CHICKEN SOUP FOR THE BUSY COORDINATOR

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PERFORMING SUBJECT ELIGIBILITY ASSESSMENT & DOCUMENTATION

Scenario

Study Z was monitored recently and one of the findings was that the eligibility assessment was not documented for all the enrolled subjects. Upon clarification with the Principal Investigator (PI), all the enrolled subjects had been assessed, fulfilled the inclusion criteria and did not meet any of the exclusion criteria. However, the PI was unaware that the eligibility assessment needed to be documented. The PI asked the study's Clinical Research Coordinator (CRC) for tips on how it should be done properly moving forward, and the appropriate corrective measures.

How could the CRC advise and assist the PI on the eligibility assessment process and documentation?

The CRC shared with the PI on the following:

Who is allowed to carry out the assessment?

The PI may delegate the responsibility of carrying out the eligibility assessment to qualified study team member(s) appropriate to the study risks and ensure they are trained on the study's inclusion and exclusion criteria listed in the DSRB / IRB approved protocol.

When is the eligibility assessment carried out?

Eligibility assessment may be conducted during the pre-screening or screening process (Note: prior DSRB / IRB approval must be obtained).

Pre-screening - Preliminary screening maybe conducted to identify potential subjects by reviewing database or medical records prior to informed consent. The CRC could help the PI/ study team to maintain a list of all potential subjects who were approached for the study regardless of whether they signed the informed consent document or not in the Subject Screening and Enrollment log.

Screening – The study team may perform screening for the purpose of determining the subject's eligibility for enrolment into the study after obtaining informed consent from the subject. The CRC could help the PI to maintain a record of all the individuals who had consented to participate in the study and the list of potential subject who met the eligibility criteria in the study's Subject Screening and Enrollment log.

How should the eligibility assessment be carried out?

The delegated individual should adhere to the DSRB approved inclusion and exclusion criterion. The PI and/or designee must to go through each inclusion and exclusion (I/E) criteria and ensure that the potential subject fulfils all the inclusion criterion and none of the exclusion criterion.

What and where should eligibility assessment be documented?

The PI / study team should ensure that the subject's eligibility assessment is documented adequately in the source documents. The documentation should include the individual who conducted the eligibility assessment; whether the subject had met all the eligibility criteria; when and what assessment(s) were performed, and the reasons why a subject was not enrolled (including in the Subject Screening and Enrollment log).

However for this scenario, as the subjects had already been enrolled, the PI/CRC may write a Note-to-file to describe and confirm that the eligibility assessment was performed for all the subjects, the process involved and relevant details.

Tips to ensure eligibility assessment documentation is carried out

The study team may develop an eligibility checklist based on the study inclusion or exclusion criteria approved by the DSRB / IRB to collect and verify screening information on all potential subjects who have consented to participate. The checklist should include:

- ✓ The DSRB / IRB reference number, study title and the version of protocol
- ✓ All the inclusion and exclusion criteria(s) must be listed on the checklist.
- ✓ A statement as to whether the subject is eligible to be enrolled into the study by the assessor.
- ✓ A footer version number and date are needed for tracking purposes.
- ✓ Reminder: The checklist must be updated whenever there is a DSRB / IRB approved protocol amendment to the I/E criteria.

The study team member delegated to perform the assessment should go through each I/E criteria and indicate a "Yes" for all inclusion criteria and "No" for all exclusion criteria; and sign off and date on the checklist.

References:

- NHG Proper Conduct of Research SOP 501-A02: Responsibility of the Research Team, 501-B05: Documentation, 501-C02: Subject Recruitment and Screening, NHG Proper Conduct of Research Checklist Template 504-008: Eligibility Checklist

Article Contributed By: **Ms. Jiao Hongli, Senior CRC, TTSH, Edited By: NHG-RDO**

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(researchcoord@nhg.com.sg)