Who must comply with this procedure?

Principal Investigator and all staff conducting research at, or under the auspices of, Monash Health or which involves Monash Health staff, resources, patients, their tissue samples, test results or medical records.

This procedure applies in the following setting

This will provide researchers with sound practices for managing all data throughout the projects life and addresses the ownership of research materials and data, their storage, their retention beyond the end of the project, and appropriate access to them by the research community.

Definitions

Data

Data are pieces of information, for example:

- what people say in interviews, focus groups, questionnaires, personal histories and biographies;
- analysis of existing information (clinical, social, observational or other);
- Information derived from human tissue such as blood, bone, muscle and urine.

Identifier – Details attached to data, such as name and/or contact information, that identify an individual. It may remain possible to identify an individual even after all identifiers have been removed, if a code number has been assigned and there is access to the code, or if the data or tissue can be cross linked to other data or tissue banks.

Data may be collected, stored or disclosed in three mutually exclusive forms:

- individually identifiable data - where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- re-identifiable data - from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets,
- non-identifiable data -which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

Precautions

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Strategic Policy

Researchers must maintain the same level of care and protection to primary research records as to the analysed research data.

Researchers must keep clear and accurate records of the research methods and data sources, including any approvals granted, during and after the research process.

Researchers must retain data, including electronic data in a durable, indexed and retrievable form, and manage primary materials according to ethical protocols and relevant legislation.

Researchers given access to confidential information must maintain confidentiality. Confidential information must only be used in the ways agreed with those who provided it. Particular care must be taken when confidential data are made available for discussion.

Rationale

The responsible conduct of research includes the proper management and retention of research data. Retaining the research data is important because it may be all that remains of the research work at the end of the project. While it may not be practical to keep all the primary material (such as ore, biological material, questionnaires or recordings), durable records derived from them (such as assays, test results,

transcripts, and laboratory and field notes) must be retained and accessible.

The researcher must decide which data and materials must be retained, although in some cases this is determined by law, funding agency, publisher or by convention in the discipline. The central aim is that sufficient materials and data are retained to justify the outcomes of the research and to defend them if they are challenged. The potential value of the material for further research must also be considered, particularly where the research would be difficult or impossible to repeat.

The Principles of the International Conference on Harmonisation – Good Clinical Practice (ICH GCP) state that "All clinical trial information must be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification".

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 must be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor".

1. During the research project:

1.1 The Head of Department or Principal Investigator(s) conducting the research is/are responsible for the storage of data collected by their researchers, and for maintaining clear and durable records concerning the location of stored data. The original data must be able to be distinguished from all subsequent analyses and the preparation of material for publication.

1.2 The study coordinator/investigator will keep a study document file as a central record of all important issues involving the study. It is important to keep all paper work for a study in an orderly fashion and to have a paper trail that can be followed throughout the study. Keep in mind that your study may be audited at any time.

1.3 The Principal Investigator(s) is/are responsible for ensuring that all research data is kept in a safe and secure storage location, even when not in current use. Examples include USB, locked filing cabinets, password protected laptop.

1.4 The Principal Investigator(s) is/are responsible for ensuring that all data reported in the Case Report Form, derived from source documents, must be consistent with the source documents or discrepancies explained.

2 After completion of the research project, the researchers are responsible for compliance with the following practices:

2.1 Researchers must decide which data and materials must be retained. However, in some cases this is determined by law, funding agency, publisher or by convention in the discipline.

2.2 Researchers must retain research data for sufficient time to allow reference to them by other researchers and interested parties. Original data is the property of Monash Health and must be retained as follows:

- 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).

2.3 If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

2.4 Researchers must retain data, including electronic data in a durable, indexed and retrievable form, and manage primary materials according to ethical procedures and relevant legislation.

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

Data; Records; Management; Secure

Document Management
Policy supported Human Research Strategic Policy
Executive sponsor: Chief Medical Officer
Person responsible: Director, Clinical Research