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WHO CAN OBTAIN CONSENT?

HEALTH PRODUCTS ACT (HPA)/MEDICINES ACT (MA)

regulated by Health Science Authority (HSA)

- ✓ Investigators who is a **qualified practitioner**
- ✓ For pharmacist-initiated studies: Investigator who is a **qualified practitioner or pharmacist**
- ✗ Other study team members (e.g. CRC)

However, they may assist in the informed consent process

HUMAN BIOMEDICAL RESEARCH ACT (HBRA)

regulated by MOH

- ✓ Principal Investigator
- ✓ Any qualified member of study team

OTHER RESEARCH STUDIES

not regulated under HBRA, HPA or MA

- ✓ Principal Investigator
- ✓ Any qualified member of study team



Ensure person obtaining consent is:

- Holding a study role approved by IRB to obtain consent
- Trained in the informed consent process approved by IRB for the specific study
- Training is documented in the investigator file
- Delegated in the Study Responsibility / Delegation Log

WHO CAN BE A HBR PRESCRIBED WITNESS?

- ✓ An adult ≥ 21 years of age
- ✓ Able to read & understand the language used during consent discussion
- ✓ Able to be present for the **ENTIRE** informed consent process
- ✓ Witness should **NOT** be the same person taking consent

WHEN IS AN IMPARTIAL WITNESS REQUIRED?

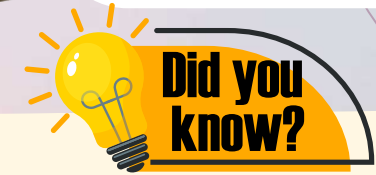
- ✓ Subjects/ legal representatives (LR) unable to read or understand the ICF language provided by the study team due to illiteracy or visual impairment **OR**
- ✓ Mentally competent subjects unable to personally sign and date the ICF due to physical disability



Questions on how to conduct research?

Chat with our SARAH bot!

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



THE IMPARTIAL/ PRESCRIBED WITNESS SHOULD ASCERTAIN:

- The identity of the person giving the consent
- The subject/LR understood the information given to them
- That consent was given voluntarily without any coercion/intimidation