

QUALITÉ

Issue 2010/03

In This Issue:

- **NON-COMPLIANCE REPORT**
Manpower constraint leading to compromise and omission of informed consent taking.
A Principal Investigator failed to obtain informed consent from research subjects.
To read the entire article, please [click here](#).
- **THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES (Part 2/5 series)**
No. 3 Determining that Adequate Resources are Available to Conduct the Study
No. 4 Managing the Medical Care of Research Participants

The Principal Investigator's Roles & Responsibilities

No. 3 : Determining that Adequate Resources are Available to Conduct the Study

Before starting a study, the Principal Investigator should ensure that the site demonstrates a **potential for recruiting the required number of suitable participants within the agreed recruitment period**. The Principal Investigator should assess if the site has the required subject pool and the potential number of subjects that would meet the study's eligibility criteria.

Having **adequate and qualified staff to conduct of the research study** is also important to ensure that the study is conducted properly and within stipulated timelines. Training on protocol related matters should be provided by the Principal Investigator or a designated trainer. Additional research training are available in NHG (www.research.nhg.com.sg). The Principal Investigator is responsible for ensuring that the workload delegation amongst team members, including research

coordinators, is appropriate.

In instances where the study may require investigational tests or procedures, the Principal Investigator will need to consider whether the site has **adequate facilities to conduct the study**. Example of facilities include laboratories, MRI, secure storage space for study drugs, investigator files, blood samples etc.

Ensuring adequate time to conduct and supervise the research study and complete it within the agreed period is similarly important. The Principal Investigator should consider his/her time and availability to conduct and oversee the study for the entire duration. The Principal Investigator and his/her team should also take note that extra time may be required for additional subject visits or management of adverse events