The Principal Investigator's Roles & Responsibilities

No. 5 : COMMUNICATE WITH REGULATORY AGENCIES AND OBTAIN APPROVAL TO CONDUCT STUDY

Obtaining DSRB and HSA Approval

Before initiating a research study involving human subjects, the Principal Investigator (PI) should obtain the written and dated approval from the NHG Domain-Specific Review Boards (DSRB). In general, approval from the DSRB is valid for a period of one year. For the conduct of clinical trials, approval from the Health Sciences Authority (HSA) is required and is issued in the form of a Clinical Trial Certificate (CTC). Each CTC is valid for a period of two years unless otherwise stated.

Documents For Approval & Ongoing Review

Documents that are to be submitted for approval include the study protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g. advertisements) and any other written information to be provided to subjects.

Documents that are to be submitted for ongoing review include protocol amendments, adverse events, non-compliance, deviations, or new information about the study. No deviation or changes to the protocol should be implemented without the documented approval from the DSRB, except where necessary to eliminate an immediate hazard(s) to study subjects.

Submitting Status Updates

Regular status updates should also be provided to the DSRB and HSA. The DSRB requires a status report form to be submitted annually, at least 30 days before the approval expires. When a study is completed, the PI should submit a study completion report (using the status report form) within 30 days after completing the study. When a study is suspended or terminated by the institution, PI or the sponsor, the PI should submit a report within 7 days.

The HSA requires a 6-monthly report to be submitted from the date of approval. If the trial is expected to continue beyond the 2-year approval period, the Sponsor (or PI for PI-initiated studies) should apply to HSA for renewal 3 months before the approval expires.

Other Changes Requiring DSRB Approval

If the PI is resigning from the institution or is going away for an extended period of time, the research project should be formally transferred to another Investigator. This Investigator assumes all the responsibilities as the PI for the conduct of the research project until the original PI returns. This change should be reviewed and approved by the DSRB. Any other changes to the study team should also be reported to the DSRB.

References:

- Singapore Guidelines to Good Clinical Practice Section 4.4
- Investigator's Manual Chapter 4 Submissions to DSRB
- Health Sciences Authority Guidelines for Clinical Trials