ALBERTA CLINICAL RESEARCH CONSORTIUM
MANAGED BY ALBERTA INNOVATES

Tool Time
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Data Collection Package

Clinical Research Stage:

Development

Pre-Initiation

Active Study

Close-out

ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

Alberta SPOR Support Unit

College of Physicians & Surgeons

Covenant Health

University of Alberta

University of Calgary

The ACRC is committed to quality and continuous enhancement. We welcome your input! Forward comments, suggestions and any feedback from Health Canada inspections to: acrc@albertainnovates.ca

Case report forms (CRFs) are the tools used for collecting participant data from the study sites. CRFs ensure that data is collected in a standard format and they may be in paper or electronic form. CRFs are developed in the pre-clinical (development) phase of the study and should accurately reflect the data specified by the protocol. They are essential documents, and as per good clinical practice should be on file before the trial formally starts[1].

Attached are several samples of common types of case report forms. Each may be modified to meet the needs of the specific study protocol:

- Concomitant medications tracking: Sample form to record participant's medication usage.
- Medical History: Sample form to record participant's medical history
- Physical Exam: Sample form used to record participant's physical exam findings.
- Vital Signs: Sample form used to record participant's vital signs.
- Baseline Visit Checklist: Checklist which may be used to ensure that all assessments scheduled to be done at the baseline visit have been completed.
- Follow up Visit Checklist: Checklist which may be used to ensure that all assessments scheduled to be done at ongoing study visits have been completed.
- Study Completion: Sample form to record and explain participant's final study status.

The following templates may be helpful to the study staff in following the flow of study assessments and procedures through a particular study visit. For the purpose of these flowsheets, we have populated the samples with examples related to a stroke study. These templates can be customized for each visit, relevant to your study:

- Research Coordinator Flowsheet (sample)
- Study Flowsheet Template (sample)
- Nursing Checklist (sample)
- Participant Diary (sample)

[1] ICH Guidance E6: Good Clinical Practice: Consolidated guideline, 8.2

Filling out case report forms:
Documentation on case report forms should follow the **ALCOA** principle[2/3]:

Attributable--documentation should be initialed and dated by the person filling out the form;
Legible--entries should be clear and easy to read;
Contemporaneous--the data should be recorded close to the time of observation;
Original--original or source data is considered of higher quality; and
Accurate--the data should be checked for accuracy and any changes recorded.

Changes: Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry. Crossing out with a single line is the accepted method for correcting a CRF entry to retain legibility. The investigator should maintain a record of any changes[4]

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[2] Handbook for Good Clinical Research Practices, Guidelines for Implementation, World Health Organization 2002, p94
[3] Guidance for Industry, Computerized Systems used in Clinical Investigations, FDA 2007, p2
[4] ICH GCP E6 (4.9.3)