Western Health

STANDARD OPERATING PROCEDURE

Case Report Forms Source Documents Record Keeping and Archiving

Standard Operating Procedure

Western Health

SOP reference	007
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Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs, WH EMR and corporate records requirements

1. AIM

To describe the procedures related to the completion of case report forms, source documents, record keeping and archiving.

2. SCOPE

Applicable to all clinical research projects undertaken at Western Health (WH), including Investigator initiated research, collaborative research , commercially sponsored research and all phases of clinical investigation for medicinal products, medical devices and diagnostics for which WH is responsible for the conduct of the trials as a study site.

3. APPLICABILITY

Principal Investigator (PI), Associate Investigator(s), research coordinators and other staff delegated research/trial-related activities by the PI.

The PI is responsible for supervising any activities described in this Standard Operating Procedure (SOP) that have been delegated to ensure they are conducted appropriately. The PI remains responsible for any delegated activity.

4. PROCEDURE

For investigator initiated trials where WH is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

All research study information (clinical trial or other) should be recorded, handled and stored/digitised in a way that maintains data integrity and allows its accurate reporting, interpretation and verification. This principle applies to all records referenced in the WH SOPs, irrespective of the type of media used and format (paper vs digital).

4.1. Completion of Case Report Forms (CRF) and Data Collection Forms (DCF)

The investigator(s) should:

STEP	ACTION
4.1.1	Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the Case Report Forms (CRFs) and in all required reports.
4.1.2	Ensure that data reported on the CRF/DCF, that are derived from source documents, be consistent with the source documents or the discrepancies should be explained.
4.1.3	Ensure that any change or correction to a CRF is dated, initialled, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes and corrections.
4.1.4	Retain records of the changes and corrections.
4.1.5	The participant's identity should remain confidential. The participant should only be identified on the CRF/DCF by means of the allocated study number and/or initials. The Subject Identification Log (a confidential record of participants with their full name and study number) must be kept separately and securely by the PI.

4.2. Source documents, record keeping and archiving

The investigator(s) should:

STEP	ACTION
4.2.1	Keep original source documents (where the data was first recorded) and take measures to prevent accidental or premature destruction of these documents. This includes sending progress notes to be included in the Medical Records.
4.2.2	Maintain the trial documents as specified appropriate for your study in the WH Trial Master File (TMF) Checklist, as required by the applicable regulatory requirement(s), and take measures to prevent accidental or premature destruction of these documents.
4.2.3	Ensure that financial aspects of the trial are documented in an agreement between the sponsor and the investigator/institution.
4.2.4	Ensure that upon request of the monitor, auditor, Human Research Ethics Committee (HREC), or regulatory authority, make available for direct access all requested trial related records.
4.2.5	In Victoria, the minimum recommended period of retention of health information is 7 years after the last occasion on which a health service was provided to the individual (Health Records Act (2001)). The minimum recommend period of retention of research data is 5 years from the date of publication – whichever is the later. Documentation should be maintained as specified in the Australian Code for Responsible Conduct of Research 2007 (Part A, Section 2.1) as indicated below: • For short term research projects, that are for assessment purposes only (e.g. research projects completed by students), retention of research data for 12 months after completion of the project may be sufficient. • Study documentation should be maintained for a minimum of 15 years for adult studies or 25 years for paediatric studies after trial closeout. • For areas such as gene therapy, research data must be retained permanently (e.g. patient records).
4.2.6	For legal reasons, sites may consider indefinite archiving periods. • The Therapeutic Goods Administration (TGA) position on document retention states: "The TGA requires records to be retained by the sponsor for 15 years following the completion of a clinical trial. However, in Australia the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product" • International Conference on Harmonisation (ICH)-Good Clinical Practice (GCP) requirements for record retention state: "Ensure that essential documents are retained until at least 2 years after

	the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor".
4.2.7	Original documents or certified scanned copies should be retained.
4.2.8	Generate certified copies according to ICH-GCP guidelines.
4.2.9	Ensure that source data does not deteriorate. Equipment printouts often use thermal paper that is not stable and may not be legible for the entire period that records must be stored for. Printouts should be photocopied and certified as true copies.
4.2.10	Record all interactions with participants in accordance with local policies.
4.2.11	Research data should not be captured, managed and stored on portable devices. Only if deemed necessary should certain data be transferred and saved on portable devices such as: USB, portable computer or mobile phone. If data is to be temporarily stored on portable devices, the following must be adhered to: • Device must be password protected • Only the minimum data required to perform the intended activity should be downloaded into a portable device • All data on portable devices must be de-identified, non-identifiable data • Portable devices must not contain patient Master list or any other information that could facilitate the identification of patients • All data should be properly deleted from the portable device once its use has been fulfilled
4.2.12	Research data, including de-identified data, should not be shared through non Western Health data sharing accounts. Email and Drop Box are not WH approved applications for sharing de-identified research data. The storage, retrieval and disposal of records must be conducted in accordance with the WH medical records or corporate records policies, whichever is applicable to your particular research project. The relevant policies can be accessed via the below web link. If in doubt, please contact the corporate records department.
4.2.13	For paper records to be digitalised, certified copies must be created through a validated process in accordance with GCP ICH.

1. GLOSSARY

Associate Investigator

Any individual member of the project team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as "Sub-Investigator"

Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.

Certified Copy

A copy (irrespective of the type of media used) of the original record that has been verified (i.e. by a date and signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Principal Investigator (PI)

An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Source Documents

Original documents (where the data was first recorded), data, and records (e.g., hospital records, clinical and office charts,

laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Standard Operating Procedure (SOP)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

Therapeutic Goods Administration (TGA)

Authority responsible for regulating medicines, medical devices, blood, and tissues.

Trial Master File (TMF)

A file that contains all the applicable essential documents that demonstrate that the study/trial has been conducted in accordance with regulatory requirements and ICH GCP, enabling both the conduct of a project and the quality of the data produced to be evaluated. The preparation and maintenance of the Study File resides with the Site Investigator and set up at the start of a trial and is archived at the end of the trial. This may also be called the "Study Site Master File" or "Investigator Site File".

2. REFERENCES

1. Based on VMIA GCP SOP No.007 Version:1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.007 Version:1.0
3. WH Corporate Records Management: http://inside.wh.org.au/departmentsandservices/CorpRecordMgt/Pages/default.aspx
4. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, section 4.
5. Health Records Act (2001) (Vic) – Schedule 1 The Health Privacy Principles
6. NHMRC Australia Code for the Responsible Conduct of Research (2007)
7. NHMRC National Statement on Ethical Conduct in Human Research (2007)

3. AUTHORS/CONTRIBUTORS

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4. PRIMARY PERSON/DEPARTMENT RESPONSBLE FOR DOCUMENT

Western Health Office for Research