SOP 08 Case Report Forms and Source Documents

1.1 Purpose

To describe the procedures related to the completion of electronic and paper based Case Report Forms (CRF), and maintenance of Source Documents.

1.2 Scope

This Standard Operating Procedure (SOP) applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants, facilities and or staff. All study personal involved in the clinical study must operate within their scope of practice.

1.3 Procedure

8.1 Completion of Case Report Forms

Where electronic medical records (EMR) are used, a validation system is required with an inbuilt correction and audit trail feature. In the case where there is no inbuilt validated audit trail, printed records of the changes and corrections (e.g. data queries) must be retained.

The Investigator must:

- Ensure the accuracy, completeness, legibility, (including any changes or corrections) and timeliness of Source Data and data recording adheres to the Protocol, monitoring plan requirements and also the Supervision Plan.
- Ensure that any party delegated to perform data entry or signing for data completeness is recorded on the Delegation Log and is trained to perform those trial related duties and functions.
- Ensure that changes to the paper Source Document do not obscure the original entry, are traceable (signed and dated) and explained (i.e. an audit trail should be maintained).

Source Data are defined as: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Collection of accurate Source Data (contained in Source Documents) is essential for compliance with GCP. The format used (whether paper or electronic) should permit the

reconstruction of the clinical care given to the participant and describe any significant participant-related events that may occur during the conduct of the trial.

Source Data should be attributable, legible, contemporaneous, original and accurate (ALCOA). Changes to Source Data should be traceable, should not obscure the original entry, and should be explained if necessary. In addition, Source Data in electronic Form should be complete, consistent, enduring, and available (ALCOA +).

The CRF is defined in ICH GCP as: A printed, optical or electronic document designed to record all of the Protocol required information to be reported to the Sponsor on each trial subject. The data collected in the CRF is used as the basis of the trial report and any publications, as well as making up part of the data for regulatory approval for the unapproved therapeutic goods. The PI has ultimate responsibility for the content of the CRF but may delegate the task to suitably qualified individuals. The PI should, however, maintain oversight of the quality of the data provided to the Sponsor.

Access to the participant's trial related information should be limited to authorised users. Where access (e.g. for trial monitors, auditors and inspectors) cannot be limited to trial participants, certified paper copies of trial related information should be printed.

8.2 Source Documents

The Investigator must:

- Maintain adequate Source Documents and trial records including all key observations on each of the trial participants.
- Store all trial related documents in a Study Master File/Satellite Site Study File as required by the applicable regulatory requirement, Sponsor and Protocol and take measures to prevent accidental or premature destruction of these documents.
- Ensure, for both paper and electronic documents, all changes, corrections and amendments are tracked, and version dates and numbers, are updated to reflect the changed data and to maintain the integrity of the data. An explanation of the changes is noted in a record of change.
- Ensure all staff are aware that, upon request, direct access to all trial related records is given to the monitor, auditor, HREC, RGO or regulatory authority, to enable Source Data verification, Sponsor audits or regulatory inspection. Direct access is stipulated in the CTRA and outlined to the participant via the PICF.
- Ensure that for telehealth consultations, the call is documented in the participant's health and medical record at each site as documented in the Supervision Plan, which will detail where the original and certified copies are stored. The written record will include a brief summary of the Protocol number, consultation; follow up instructions and that the visit was conducted via telehealth.
- For paper records, ensure that the agreed approach to Source Documents in the Supervision Plan is followed. This could include requiring a certified copy of any key Essential Documentation generated at the Satellite Site to be sent to the Primary Site for filing in the SMF e.g. SAE reports, to allow remote monitoring by the Sponsor and for auditing and inspection purposes. These can be sent via email or post.

- Where EMR are in use, access to the patient's/participant's trial related information must be limited to authorised users only. The Investigator must ensure appropriate controls are in place to allow access to the patient's/participant's EMR for the purpose of monitoring the study. Authorised users should include CRAs, auditors and regulatory inspectors, subject to those users meeting local access requirements.
- Where there is not a locally accepted practice to limit access in the EMR to limited patients/participants, other measures must be put in place to ensure the patient's/participant's privacy and confidentiality are respected e.g. print the trial related information, sign as a certified copy and place in a paper record for access by Sponsor, regulatory inspectors and auditors etc.

For teletrials, providing access to the Satellite Site EMR from the Primary Site (for PI oversight and study monitoring) is to be encouraged in order to increase the efficiency of study conduct under the Teletrial Model.

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association

ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

○ Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	*13/11/2025*	Initial Version	Katie Ozdowska