CHICKEN SOUP FOR THE BUSY COORDINATOR

MAY 2019

WTINESS REQUIREMENT FOR INFORMED CONSENT PROCESS

Case scenario

Mary is the Clinical Research Coordinator for a clinical research. During the informed consent process, the Principal Investigator (PI) asked Mary to sign as the witness on the informed consent form for Subject A.

Should Mary sign as the witness on the informed consent form? What should Mary do?

How to determine the witness requirement for the informed consent process?

✓ Check if the study is a clinical trial regulated by Health Sciences Authority (HSA) or Human Biomedical Research (HBR) Study regulated by MOH.

	If study is regulated by HSA under the Health Products (Clinical Trials) Regulation/ Medicines (Clinical Trials) Regulations 2016	**If study is regulated by MOH under Human Biomedical Research Act (HBRA)**
When is the impartial / prescribed witness required?	✓ An Impartial witness is required when the subject is - ▪ Unable to sign or date the consent form, or ▪ Unable to read the information in the consent form.	✓ A witness is always required unless the research is - ▪ not invasive, ▪ not interventional, and ▪ not restricted human biomedical research. Reminder: An Impartial witness is required for a HBR study where the subject is unable to read/ understand the language of the ICF, the witness should also fulfil the impartial witness requirements.
Who can be an impartial / prescribed witness?	✓ An Impartial witness must be independent of the study and not be influenced by people involved in the study. → Study team member cannot be an impartial witness.	✓ A witness must be at least 21 years old, has mental capacity and must not be the same person who's taking the consent. → Study team member can be a prescribed witness, unless the situation requires an impartial witness to be present (e.g. subject who are unable to read)
Role of the impartial/ prescribed witness	✓ An Impartial witness should attest that ▪ information in the consent form has been accurately explained to the subject, ▪ information in the consent form has apparently been understood by the subject, and ▪ the subject has voluntarily agreed to participate in the study.	✓ A witness must take reasonable steps to ascertain ▪ the identity of the individual giving the appropriate consent, and ▪ that consent has been given voluntarily without any coercion or intimidation.

Note: For non-HSA regulated clinical trial or HBR Studies, the consenting process should follow your respective institutional policies and/ or SOPs.

References:

- Health Products (Clinical Trials) Regulations, Medicines (Clinical Trials) Regulations
- Human Biomedical Research Act, Human Biomedical Research Regulations
- ICH E6 R2 Guideline for Good Clinical Practice
- NHG Proper Conduct of Research SOP 501-C01: Informed Consent Document and Process
- NHG Investigator's Manual 3rd Edition and Addendum to Investigator's Manual 3rd Edition, Chapter 5.5: Subjects Who are unable to read

Recommended course: NHG PCR200 Study Conduct I: Subject Recruitment and Informed Consent

Article Contributed By: **Ms. Chong Limei, Senior Regulatory Specialist, Health Sciences Authority**
Edited By: NHG-RDO

Proudly brought to you by: Clinical Research Coordinator Society (CRCS)
(researchcoord@nhg.com.sg)