CHICKEN SOUP FOR THE BUSY COORDINATOR

September 2023

What Should Be Done When A Study Is Completed?

Scenario

A Principal Investigator (PI), Dr Bee had completed his PI-initiated ABC research study. He is unsure of what steps should be taken to close his research study. What must he do to ensure the proper closure of the study?

Dr Bee's research study is deemed to have been completed as **all** the following criteria have been fulfilled:

- ☑ The research is permanently closed to the enrollment of new participants.
- ☑ All participants have completed all research-related interventions.
- ☑ Collection and analysis of individually identified data has been completed.

What Should Be Done Upon Study Completion

1. The PI should submit a study completion report within 30 days after completion of the study to notify the IRB to close the research study. *Note: Completion reports should comply with the approving IRB's submission timeline.*

Research Data

2. Dr Bee is responsible for ensuring that all essential documents are complete and up to date, study materials returned or disposed, and all data queries are resolved before closing the study site. He must ensure the accuracy and completeness of data in all study databases and report. *For a list of the essential documents to be maintained for the conduct of a clinical trial, please refer to sections 8.2, 8.3 and 8.4 of the ICH GCP E6 (R2).*
3. The PI must retain the research data for a minimum period of 6 years *(per institution's guideline)*. He may retain research data for a longer period, where it is specifically indicated. Should Dr Bee deem it necessary to archive the database for future reference, he should continue to comply with the guidelines for the storage of data. He shall be responsible for the safekeeping of archived database.

Additionally, Dr Bee may use the Study Closure Checklist to ensure that all necessary aspects of the research study closure and archival have been addressed.

Additional Reminders

- The PI and/or designee is responsible for arranging with Finance to close the research account (if applicable) and arrange for archiving of the study documents.
- Retain the research data according to institution policy, Research Collaboration Agreement (RCA) or Clinical Trial Agreement (CTA), where applicable.
- Clearly indicate the retention period on the source documents kept in medical records.
- For Clinical trials regulated under the Health Product Act (HPA) or Medicines Act, check and comply with the minimum retention period.
- Databases that are created with the intention of using the stored data for future research should be registered as a Standing Database (SDB). Prior permission must be sought from the relevant institutional authorities before the setting up of SDBs. Comply with respective institutions' SOPs and/or guidelines for the registration of a Standing Database.

REFERENCES

1. NHG investigator Manual _Edition 4
2. Investigator File Contents Template & Study Closure Checklist are available at https://www.research.nhg.com.sg > Resources > Proper Conduct of Research SOP & Templates.
3. NHG PCR SOP 501-B05 Documentation

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