

### TARGET AUDIENCE and SETTING

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All Monash Health staff and students conducting research on the campuses of Monash Health and the individual research institutes and groups for whom the Monash Health Human Research Ethics Committee provides research governance and services.

### PURPOSE

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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

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**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

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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.

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## Privacy and Confidentiality in Research

## Procedure

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

### PROCEDURE

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**During the application process, in the case of research involving human genetics, the following must be described in the ethics application form:**

- 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

**During the application process, in the case of research involving data banks the following must be described in the ethics application form:**

- How their research data will be collected, stored, used and disclosed, and outline how that process conforms to 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 Human Research Ethics Committee.

**During the application process, 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.

**During the application process, 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 a Monash Health Human Research Ethics Committee 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 2007 updated 2018*.

**Prior to the commencement of a research project Principal Investigators 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 Human

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Research Ethics Committee 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.

### REFERENCES

NHMRC *National Statement on Ethical Conduct in Human Research 2007 updated 2018*

Health Privacy Principles: *Health Records Act 2001*:

<http://www.health.vic.gov.au/healthrecords/overview.htm>

Australian Privacy Principles:

<https://www.oaic.gov.au/privacy/australian-privacy-principles/>

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