CHICKEN SOUP FOR THE BUSY COORDINATOR

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Impartial Witness & Witness In Informed Consent-Taking For HBR Studies

Scenario

John is the Clinical Research Coordinator (CRC) who will be assisting the Principal Investigator (PI), Dr Robert, with consent-taking for a COVID-19 related Human Biomedical Research (HBR) study. Dr Robert is uncertain whether impartial witness or witness are required. How can John advise Dr Robert?

Informed consent discussion should be conducted by the Principal Investigator or any qualified member of the study team who is listed in the study responsibility log as the designated person for conducting the informed consent discussion. The Informed Consent must be obtained from the research subject or the subject's legal representative prior to any study procedures unless the waiver or alteration of the process, or any part thereof, has been approved by the DSRB and Regulatory Authority (where applicable).

Use of Impartial Witness:

An Impartial Witness is required to be present during the informed consent process in any of the following scenarios:

- The subject or the subject's legal representative is unable to read the informed consent form.
- The subject or the subject's legal representative is unable to sign or date the informed consent form.

The role of an Impartial Witness is to attest that the information in the informed consent has been accurately explained to the subject or the subject's legal representative, the informed consent has been apparently understood by the subject or the subject's legal representative, and the subject or the subject's legal representative has voluntarily agreed to participate in the HBR study.

There is no regulatory provision regarding who can act as the impartial witness so long as the person who acts as an impartial witness is independent of the clinical trial and is not influenced by people involved in the HBR study. Impartial witness should be present during the informed consent process.

The possible choices would be either a family member, friend, clinic staff (who is not part of the study team), or a layperson. The choice of an impartial witness should be made in the best interest of the research participant.

Use of Prescribed Witness in Human Biomedical Research (HBR) studies

HBR studies involves the use of individually-identifiable health information (HI) or individually-identifiable human biological material (HBM).

Witness is one of the core elements for HBR studies consent process:

- Witness may not necessary be impartial.
- Witness could be anyone above 21 year old, including study team member, who has mental capacity.
- Must not be the same individual as the person taking the appropriate consent.

Note

- For studies which are invasive and/or interventional, the presence of a prescribed witness is not required if following conditions are met:
  (i) the research is interventional but the intervention involves no more than minimal risk to the research subject;
  (ii) the research subject is able to read and sign the appropriate consent form; and
  (iii) the research is not restricted human biomedical research
- If the subject is unable to read or personally sign and date on the informed consent form, the witness should be an impartial witness and should not be a member of the study team.
- When subject is vulnerable or illiterate, impartial witness is necessary to protect the safety and welfare of the research subject.
- For clinical trials regulated by HSA, the study team needs to adhere to the Health Products Act/ Medicines Act as stipulated in the HSA website.

References:

1. DSRB Guidance on the requirement of appropriate consent for the conduct of Human Biomedical Research and Handling of Human Tissue
2. PCR SOP 501-C01 Informed Consent Form and Process

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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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