Data Storage, Retention, Privacy and Confidentiality in Research Procedure

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TARGET AUDIENCE and SETTING

Principal Investigators and all staff conducting research at, or under the auspices of, Monash Health or which involves Monash Health staff, resources, and/or patients.

PURPOSE

To inform researchers of requirements for managing data throughout a project's life and to address data ownership, storage, retention, access and sharing.

The *Health Records Act (Vic)* 2001 creates a framework to protect the privacy of an individual's health information. It regulates the collection and handling of health information. It establishes the Health Privacy Principles that apply to health information collected and handled in Victoria by the Victorian public sector.

Research depends on participants volunteering information. A participant is more likely to provide honest responses when their identity is not going to be exposed / identified.

Privacy must be addressed from start-up to completion of the project, with safety nets in place to guarantee confidentiality.

The amount of data collected must be the minimum amount required to ensure sufficient sampling of the population.

In Victoria, all research must comply with the *Health Records Act* 2001(Vic) Statutory Guidelines on Research issued for the purpose of Health Privacy Principles 1.1(e) (iii) & 2.2(g) (iii).

All research must comply with the Commonwealth of Australia *Guidelines approved under Section 95A of the Privacy Act* 1988.

DEFINITIONS

Data

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 or contact information, which identify an individual. It may remain possible to identify an individual even after all identifiers have been removed. For example, if a code number is assigned to the data but there is access to the code, or if the data or tissue can be cross linked to other data or tissue banks.

Types of Data

Data may be collected, stored, or disclosed in the following four forms:

i. **Individually identifiable data** - where the identity of a specific individual could reasonably be ascertained through identifiers such as the individual's name, image, date of birth or address.
ii. **Re-identifiable data** – where identifiers have been removed and replaced by a code, an individual could be reidentified by, for example, using the code or linking different data sets.
iii. **Non-identifiable data** – where data has never been labelled with identifiers or all identifiers have been permanently removed, so there are no means by which a specific individual could be identified. A subset of non-identifiable data is data that can be linked through other data so that it is known the data are about the same subject, but the identity of the individual remains unknown.
iv. **Anonymised data** – where identifying information has never been collected, for example, in an anonymous survey.

Privacy: A domain within which individuals and groups are entitled to be free from the scrutiny of others. NHMRC *National Statement on Ethical Conduct in Human Research 2007 – updated 2018.*

Confidentiality: The obligation placed on people is not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them. NHMRC *National Statement on Ethical Conduct in Human Research 2007– updated 2018.*

Health Information: All identifying personal information collected to provide a health service; medical and other health details plus all other personal information (financial information, names of relatives etc.)

PRECAUTIONS/CONTRAINDICATIONS

The Victorian legislation on Health Records and Information Privacy came into effect in July 2002, and sets out requirements for the collection, handling, use and disclosure of personal and health information. Researchers must be aware of their obligations with regard to the use of such information.

In addition, from 12 March 2014 the Australian Privacy Principles came into effect.

Personal identifiable information must not be collected or maintained unless absolutely necessary.

PROCEDURE

Researcher responsibilities

Researchers are responsible for:

- Conducting research in accordance with the Human Research Strategic Policy
- Maintaining the same level of care and protection to primary research records as to the analysed research data
- Keeping clear and accurate records of the research methods and data sources, including any approvals granted, during and after the research process.
- Retaining data, including electronic data, in a durable, indexed and retrievable form, and manage primary materials according to ethical protocols and relevant legislation
- Maintaining confidentiality of information, and only providing information in the ways agreed with those who provided it. Particular care must be taken when confidential data are made available for discussion.

Prior to the commencement of a research project, the Principal Investigator must:

- ensure all research staff are properly trained in procedure to maintain confidentiality;
- communicate to participants, before obtaining their consent, information on how their privacy and confidentiality will be protected. If consent is to be waived, the HREC must be satisfied that there is sufficient protection of participant privacy, and there is an adequate plan to protect the confidentiality of data;
- protect the identity of participants when disseminating information and storing material;
- Inform participants about any potential to be identified in the results of research even if identifiers such as name and address have been removed.

Data Ownership

Original data are the property of Monash Health.

Data Storage

Heads of Department and Principal Investigators are responsible for the storage of data collected by their researchers and maintaining clear and durable records concerning the location of stored data.

- A study document file must be maintained as a central record of all important issues involving the study.
- Paperwork must be kept in an orderly fashion so that a paper trail of study progress can be easily followed.
- Data reported in the case report forms must be consistent with the source documents, and any discrepancies must be documented and explained.
- Data must be kept in a safe and secure location, even when not in current use. For example, locked filing cabinets, password protected devices, Monash Health One Drive, Monash Health 365 restricted Teams or SharePoint folder, or a Monash University hosted platform available through HELIX, such as REDCap.
  Collected data must be distinguishable from all subsequent analyses and the preparation of material for publication.

Researchers should bear in mind that a study can be audited at any time.

Data Retention

Researchers must decide which data and materials are to be retained. In some cases, this is determined by law, funding agency, publisher or convention in the discipline. Data must be retained for sufficient time so they can be referenced by other researchers or interested parties.

Minimum retention periods for research data differ depending on the participant age and project type. The minimum retention periods are outlined in the table on the next page.

Project Type	Participants 18 years of age and over	Participants under 18 years of age
Clinical trial	Data must be retained for 15 years following completion of the trial	Data for an individual must be retained for 15 years after that individual reaches 18 years of age
Research involving access to medical records	Data must be retained for 7 years following completion of the study	Data for an individual must be retained for 15 years after that individual reaches 18 years of age
Research not involving access to health records	Data must be retained for 5 years	Data for an individual must be retained for 15 years after that individual reaches 18 years of age
Genetic research (including gene therapy)	Data must be retained permanently	Data must be retained permanently
Registries	Data must be maintained indefinitely	Data must be maintained indefinitely
Research that led to a ground-breaking or significant discovery	Data must be retained indefinitely – the principal investigator must seek approval from the executive director responsible for research to archive data with the Public Records Office of Victoria (PROV)	Data must be retained indefinitely – the principal investigator must seek approval from the executive director responsible for research to archive data with the Public Records Office of Victoria (PROV)

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.

Data Access and Sharing

Sharing of data must be done in accordance with the relevant ethics and governance approvals and in compliance with:

- Monash Health Privacy Release of Information Procedure
- Monash Health Collaborative Research across Institutions Procedure

Researchers should obtain informed consent for use and sharing of data from the individuals whose data is being collected. Sharing of data should be considered in the planning stages of a research project so appropriate consent can be obtained.

Data Privacy and Confidentiality:

- **In case of research involving human genetics, the following must be described in the ethics application:**
  The method by which the confidentiality and privacy of stored genetic information or research results relating to identified or re-identifiable participants will be ensured. Such information or research results must be disclosed to treating clinicians only in accordance with the consent given for the research.

- **In the case of research involving data banks the following must be described in the ethics application form:**
  How data will be collected, stored, used and disclosed, and an outline of how that process aligns with the National Statement. Any formal research in which the information contained within a database is to be used or disclosed must first be approved by the approving HREC.

- **In the case of research involving human tissue samples, the following must be described in the ethics application form:**
  A procedure in relation to the collection, storage, use and disposal of human tissue in research, to cover issues of confidentiality, and privacy of samples and information. Please refer to the Use of Human Tissue in Research Procedure.

- **In the case of research involving people who may be involved in illegal activities, the following must be described in the ethics application form:**
  In research that may potentially discover illegal activity, but is not designed to expose it, researcher's must explain to participants as clearly as possible, the extent to which the researcher will keep confidential any information about illegal activity by participants or others, and the response the researcher will make to any legal obligation or order to disclose such information.

During the review of an ethics application, the Monash Health HREC must:

- Approve the research in which the health information is to be used, under the Statutory Guidelines on Research issued for the purposes of Health Privacy Principles and the *Health Records Act* 2001 (Victoria) and in accordance with the Australian Privacy Principles.

- Only give approval under the Act for the collection, use or disclosure of health information for the purpose of research, in the public interest, in accordance with the Guidelines.

- Be constituted in accordance with the *National Statement on Ethical Conduct in Human Research 2023.*

BACKGROUND

Responsible conduct of research includes proper storage and retention of research data. Retaining 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 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.

Data and materials must be retained so that there is sufficient evidence 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 requirements under ICH GCP are to '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'.

The Therapeutic Goods Administration (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'.

KEY STANDARDS, GUIDELINES OR LEGISLATION

1. Australian Commission on Safety and Quality in Health Care – National Clinical Trials Governance Framework and User Guide(February 2022)
2. Australian Code for the Responsible Conduct of Research
3. National Statement on Ethical Conduct in Human Research
4. Therapeutic Goods Administration – Australian Clinical Trial Handbook
5. Health Records Act 2001 (Vic)
6. Australian Privacy principles (March 2014)

Document Governance	
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