CHICKEN SOUP FOR THE BUSY COORDINATOR

Oct 2020

Documentation for Pre-Screening and Screening Process of Research Subjects

CRC Eugenia is assisting PI, Dr Gavin in the recruitment of subjects for Study XYZ. Patients will first be identified through pre-screening process via referrals from doctors or by study team. They will then be approached by the study team for more study details after giving verbal consent to the attending physicians to be contacted for the study. Informed Consent will then be obtained followed by a screening process to determine eligibility for the study. If they are eligible, they will be recruited into the study. However, if they are not eligible, they will stop at this stage of the study.

- How should the PI / CRC document the above process for both eligible and ineligible subjects?
- Should CRCs keep (maintain) identifiers of patients who did not consent to study participations?

Definition:

Preliminary Screening / Pre-screening **-** The process of identifying potential subjects (e.g. reviewing databases or medical records) prior to informed consent, screening or enrolment.

Screening - the process of conducting a series of tests, clinical procedures and review of relevant records (e.g. reviewing databases or medical records), performed solely for the purpose of determining eligibility for research after informed consent has been obtained from the subject.

Important Pointers:

Pre-screening Process

- Written consent is not required for pre-screening. However, the referring physician or healthcare provider should have obtained verbal consent or permission from the potential subjects to be contacted prior to direct contact by the study team members. If verbal consent is taken, the verbal agreement must be documented.
- Pre-screening process must have prior approval by the DSRB.
- A list of all potential subjects who were approached for the study regardless of whether they signed the informed consent document or not should be maintained.
- Pre-screening logs should not contain any identifiers.

Screening Process

- The research team may perform screening only after informed consent has been obtained from the subject.
- The research team must maintain a record of all individuals who consented to participate in the study Subject Screening and Enrolment log and Subject Identification Log.

How to keep track of the list of subjects who had refused participation?

- Individually identifiable information (such as name, identity card number, address, etc.) for potential subjects who did not provide consent to participate in the study should not be kept by the research team.
- To track the potential subjects screened, the study team may collect only the year of birth instead of the full date of birth, together with the potential subject initials.

What information should be documented if the subject failed or passed the eligibility Screening?

- If subjects failed the eligibility screening and was not enrolled into the study, the reason why the subject was not enrolled should be documented in the Subject Screening and Enrolment Log. The log should not contain any subject identifiers.
- A list of potential subjects who meet the eligibility criteria should be maintained in the Subject Screening and Enrolment log. This log should be filed in the site's Investigator File.
- The PI should ensure there is adequate documentation of the subject's eligibility assessment in the source documents / medical records.

Reference:

1. NHG Proper Conduct of Research SOP: 501-C02 Subject Recruitment and Screening
2. 509-007 Subject Screening and Enrolment Log
3. 504-008 Eligibility Checklist

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