Research case report forms, source documents, record keeping and archiving

Procedure

MonashHealth

Who must comply with this procedure?
Principal Investigator and all staff conducting research at, or under the auspices of, Monash Health.

This procedure applies in the following setting:
This procedure is applicable to all Monash Health staff, patients, clients and their families and carers.
Research and Ethics case report dorms, source documents, record keeping and archiving

Precautions

- The Therapeutic Goods Administration 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 – Good Clinical Practice 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 are retained for a longer period however, if required by the applicable regulatory requirements or by an agreement with the sponsor".

1. Completion of case report forms

1.2 The investigator(s)/ institution must:

- Ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms (CRF) and in all required reports.
- Ensure that data reported on the CRF, that are derived from source documents, be consistent with the source documents or the discrepancies are explained.
- Ensure that any change or correction to a CRF is dated, initialled, and explained (if necessary) and is not obscure the original entry (i.e. an audit trail maintained); this applies to both written and electronic changes and corrections.
- Retain records of the changes and corrections.

2. Source documents, record keeping and archiving

2.1 The investigator(s) must:

- Keep original source documents (where the data was first recorded) and take measures to prevent accidental or premature destruction of these documents.
- Maintain the trial documents as specified in - The Research study site master file documents procedure, and as required by the applicable regulatory requirement(s) and take measures to prevent accidental or premature destruction of these documents.
- Ensure that financial aspects of the trial are documented in an agreement between the sponsor and the investigator/institution.
- Ensure that upon request of the monitor, auditor, Human Research Ethics Committee, or regulatory authority, make available for direct access all requested trial related records.
- Study documentation are maintained for the following minimum retention periods:
  - For participants 18 years and over, 15 years following the completion of a

clinical trial;
  - For participants under 18 years, 15 years following completion of a clinical trial or until the youngest participant has reached 25 years of age, whichever is longer;
  - For participants 18 years and over, 7 years following completion of a clinical research study;
  - For participants under 18 years, 7 years following completion of a clinical research study or until the youngest participant has reached 25 years, whichever is longer;
  - For ongoing studies such as registries, data must be maintained indefinitely;
  - For research that led to a ground-breaking or a significant discovery, data must be retained indefinitely. In this instance, the Principal Investigator would seek approval from the Executive Director responsible for research, prior to archiving the documents with the Public Records Office of Victoria (PROV).
- Original documents are retained; scanned copies are not yet generally accepted as archives.

Useful resources

National Statement on Ethical Conduct in Human Research (2007) under rolling review.

Australian code for the responsible conduct of research (2007)

TGA (2000). *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), Glossary 1.28*, Department of Health and Ageing, Australian Government, Canberra.

Health Records Act 2001 (Vic)

Keywords or tags

CRF, Data; Records; Management; Secure

Document Management
Policy supported: Research and Ethics Operational Policy
Executive sponsor: Chief Medical Officer
Person responsible: Director of Clinical Research