

## Assessment of Eligibility of Research Subjects Prior to Recruitment

### Case Study—Recruitment Error

In a recent study, a subject was recruited even though she did not meet the inclusion criteria. Subject A was first screened by a Clinical Research Coordinator (CRC) at the clinic. The CRC was uncertain whether the subject had met the study inclusion criteria of “Benign Carcinoma” and contacted another CRC for help. Over the phone, the 2nd CRC advised that the subject can be recruited. Subsequently, the subject signed the Informed Consent Form (ICF) and blood specimens were collected.

The mistake was identified during an internal audit. The subject was informed of the error and she was withdrawn from the study. The blood samples collected were also discarded. The withdrawal was documented and filed together with the 'signed patient consent'. A Non-Compliance Report (NCR) to notify DSRB of the above issue was also submitted.

Post event, the Principal Investigator (PI) was required to -

- 1) Retrain the CRCs on the inclusion and exclusion criteria.
- 2) Ensure that all team members are clear about what constitutes a malignant versus benign histology.
- 3) Reinforce the need to contact PI when in doubt and
- 4) Ensure that all new recruitment(s) are verified by two study team members.

### Useful Tips & Recommendations

Here are some additional practical tips that you can use to ensure appropriate subject recruitment.

#### Before recruitment:

The PI must ensure that:

- 1) There is a recruitment plan. This plan should be developed in accordance with the recruitment strategies approved by DSRB.
- 2) The Eligibility checklist (if applicable) tallies with the approved DSRB application/ protocol.
- 3) A study initiation meeting has been conducted 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).
- 4) The individual performing the eligibility check has the appropriate qualifications and training, and had been authorised by the PI to discharge these responsibilities.
- 5) There are supporting source documents such as laboratory results to confirm subject’s eligibility.

The CRC/delegated study team member should:

- 1) Understand the inclusion and exclusion criteria and know

how to use the subject eligibility checklist (if applicable).

- 2) Know the type of source documents that can be used to determine the subject’s eligibility and where to locate these source documents.
- 3) Know where and how to document the subject eligibility assessment.

#### Upon recruitment of subjects:

The PI must ensure that:

- 1) All recruited subjects fulfilled the inclusion and exclusion criteria.
- 2) The recruitment progress is being monitored and to propose alternative screening and recruitment strategies if necessary.
- 3) When adopting an alternative approach, the DSRB is informed and approval granted prior to execution.

The CRC/delegated study team member should:

- 1) Assess the subject by using an eligibility checklist (if applicable) prior to enrolment.
- 2) Contact the PI when in doubt.
- 3) Document the subject screening process in the study related documents (e.g. medical record, subject assessment checklist, subject screening and enrolment log) and also to sign and date on the documents.

### Conclusion

Successful recruitment involves the development and implementation of a well-coordinated plan that requires effort from the entire research team. The PI must ensure that recruitment does not deviate from the approved IRB research protocol. For studies that fall under the Human Biomedical Research Act, a deviation from the approved research protocol may constitute as a [contravention](#) and liable to be charged.

### References

- A. [NHG Proper Conduct of Research Standard Operating Procedures:](#)
  1. PCR SOP 501-A02: Responsibilities of the Research Team
  2. PCR SOP 501-B03: Study Initiation
  3. PCR SOP 501-B05: Documentation
  4. PCR SOP 501-C02: Subject Recruitment and Screening
- B. [Human Biomedical Research Act](#) section 22(3)(a)

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