

Case Report Forms, Source Documents, Record Keeping and Archiving

Standard Operating Procedure

Office of Health and Medical Research

Queensland Health

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Amendment History

Version	Date	Author/s	Amendment Details

1 Purpose

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

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

3 Applicability

Principal Investigator, Associate/Sub-Investigator(s), Research Coordinators and other staff delegated project-related activities by the Principal Investigator.

4 Procedure

4.1. Completion of case report forms (CRFs and e-CRFs)

The investigator(s)/ institution should:

- Ensure the accuracy, completeness, legibility, and timeliness of data collection is adhered to according to the protocol. **ICH GCP 4.9.1**
- Ensure the accuracy, completeness, legibility, and timeliness of data collected in the CRFs or e-CRFs and other required documents submitted to the sponsor or Coordinating Investigator is adhered to according to the protocol.
- Ensure that data reported on the CRF or e-CRFs, which is derived from source documents, is consistent with the source documents. Any discrepancies should be explained. **ICH GCP 4.9.2**
- Ensure that any change or correction to a paper CRF is made with a single stroke through the incorrect information, dated, initialled, and explained (if necessary). The original entry should not be obscured (i.e. an audit trail should be maintained). eCRF's are required to have an inbuilt correction and audit process. However, if there is no inbuilt audit trail, see below. **ICH GCP 4.9.3**
- Retain records of the changes and corrections (eg data queries) to demonstrate an audit trail.

4.2. Source documents, record keeping and archiving

The investigator(s) should:

- Keep original source documents (where the data was first recorded) and take measures to prevent accidental or premature destruction of these documents. **ICH GCP 4.9.7**
- Ensure that any change or correction to any source data is made with a single stroke through the incorrect information, dated, initialled, and explained (if necessary). The original entry should be not obscured (i.e. an audit trail should be maintained). This applies to written changes or corrections. **ICH GCP 4.9.3**
- Where an investigator is using their own electronic CRF documents, changes and amendments should be tracked, and version dates (and numbers, depending on the

degree of change) should be altered to reflect the changed data. An explanation of the changes should be added in the footer, or noted in a record of changes. **ICH GCP 5.5.3**

- Ensure that a copy of the signed and completed Participant Information Sheet and Consent form has been filed in the appropriate place in the hospital chart (follow local Medical Records guidelines). **(Institutional guidelines)**
- Maintain the trial documents as specified in QH SOP 2 appendix 2 - The Study Site Master File and Essential Documents and as required by the applicable regulatory requirement(s) and take measures to prevent accidental or premature destruction of these documents. **ICH GCP 4.9.4**
- Ensure that upon request of the monitor, auditor, HREC, Governance Officer or regulatory authority, make available for direct access, all requested project related records as outlined in the Clinical Trial Agreement and Patient Information Sheet and Informed Consent Form. **ICH GCP 4.9.7**
- Ensure that in those instances where a study participant does not have a medical record for that institution, that a medical record is created in accordance with local hospital requirements. **(Institutional guidelines)**

4.3. Archiving

- Study documentation should be maintained as specified in the Australian Code for the Responsible Conduct of Research (Part A, Section 2.1) (http://www.nhmrc.gov.au/files_nhmrc/file/publications/synopses/r39.pdf) as indicated below:
 - For short term research projects, that are for assessment purposes only (eg research projects completed by students), retention of research data for 12 months after completion of the project may be sufficient.
 - For clinical trials, data should be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies after formal notification is received that all study procedures are completed and the study is closed.
 - For areas such as gene therapy, research data must be retained permanently (eg patient records).
 - If the work has community or heritage value, research data should be kept permanently, preferably within a national collection.
- For legal reasons, sites may consider indefinite archiving periods.
- The 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”.
- ICH-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”.

- Original documents should be retained. Scanned copies are acceptable if certified as true and correct. **ICH GCP 1.51 and 1.52**
- A Document Retention Sticker must be placed on all volumes of the Participant's medical record in an appropriate position as guided by local Medical Records practice. **(Institutional guidelines)**
- Queensland Government has a "Standing Offer" arrangement for the provision of records storage, retrieval and destruction services (off-site) for non-commercially sponsored research. For details, refer to the following weblink: <http://qcd.govnet.qld.gov.au/Pages/Details.aspx?SOANumber=QGCPO747-08>. This service is NOT available for commercially sponsored research.
- For commercially sponsored research, private archiving arrangements should be negotiated with the study sponsor (and the site Medical Records Department, if applicable at that site) prior to commencement of the study. These details should be noted in the study contract.
- Identifiable information that is part of a commercially sponsored clinical trial (eg Participant Identification Log and Participant Information Sheet and Consent Forms) should be separated from the main study documents, and archived with the Principal Investigator – in case identification of participants is required at a later time. A reference to the type and location of these documents should be filed with the archived study documents. **ICH GCP 8.3.21**
- A copy of the Subject Identification Log listing all contact details plus hospital specific medical record number to be used for future reference should be kept in a file with the Principal Investigator to be used for future reference.

5 Glossary

Case Report Form (CRF and e-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 subject.

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 subjects 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.

Investigator

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, one investigator should be designated as the responsible leader of the team and should be called the site 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. medical/hospital records, clinical and office charts, laboratory notes, memoranda, subjects' 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, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Sub / Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

6 References

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, section 4.