CHICKEN SOUP FOR THE BUSY COORDINATOR

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Subject Recruitment: Performing Subject Eligibility Assessment & Documentation

Scenario

Professor X had just obtained the IRB approval for a new vaccine clinical trial. He is excited to start the study and his Clinical Research Coordinator (CRC) will be assisting him with recruitment. Participants will first be identified through referrals from doctors or by study team via the pre-screening process.

What is Pre-screening & Screening?	
Pre-screening	Pre-screening refers to the identifying the potential subjects and activities conducted **BEFORE obtaining the informed consent** from the subject (e.g., reviewing databases or medical records). However, this activity must have prior approval by the DSRB and be in compliance with institutional requirements.
Screening	Refers to the process of conducting a series of tests, clinical procedures and review of relevant records (e.g., databases or medical records), performed solely for the purpose of determining eligibility for research **AFTER informed consent has been obtained** from the participant or Legal Representative**.** A record of all individuals who consented to participate in the study Subject Screening and Enrolment log and Subject Identification Log must be maintained in the Investigator File.

What is Professor X's Responsibility as the PI?

Professor X is responsible for ensuring that only eligible participants are recruited into the clinical trial. He must ensure that all the members of the research team involved in recruiting participants are:

- ✓ Qualified by education, training and experience to assume responsibilities associated with proper conduct of a research study (i.e., participant recruitment)
- ✓ Appropriately trained on the study's eligibility criteria (inclusion and exclusion criteria), and
- ✓ Ensure adequate documentation of the participant's eligibility assessment in the source documents.

How should Professor X and CRC Perform Subject Eligibility Assessment & Documentation?

Eligibility Assessment:

- Subject's eligibility should meet the IRB approved protocol-specific **inclusion/exclusion (I/E) criteria**. To be eligible, all inclusion criteria must be met and none of the exclusion criteria is met.
- Eligibility must be assessed during screening prior to randomization or starting any study interventions.
- Any I/E criteria that requires a medical judgment must be done by a medically qualified study team member.
- Documents used during eligibility review includes the protocol and source documents related to eligibility review (e.g., lab reports, investigation results etc.)

Eligibility Assessment Documentation:

- The CRC may develop an **eligibility checklist** based on the IRB approved study I/E criteria to collect and verify screening information on all potential participants who have consented to participate.
- The PI should ensure there is adequate documentation of the participant's eligibility assessment in the source documents (i.e., medical records).

What Information Should be Documented and Where, if the Participant Failed or Passed the Eligibility Screening?

- If participants failed the eligibility screening and was not enrolled into the study, the reason for screen failure and why the participant was not enrolled should be documented in Subject Screening and Enrolment Log. The log should not contain any subject identifiers.
- A list of potential participants who met the eligibility criteria should be maintained in the Subject Screening and Enrolment log. This log should be filed in the site's Investigator File.

References:

1. NHG Proper Conduct of Research SOP: 501-C02 Subject Recruitment and Screening,
2. NHG Investigator Manual 4th Edition, Chapter 1.3 Role of Institutions, Department and Institution Representatives, Investigators and Other Study Team Members, Chapter 3.3.1 Qualifications and Agreements

Additional resources:

- NHG (509-007) Subject Screening and Enrolment Log, NHG (504-008) Eligibility Checklist
- https://www.hsa.gov.sg/clinical-trials/conducting/principal-investigator > Medical or Dental decisions to be made by qualified practitioners

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