NON-COMPLIANCE REPORT:

Patient Enrolled into Trial before Screening Procedures and Registration were Complete (Protocol Non-Compliance)

Background

A patient was enrolled into a clinical trial by his physician and was dispensed study medication before the results of a specific screening test were out and registration complete. As the subject had to return to his country, he was discharged with the study medication, although advised not to start until notice was given to do so.

When the full results were out and found to satisfy all inclusion and exclusion criteria, the study nurse proceeded to register the subject through the clinical trial management website.

Due to an error in the system, the registration was unsuccessful. Subsequently, the subject started the medication while the study nurse attempted to resolve the registration problem. However, as treatment started before subject was registered, the subject did not fully meet the inclusion/exclusion criteria and the team was found to be non-compliant with the protocol.

Findings

The study team should not have enrolled the patient into the study until all relevant test results have been obtained to establish a complete determination of his/her eligibility to participate. The research nurse was not thoroughly familiar with the protocol requirements. The Principal Investigator has the responsibility of ensuring his/her study team members are adequately informed about the study procedures and the use of the investigational product. There also appeared to be a lack of communication between the study nurse and the Investigator when the problem arose during registration

Tips for PI

1. At the start of a new study, it is always a good idea to walk through the work flow with your study team members to ensure that every member is familiar with his/her study responsibilities.

2. Encourage discussion of the study progress among your study team members. Discuss any problems or difficulties that may arise during the conduct, and the plans to resolve them timely at the study site

3. If the study is complex or if you have new research staff in your team, you could develop a checklist listing the study procedures, the timelines and the members in charge. In this way, you ensure that your team members know what they need to do.