Purpose

Barwon Health acknowledges that research data and records must be managed in accordance with relevant codes, guidelines and legislation. This policy supports Barwon Health's commitment to comply with the Australian Code for the Responsible Conduct of Research (2007) (hereafter referred to as 'The Code'), Section 2, *Management of Research Data and Primary Materials*.

The Code points out that all individuals and institutions involved in performing research have a responsibility to ensure that research data and records are well managed by:

- identifying the ownership of research data and records,
- maintaining a register of research data and records stored in a department,
- arranging for secure storage and retention beyond the end of the project,
- arranging appropriate data access for the research and wider communities.

Note that this Policy excludes research tissue samples and biobanks.

Target Audience

All Barwon Health employees, visiting staff and students performing research at all Barwon Health sites.

Definitions

Data policy	A broad set of high-level principles forming a guiding framework in which data management can take place.
Destruction	The irreversible (no reasonable risk that any information may be recovered later) physical obliteration of all existing copies of data carried out using appropriate methods such as shredding or pulping and in the case of electronic data, rendering them unreadable.
Disposal	Any action that changes the circumstances of data or removes data from their usual setting including destruction, damage, alteration or transfer of custody or ownership of data.
Metadata	Schematised information about attributes of an item or collection of research data that enables it to be identified, retrieved and re-used. Important metadata elements may include subject matter, creators and owners, and technical or contextual information that enables the data to be understood.
Owner	The researcher nominated in project planning as the owner of the research data or as nominated following review when Higher Degree by Research (HDR) Candidates move or leave the project.
Principal investigator	Person responsible for the conduct of the research project, including assigning roles and authorisations of relevant tasks.
REGI	Research, Ethics, Governance and Integrity Unit
Research data	The data, records, files or other evidence, irrespective of their content or form (e.g. in print, digital, physical or other forms), that comprise a research project's observations, findings or outcomes, including primary materials and analysed data but excluding human tissue samples.
Research data management	Research data management is a general term defining the way the information used or generated during a research project is organized, structured, stored, and cared for.

Research Data Management Plan	A research Data Management Plan (DMP) describes how research data are collected or created, how data are used and stored during research and how data are made accessible for others after the research has been completed, and how data are disposed of.
Research records	Information and materials created, received, used or maintained as evidence of, or information about, the official business and decision-making related to research activities, in print, digital or physical forms. These records include (but are not limited to) correspondence (including electronic mail as well as paper-based correspondence); project files; grant applications; ethics applications; technical reports; research reports; master lists; signed consent forms; information sheets for research participants; research agreements of collaborative research projects.
Research registry	A catalogue of research data sets and records pertaining to each research project.
Researchers	All Barwon Health staff, adjuncts and visitors engaged in research in all departments, irrespective of their location.
Third-party research data	Any kind of research data that are owned by another researcher, individual or entity that are being used for different research purposes from that for which they were originally created, or that are being used by HDR Candidates other than the owner.

Policy

Application & Responsibilities

This policy applies to all Barwon Health employees, visiting staff and students performing research at all Barwon Health sites. The policy outlines responsibilities for all aspects of the management of research data and records generated or used in a research project.

Research Data Management Planning

Good practice in research data management is the result of good planning made from the outset of a research project and continued throughout the research lifecycle.

Researchers are required to complete a Data Management Plan (DMP) Checklist for each research project to formalise decisions relating to retention, storage and disposal of research data. The DMP Checklist should be completed in preparing the ethics submission and appropriate information incorporated into the research protocol.

Data Ownership

Researchers must ensure that ownership of research data is identified and documented at the data management planning stage of a research project, and reviewed and updated whenever appropriate. The documentation should detail the agreed exit procedures, and how ownership and storage of data and materials will be affected by researchers changing institutions, or withdrawing from collaborative projects.

Data identified as owned by an individual may be removed from Barwon Health by the individual on leaving Barwon Health. The individual should advise the head of unit of their intention to take the data, and agree to and document any ongoing access for the unit. If an individual leaves without claiming their data, the ownership defaults to Barwon Health.

External custodians of research data

When data are obtained from limited access databases, or via a contractual arrangement, or where third party research data are being used, the location of the original data or key information regarding the database from which it was collected must be documented. (See section on Registry of Research Data and Records.)

Collaborative research projects

All collaborative research across institutions must have a research agreement which covers data ownership, storage, disposal and any associated costs. Research agreements must be recorded in Barwon Health's research registry. (See section on Registry of Research Data and Records.)

Registry of Research Data & Records Stored in an Institution

The Research Directorate is responsible for maintaining a registry of where research data and records are stored. Where data are obtained from another source, the location of the original data or key information regarding the database from which it was collected must be documented in the Registry.

The Registry should contain a standard minimum set of metadata, including name of Principal Investigator, project start date, ethics approval number, archive storage identifier.

Note that the following are requirements under The Code:

'institutions must provide facilities… for maintaining records of where research data are stored' (Section 2.2);
researchers must 'retain research data, including electronic data, in a durable, indexed and retrievable form'; (Section 2.6.4) and
researchers must 'maintain a catalogue of research data in an accessible form.' (Section 2.6.5)

Storage of Research Data and Records

Department Heads are responsible for organising secure storage of research data.

The Research Directorate is responsible for organising secure storage of research records.

Confidentiality and Consent

Researchers must respect any confidentiality agreement made with participants about stored data and ensure documentation of same for the awareness of future users. In particular, researchers must establish consent processes that include information about the form in which the data will be stored (specifically about identifiability of subjects) and where it will be stored, and the purposes for which the data will be used and/or disclosed.

Where researchers are in doubt about confidentiality and consent, they must consult the National Statement on Ethical Conduct in Research Involving Humans, and seek advice from REGI.

Security and Protection

Researchers must secure their data so that:

- data are not available for uses other than those for which participants have given consent;
- there is no unauthorised access to that data by individuals not listed in the data management planning documentation provided in the ethics submission;
- electronic research data are collected in a manner that enables auditing. In particular, where multiple users have access to the data, any changes to the data (which include creating new records) should be attributable to a specific user.

Researchers should be aware of Barwon Health's Security of Information Procedure.

Access to Research Data and Records

The plan for data management should specify who has access to research data and records, and in particular what level of access they have. In the case of electronic data for example, particular users may have access to enter new data, and no authorisation to export the data for further use. The storage format of electronic data should allow for these restrictions.

It is recommended that Barwon Health researchers use a local web-based data management system (e.g. RedCap) for collecting, storing, managing and auditing access to and use of research data, as well as for conducting surveys. (See 'Where to Get Advice Section' for information about RedCap support.)

Period of Retention of Research Data and Records

As a starting point the period of retention needs to align with the periods set out in section 2.1.1 of The Code, any local or state archives Acts as well as discipline specific norms.

Minimum recommended period

In accordance with state legislation and The Code, the minimum recommended period for retention of research data is 5 years from the date of publication.

Particular cases

In any particular case, the specific type of research should determine the period for which data should be retained:

- For research in areas such as gene therapy, research data must be retained permanently, e.g. patient records.
- Data collected through research involving children must be retained until the age of maturity, i.e. 18 years.
- If the work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection (confidentiality issues would need to be addressed).
- Clinical trial data must be retained for at least 15 years from the end of the trial.
- Most quality assurance activity should be kept for 1 year from the completion of the project, however if the project results are published, or the results are controversial (as judged by the researcher, and REGI may advise longer storage at the time of submission of the final report), or are the basis for a significant change in practice, they should be kept for 5 years. There may be value in keeping some quality assurance project data for more than 1 year and up to or longer than 5 years (advice should be obtained from the Research Directorate).
- Funding bodies may have specific requirements for retention of data and records. Researchers should be aware of any conditions of any award or obligations of contracts supporting their research.
- If legal action is taken which involves a research project, all data and records must be kept until after all avenues of legal action have been exhausted.
- All other research data should be kept for a minimum of 5 years.

The requirements outlined above are the minimum requirements for retention.

Long term preservation

Consideration should be given to the long term preservation of research data and records of archival value. For example, projects that:

- have made a major contribution to research;
- were controversial, challenged, subject to extensive debate or interest;
- involve the use of major new or innovative techniques; and
- involve a 'first of a kind' process or product or significantly improved or changed procedures.

Destruction of Research Data and Records

The destruction of research data can only be authorised by the Department Head. The Department Head should liaise with the coordinator of the department register and the databank trustee to establish that it is appropriate to destroy the data and records as per this policy. A record of approval for destruction must be recorded by the Research Ethics, Governance & Integrity Unit.

When data are destroyed, this should be done in such a way as to ensure complete destruction of the information, for example:

- data stored in a paper format should be shredded;
- data stored in an electronic form should be destroyed by rewriting or reformatting – 'delete' instructions are not sufficient to ensure that all system pointers to the data incorporated in the system software have also been removed (researchers should seek advice from REGI if they are unsure how to do this or do not have appropriate levels of access to IT systems);
- audiovisual tapes should be destroyed by 'magnetic field bulk erasers'.

The following resources are available to assist in planning and implementing good research data management practice:

- Guidelines for the Management of Research Data at Barwon Health
- Research Data Management Planning Checklist.

Where to Get Advice

Barwon Health Research Directorate http://www.barwonhealth.org.au/research

Research, Ethics, Governance and Integrity Unit (REGI)
http://www.barwonhealth.org.au/research/column-1/regi

Contact REGI REGI@barwonhealth.org.au for:

- Ethics and governance queries
- Advice about confidentiality and consent
- Support in the use of the Data Management Planning Checklist
- Advice about how to organise the destruction of data, for example, where a researcher's level of access to information systems may be insufficient.

Biostatistics Unit http://www.barwonhealth.org.au/biostatistics-unit

RedCap is a centrally located data management system. It enables restrictions to be applied to data access for approved users only, and it provides a full audit logging capability, consistent with this policy. It is endorsed by the Barwon Health Human Research and Ethics Committee.

For information, email redcap-admin@barwonhealth.org.au at the Biostatistics Unit.

Barwon Health Library http://library.barwonhealth.org.au/
For support in literature searching and managing the results, and the Data Management Planning Checklist contact the Library Library@barwonhealth.org.au

Data Access and Requests
The Barwon Health Decision Support team provides data, analysis and report development services. See Decision Support Access and Processing of Requests for further details on how to access data and information on the request process. Contact the Decision Support team bhba@barwonhealth.org.au

Australian National Data Service (ANDS)
http://www.ands.org.au/

Evaluation

Review and evaluation may be performed by any interested research-active Barwon Health employee, with changes to this document allowable only with the approval of the Director of Research.

Adherence to this policy will be reviewed through random audit of research data management of Barwon Health ethics approved research.

Key Aligned Documents

Decision Support Access and Processing of Requests, PROMPT: Barwon Health\Knowledge and Information Services\HIS

Employee Code of Conduct, PROMPT: Barwon Health \ Workforce \ HR

Privacy Policy, PROMPT: Barwon Health \ Knowledge and Information Services\HIS

Security of Information, PROMPT: Barwon Health \ Knowledge and Information Services\HIS

Key Legislation, Acts & Standards

Australian Government, NHMRC. (2007). Australian code for the responsible conduct of research. Retrieved January 15, 2016 from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/r39_australian_code_responsible_conduct_research_150107.pdf

Australian Government, NHMRC. (2015, May). National statement on ethical conduct in human research (2007) – Updated May 2015. Retrieved January 15, 2016 from https://www.nhmrc.gov.au/guidelines-publications/e72

References

N/A

Contributors

	Name	Position	Service / Program
Lead Reviewer:	Dr Stephen Lane	Senior Biostatistics Officer	Biostatistics Unit, Research Directorate
Contributors:	Ann Ritchie	Director Library & Literacy,	Library
	Mari-Elisa Kuusniemi	Research Librarian	Library
	Prof Richard Page	Director	Orthopaedics
	Dr Giuliana Fuscaldo	Manager, REGI	Research Directorate
	Dr Sharon Hakkennes	Director Health Informatics	Knowledge & Information Services
	Tom Conway	Acting Chief Knowledge and Information Officer	Knowledge & Information Services
	Ross Arblaster	Decision Support and Data Integrity Operations Manager	Knowledge & Information Services
Committee/s:	Members	Education, Training & Research Governance Committee	Meeting December 2015