

INFORMED CONSENT PROCESS DOCUMENTATION

After consent has been obtained for research participation, the following should be documented -

- ✓ Protocol reference
e.g. protocol title, protocol no., ECOS ref. no.
- ✓ Date of consent
- ✓ Description of the consent process
 - Who took consent
 - Language used for consent process
 - Presence of impartial witness, prescribed witness, translator, legal representative (LR) verification for consent
 - If adequate time was given to consider participation
 - Any other significant information
- ✓ If a signed copy of ICF was given to the subject / LR



Questions on how to conduct research?

Chat with our SARAH bot!

Login to **Pair***
(<https://pair.gov.sg>) & search for **SARAH** under Browse Assistants



Who should document?

The study team member who obtained consent



Where to document this?

In the subject's medical records. If no medical records available, create your own study template / checklist to document this



When to document?

Record on the day consent was obtained

**Pair is an Open Government Product*

Access all NHG Health PCR SOPs & templates [here!](#)



INFORMED CONSENT CHEAT SHEET

Subject / Subject LR	Study Team Member	Informed Consent Form (ICF) Language	Translator Required?	Impartial Witness Required?	For HBRA Studies Prescribed Witness Required?
Literate in English	Literate in English	English	✗ NO	✗ NO	
Literate in local language (i.e. Chinese, Malay, Tamil)	Literate in local language	Local language	✗ NO	✗ NO	✓ YES
	Literate in English, unable to communicate in local language	Local language	✓ YES	✗ NO	
	Literate in English + local language	English ICF + Short Consent Form in local language	✗ NO	✓ YES	
	Literate in English, unable to communicate in local language	English ICF + Short Consent Form in local language	✓ YES	✓ YES	✓ YES
Illiterate or unable to read due to visual impairment	Literate in English, unable to communicate in local language	English	✓ YES	Impartial witness can also be translator if literate in local language	Impartial witness can also act as a prescribed witness
	Literate in English + local language	English & local language Choose the language that impartial witness is literate in	✗ NO		