer:
In situations where a Chinese/Malay/Tamil translated informed consent document is not available, a Short Form may be used. The Short Form Consent Document states that the elements of informed consent have been presented orally to the subject / LAR. A witness to the oral presentation of the Patient Information Sheet is required, and must be fluent in both English and the language of the subject / LAR. After the study is explained, the witness must sign both the Short Form Consent Document and a copy of the PIS/CF. The subject / LAR must sign the Short Form Consent Document. The person obtaining consent must sign a copy of the PIS/CF. The subject / LAR must be given a copy of the signed short form consent document and the signed written summary of the information that is presented orally.

No DSRB approval is required for the Short Form, provided that the information contained within is not altered.

The forms may be downloaded from NHG B2B Research website → Bench → Downloads
Short Form Consent Document Template – Chinese 207-005
Short Form Consent Document Template – Malay 207-006
Short Form Consent Document Template – Tamil 207-007

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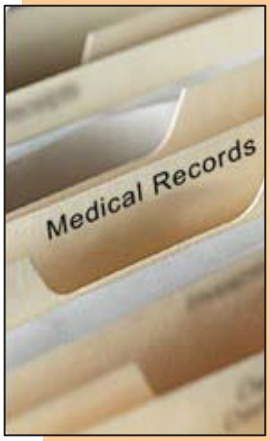
3. What should I do after the written information is explained to the patient and the Consent Form is signed?



Answer:
A copy of the signed and dated Patient Information Sheet and Consent Form must be given to the subject. The full set of the original copy should be kept in a study file. The person who conducted the informed consent discussion must document on the subject's medical record the date of informed consent as well as the fact that a copy was given to the subject. This is not required when waiver of documentation of informed consent is approved by the DSRB, or when the study does not involve access to medical records such as a survey study or observational epidemiological study.

4. Can the ward staff/medical students assist me in obtaining consent from the subjects?

Answer:
Informed consent discussion should only be conducted by the Principal Investigator, collaborator or a member of the study team who is listed in DSRB/IRB Application Form and the study responsibility log as the designated person(s) for conducting the informed consent discussion.

Contact: rdo-qa@nhg.com.sg

References:

1. **www.hsa.gov.sg**
2. **www.moh.gov.sg**
3. **PCR SOP 501-C01 Informed Consent Document and Process**
4. **DSRB SOP 201-C08 Informed Consent Requirements**
5. **DSRB SOP 201-C09 Alteration to Informed Consent Requirements**