CHICKEN SOUP FOR THE BUSY COORDINATOR

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Pre-screening/ Screening Process: Documentation and the Use of Subject's Identifiers

Scenario
Clinical Research Coordinator (CRC) Annie is assisting the Principal Investigator (PI), Dr M with a new study. Potential patients may be identified by reviewing the database or referrals by other attending physicians. Before the study team starts recruiting subjects, they considered the following points:

- **Is pre-screening/ screening with identifiers allowed and should it be approved by IRB?**
- **Is the patient/subject's informed consent required?**

Pre-screening is the process of identifying potential subjects (e.g. reviewing databases or medical records) prior to informed consent, screening or enrolment. This process does not require prior consent of the patient. However, this activity must have prior approval by the DSRB and be in compliance with institutional requirements.

Screening is 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. Informed consent should be obtained from the subject prior to Screening.

Note: The potential subject's permission to be referred into a study must also be obtained by the attending healthcare professionals prior to direct contact by member of the research team (e.g. subject to be referred to another department/ another institution) and subject's agreement should be documented.

Additionally, Dr M and CRC (Annie) should also consider what are the necessary documentation for the following:

- **Pre-screening and screening of potential research subjects**

The research team should maintain a list of all potential subjects who were approached for the study regardless of whether they consented to participate in the study or not. Where there are pre-screening activities, this should also be documented (e.g. maintain in the Subject Screening and Enrolment log). A list of potential subjects who met eligibility criteria should be maintained in the Subject Screening and Enrolment log.

- **Can subject's information and identifiers be kept in the Pre-Screening/ Screening Log?**

If the 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 Pre-Screening Log/ Subject Screening and Enrolment Log should not contain any subject identifiers. Individually identifiable information (such as name, full date of birth, 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. Dr M should confirm with her Research Institution on what constitutes identifiers.

- **If the subject's identifiers are not kept, how does the study team keep track of individuals whom had refused participation in the study?**

An alternative way to keep track of individuals who refused participation in the study may be to collect only the year of birth instead of the full date of birth, together with the potential subject initials. It can also be documented in the source documents that the individuals refused participation for identification purposes.

Reference:
1. 501-C02 Subject Recruitment and Screening
2. 509-007 Subject Screening and Enrolment Log

Article Contributed By: **Lim Boon Khim Snr Research Nurse, KTPH**
Edited By: NHG Group Research, OHRPP

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(researchcoord@nhg.com.sg)