## TARGET AUDIENCE

Researchers undertaking research at Alfred Health.

## PURPOSE AND SCOPE

The purpose of this document is to inform researchers of the timeframes for data retention and archiving requirements for research studies undertaken at Alfred Health. This is to ensure that all materials associated with a study are securely stored in such a manner that the study details can be reconstructed at any time.

All research studies conducted at Alfred Health must be archived in accordance with these guidelines.

## GUIDELINE

**Archiving format**

There is currently no clear guidance on the types of format that research documents must be archived in (paper or electronic). As guidance emerges, archiving recommendations and processes will be modified as needed.

**Archiving timeframes**

- All documentation for **interventional** research studies - involving drugs, devices or medical interventions - is to be kept **indefinitely**. If, at some stage in the future, the Ethics Committee deems that storage is no longer required, the researchers will be notified and all materials will be destroyed in a secure manner. This would not occur until *at least* 15 years after completion of the study.[1,2,3] *(This takes into account TGA-GCP which asks for sponsored studies to retain data for 15 years, the Australian Code which asks for minimum 15 years for clinical trials and permanently for gene therapy and some records under the Public Records Act).*

- Research documentation for **non-interventional** studies, such as social science research, studies involving standalone surveys or questionnaires, or as deemed by the Ethics Committee, is to be kept for **7 years** after the date of publication. If the study is not going to be published then research documentation should be kept for 7 years following the date of acknowledgement of the final report. The documents will then be securely destroyed. *(This takes into account the Australian Code which asks for a minimum 5 years from publication date and Vic Health Records Act of health information for 7 years).*

For research involving young people (<18 years of age), the data must be kept for the required period from the time they become an adult.

*Some research data needs to be retained permanently e.g. gene therapy[1]
*Requests for a shorter data retention time for low risk, short term projects should be directed to the Ethics Committee, preferably at the time of initial ethics review.[1]
*Guidance for individual document retention that may impact on the archiving timeframe is available through the Public Records Office Victoria

Where researchers have indicated on participant information sheets that records would be kept for a particular period, the records should be kept for at least that time.

**Archiving**

Archiving is available through the Office of Ethics and Research Governance.

An archive record form must be completed for each study. This form lists the types of documents for archiving and can be amended to suit the study.

There is a cost involved in archiving. It is the researcher's responsibility to consider the cost of archiving early and incorporate this fee into the budget and clinical trial/investigation agreement.

Instructions on archiving procedures are available from the Ethics & Research Governance website.

**Preliminary procedures before archiving**
Provide Health Information Services (HIS) with a list of the medical record numbers of the patients involved, so that appropriate medical records can be kept for the required period.

Submit a Final Ethics Progress Report for the study (template is available from the Ethics & Research Governance website).

Notify all hospital departments such as Health Information Services, Pathology, Pharmacy, Radiology etc. according to the study closure requirements of the specific departments. Fees for retention of hospital medical records might be applicable.

Research information may need to be stored for some time following completion of the study and prior to archiving. Secure storage must be provided during this period to prevent unauthorised access to the information.

**Retrieval**
Requests for retrieval of archived records are processed by the Office of Ethics and Research Governance. A retrieval and re-archiving charge applies.

## KEY RELATED DOCUMENTS

- Alfred Health Policy on Research Conduct

## REFERENCES

- 1.Australian Code for the Responsible Conduct of Research
- 2. Good Clinical Practice Guidelines (Annotated with TGA comments)
- 3. Public Records Act// Retention and Disposal Authority for Patient Information Records Version 2011
- Victorian Health Records Act 2001

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