NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

Non-Compliance Report: Subject Screening and Recruitment

Background

At recent study reviews, the Research Quality Management (RQM) team observed the following non-compliances related to subject screening and enrolment:

- Recruitment process practised at the site was inconsistent with the recruitment strategy described in the DSRB Application Form.
- Recruitment materials provided to subjects were not approved by DSRB.
- Inadequate assessment and documentation of subject eligibility resulting in non-eligible subjects being enrolled.

Tips and Recommendations

A) Comprehensive training of study team members and development of site recruitment plan during the study initiation meeting.

Prior to study initiation, the Principal Investigator (PI) may conduct a study initiation meeting to ensure that all study team members have an adequate understanding of the study protocol and site-specific processes (e.g. type of source documents required). A recruitment plan should be developed in accordance with the recruitment strategies listed in Section H of the approved DSRB Application Form.

After the study initiation, the PI should monitor the recruitment progress and propose alternative strategies if necessary. When adopting an alternative approach, the PI should also inform DSRB prior to execution.

B) Ensure recruitment materials are approved by DSRB prior to subject recruitment.

During the development of the recruitment plan, the PI may consider using advertisements (e.g. newspaper advertisements, posters, brochures, and email or invitation letters) to aid in recruitment. Any recruitment material created by the study team should be submitted to DSRB for approval prior to use.

C) Maintain appropriate documentation on source documents and study documents.

The study team is encouraged to develop an eligibility checklist based on the study inclusion and/or exclusion criteria to aid in determining subject's eligibility prior to enrolment. The person performing the eligibility assessment and completing the checklist should possess the appropriate qualifications and training, and should be authorised by the PI to discharge these responsibilities. Supporting source documents (e.g. laboratory results) should also be available to confirm subject's eligibility.

Whenever possible, study documents should be maintained in hard copy for audit trail purposes unless a validated system is in place for documents to be maintained electronically.

All study documents should also have version control. The PI is ultimately responsible for ensuring that all information is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

Successful recruitment involves the development and implementation of a well-coordinated plan that will require effort from the entire research team. The PI must ensure adequate oversight of the recruitment progress, enrolment of eligible subjects and maintain effective communication among the study team members, DSRB and any other party(ies) involved in the conduct of research.

References:

- ***PCR SOP 501-A02: Responsibilities of the Research Team***
- ***PCR SOP 501-B03: Study Initiation***
- ***PCR SOP 501-C02: Subject Recruitment and Screening***

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*"The biggest risk in **this** study is just reading the consent form!"*