Documentation & Record-Keeping

Part 1: Introduction

Proper documentation is critical to the success of a clinical study. Every aspect of the study must be documented in order to obtain useful data and demonstrate compliance with Good Clinical Practice (GCP) guidelines and with all applicable regulations.

This module provides an overview of SGNHC Research Unit documentation requirements.

Part 2: Documentation Requirements

Documentation Requirements in SGNHC Research Unit Guidelines

Essential documents for the conduct of a clinical study are defined in ICH GCP 8.1 as follows:

"…those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements."

Essential documents may be audited or inspected by quality assurance monitors or by regulatory authorities to confirm the validity of the study and the integrity of the data collected.

The sponsor and the investigator/institution should maintain a record of the location(s) of their respective essential documents, including source documents. Additional documents may be developed and maintained by the sponsor or the sponsor(s) representatives.

Before a Study Begins

The following essential documents must be created and kept on file at study sites before a study begins:

- Signed **protocol** and amendments, if any.
- IRB-approved **Informed Consent** Form, **Information Sheet** and any other written information that will be given to prospective study participants to enable them to make an informed decision about enrolling in the study.
- Sample case report forms, either electronic or paper.
- Participant recruitment procedures, if any.
- Documentation that the **SGNHC Research Unit** and **Institutional Review Board** (IRB) approvals have been obtained.
- Documentation of study personnel's qualifications (e.g., curriculum vitae, professional licenses).

- Documentation of financial agreements and any other arrangements between the parties involved in conducting the study (e.g., investigator(s), institution(s), sponsor, contract research organization).
- **Investigator's Brochure**, when applicable.
- Evidence of notification, approval, or authorization of the protocol and its supporting documentation by regulatory authorities (if required)
- Evidence of approval or certification of facilities that are performing medical or laboratory tests required by the study protocol.
- Normal value(s)/ range(s) for medical, laboratory, and/or technical procedures and tests included in the protocol.

While a Study is in Progress

The following are essential documents that should be added to the file while a study is in progress:

- Amendments to the Protocol and changes to the case report forms (CRFs), recruitment materials, Informed Consent Form, and Investigator's Brochure.
- Documentation of approval of amendments by the **Institutional Review Board** (IRB) and regulatory authorities (if required).
- Informed consent forms signed by study participants.
- Signed, dated, and completed CRFs and documentation of any CRF corrections with the signature sheet.
- Curriculum vitae for investigators and co-investigators.
- **Source documents**.
- Participant screening log, enrollment log, and identification code list.
- Records of location and identification of retained tissue samples, if any.
- Staff signature log, documenting signatures and initials of all persons authorized to make entries and/or corrections to CRFs.
- Updates to CVs, license etc.

After a Study is Completed or Terminated

The following are essential documents that should be added to the file after a study is completed or terminated:

- List of all participants enrolled in the study at the site (completed subject identification code list).
- Final reports to Institutional Review Boards and SGNHC Research Unit.
- Clinical study report, which documents the study's results, if applicable.

Part 3: Examples of other Required Documents

In addition to the essential documents included in the guideline, the researcher may require other documentation. The following lists are the examples of other documentation that may apply to clinical trials.

a) Certificate of Confidentiality

b) Quality assurance Documents
c) Training Documents
d) Behavioral Therapy Documents
e) Source Documents
f) Progress Notes
g) Case Report Forms

Part 4: Summary of Key Points

- Every aspect of a clinical study must be documented in order to obtain useful data and demonstrate compliance with Good Clinical Practice (GCP) standards and with all applicable regulations.
- SGNHC Research Unit guidelines specify the essential documents that must be maintained for every clinical study. These documents are classified according to whether they are normally created before a study begins, while a study is in progress, or after a study is completed or terminated.
- Source documents are original documents created during a clinical study, from which study data are obtained. The purpose of source documents is to document the existence of study participants and substantiate the integrity of the study data collected.