

SYDNEY MEDICAL SCHOOL -RESEARCH DATA MANAGEMENT PROVISIONS 2017

1 Purpose and Application

- (1) These provisions give practical effect within the Sydney Medical School ("the faculty") to the <u>Research Data Management Policy 2014</u> ("the policy") and the <u>Research Data Management Procedures 2015</u> ("the procedures").
- (2) These provisions apply to University staff, research students and affiliates in the Faculty.

2 Commencement

These provisions commence on 1 March 2017

3 Definitions

- (1) Words and phrases used in these provisions and not otherwise defined in this document have the meanings they have in the policy and procedures.
- (2) The lead researcher or chief investigator, who has overall responsibility for data management in a research project, will be referred to in this document as the researcher. We include in this term research students, who need to act in consultation with their research supervisors, but are responsible for data management in their own research project, even in cases where their research data is shared with their supervisor.

Note: See clause 6 of the <u>policy</u> and clause 3 of the <u>procedures</u>.

4 Identification of research data and primary materials to be retained

(1) The definition of research data and the nature of such data and materials vary greatly across disciplines within the faculty.

Note: See also clause 7 of the *policy* for a working definition of research data.

- (2) Across the faculty, research data and material may include (but is not limited to):
 - (a) personal research notes (including laboratory and field notebooks);
 - (b) primary research data (including machine data in hardcopy or computer readable form)
 - (c) databases and excel spreadsheets;
 - (d) clinical data, including clinical records;
 - (e) questionnaires;
 - (f) survey questions and responses;



- (g) recordings and transcripts of interviews;
- (h) models, programs and software;
- (i) source data:
- (j) unpublished materials and online materials which are liable to disappear over time: e.g. copies of press releases, statements or speeches;
- (k) archival materials which are not otherwise readily accessible to the public;
- (I) descriptive metadata
- (m) photographs;
- (n) audio-visual materials;
- (o) test responses;
- (p) physical collections of:
 - (i) slides;
 - (ii) artefacts;
 - (iii) manuscripts;
 - (iv) specimens;
 - (v) samples;
- (q) other forms, to be developed in the future.
- (3) The research records relating to a research project include:
 - (a) ethics approvals;
 - (b) records relating to funding of the research;
 - (c) communication between researchers relating to the research; and
 - (d) any other supplementary materials required to reproduce or verify the outcomes of the research, or enable researchers to re-analyse or use the data.
- (4) When deciding which research data, research records and primary materials to retain, researchers:
 - (a) must determine which data and materials must be retained to justify the outcomes of their research, and if necessary, defend those outcomes against challenge;
 - (b) must comply with any conditions concerning retention and storage of research data that are contained in any ethics approval for the research, particularly any confidentiality obligations which attach to the data;
 - (c) must retain research data and primary materials in a form that others can interpret;
 - (d) must identify and record the instruments, methods and software used to generate or analyse the research data; and
 - (e) should retain copies of the software or source code used to generate or analyse the research data.

Note: See clause 7 and Schedule 2 of these provisions for retention periods.

(5) Researchers should document and retain physical data and primary materials in digital format, where possible, to minimise space and resources required to curate and store them.



5 Research data management plans (RDMPs)

 RDMPs record the researcher's plan for storing, retaining and disposing of research data which is acquired or generated in the course of a research project.

Note: See clause 9 of the policy and clause 5 of the procedures.

- (2) RDMPs should also record any agreements about ownership and management of research data upon the researcher leaving the University.
- (3) Researchers should retain a copy of their RDMP within their research records.
- (4) All research projects must be supported by an RDMP in the manner specified in the procedures. Examples of research projects requiring RDMPs are listed below (but, not limited to):
 - (a) projects funded by external funding bodies, such as category 1-4 grants from a government, not-for-profit or commercial entity;
 - (b) projects funded by internal grant schemes from the University and the faculty, such as Compact grants;
 - (c) projects undertaken by students such as higher degree by research students, honours students, undergraduate or visiting students.
- (5) RDMPs must be prepared and registered with the Office of the Deputy Vice-Chancellor (Research):
 - by researchers applying for external and internal funding, following the announcement of the success of the grant, or as specified in the application guidelines or conditions of awards;
 - by researchers undertaking unfunded research that is expected to produce research publications or other outputs that require verification;
 - (c) by research students (in consultation with their supervisors), as a condition of their annual performance review at the end of the first year of their candidature.

Note: see the <u>Progress Planning and Review for Higher Degree by Research Students</u> <u>Policy 2015.</u>

- (6) RDMPs must be updated when the research data management needs of the research change significantly from those captured in the current RDMP.
- (7) RDMPs must be created through the University's online portal, which links to relevant digital data store facilities. This ensures that the RDMP is registered with the Office of the Deputy Vice Chancellor (Research).

Note: See the <u>Research Data Management Guidelines</u> for the <u>RDMP checklist</u> and <u>online RDMP Tool</u>.

(8) Researchers should contact their Academic Liaison Librarian for assistance with research data management planning.

Note: See the Library website for contact details.

6 Ownership of research data and primary materials

(1) The ownership of data and primary materials is as specified in the *policy*.

Note: See clause 11 of the policy



(2) The ownership of research data and primary materials created by researchers in the Faculty may be subject to an agreement with a third party. In such cases, researchers should contact the Director, Research Grants and Contracts for assistance with research collaboration agreements or other research related contracts or agreements.

Note: See the Research Support website, Research Grants and Contracts

(3) Researchers should record the creator(s) or collector(s) of research data and materials, and note any applicable research collaboration agreements in their RDMP.

7 Retention of research data, primary materials and research records

(1) All research data must be retained in accordance with clause 9 of the <u>Research Code of Conduct 2013.</u> Minimum applicable retention periods are listed in Schedule 2 of these provisions.

Note: See the <u>Research Code of Conduct 2013</u>.

(2) Research agreements or contracts: chief investigators must be aware of any additional data retention requirements stipulated in their research agreement or contract.

Note: See the <u>Research Agreements Policy 2011</u>.

(3) Challenged results: if the results from research are challenged or are subject to a dispute (including litigation), all relevant data and materials must be retained for at least six months after notification by the University that an investigation or dispute has been finalised, regardless of the expiration of any otherwise applicable retention periods.

8 Storage of research data and primary materials

- (1) Research data must be stored in accordance with clause 6 of the *procedures*.
- (2) Researchers should:
 - store digital research data, associated records and documentation on University managed research data storage infrastructure, such as Electronic Notebook (eN) and Research Data Store (RDS);

Note: See <u>Electronic Notebook (eN)</u> and <u>Research Data Store (RDS) website</u>

- (b) store physical data, primary materials and research records in their laboratory or office, or in shared storage spaces within the Faculty.
- (3) Researchers must implement appropriate security for research data. This may include locks for physical storage, signs indicating who should be contacted regarding storage, and password-protected encryption for digital files. Researchers should contact the School Executive Officer, or Faculty Research Manager to arrange storage space for physical data and materials that cannot be stored in individual researchers' offices.
- (4) Researchers should document the location of physical and digital research data and primary materials in their RDMP.



9 Preferred formats

- Formats for data retention should be in accordance with clause 8 of the procedures.
- (2) Researchers should contact the Research Data Manager for advice on preferred digital file formats.

Note: See the <u>Research Data Management Guidelines</u> website or contact the Research

Data Manager

(3) Researchers should document their choices of file format in their RDMP.

10 Sharing research data and metadata

(1) Researchers should plan to make completed research data sets available for reuse as specified in the *policy* and *procedures*, unless this is prevented by the requirements of legislation or University policy, or ethical, contractual, or confidentiality obligations.

Note: See clause 12 of the *policy* and clause 10 of the *procedures*.

See also the Research Data Management Guidelines website

- (2) Subject to clause 10(1), research data may be shared at any stage of a research project. There are many ways to share research data, including:
 - (a) creating a record for a dataset in the University's Research Data Registry and advertising that record to Research Data Australia;
 - (b) depositing completed research datasets in the University's open access institutional repository, Sydney eScholarship Repository; and
 - (c) depositing completed research dataset in an open access, mediated access or restricted access discipline repository.
- (3) When sharing data to support research publications, researchers may deposit supplementary data sets in a preferred format in the University's open access institutional repository, and provide a persistent link to their publisher.
- (4) Researchers should contact the Research Data Manager for advice on depositing supplementary datasets in the University's open access repository.
- (5) Researchers should contact the Research Data Manager for assistance with sharing research data at any stage during or following their research project.
- (6) Chief investigators and research students (in consultation with their supervisors) should document decisions regarding data sharing in their RDMP.

11 Disposal of research data and primary materials

Researchers should state their intentions about disposing of data or materials (including sharing, archiving or destruction) in their RDMP.

Note: See clause 10 (5) of the policy.



12 Retaining and managing data, primary materials and records when a researcher or research student leaves the University

(1) Researchers:

- (a) When a researcher leaves the University, they must:
 - ensure that data has been retained on University's Research Data store;
 - (ii) create a record for those research dataset(s) and any associated primary materials within the University's Research Data Registry; and
 - (iii) provide a reference for that record to their chief investigator and the Associate Dean Research.
- (b) Researchers should contact the Research Data Manager to create a record for their dataset(s) in the Research Data Registry.

Note: See the Library website for contact details

(c) At the end of the retention period, the Associate Dean Research must make a recommendation to their Head of School to share, retain, archive or destroy the research data and materials. This recommendation must be based upon the record within the RDMP and subject to the requirements of legislation, University policy and any applicable ethical, contractual or confidentiality obligations.

Note: See clause 10(5) of the *policy*.

(2) Research students:

- (a) At the end of their project, or when they leave the University, research students must:
 - ensure that their supervisor has access to or copy of research data, research records and where applicable, primary materials (retained physical materials), in accordance with the arrangements recorded in their RDMP; and
 - (ii) create a record of those research dataset(s) within the University's Research Data Registry in accordance with the arrangements recorded in their RDMP.
- (b) Research students (in consultation with their supervisors) should contact the Research Data Manager to create a record for the data in the Research Data Registry.

Note: See the <u>Library website</u> for contact details and see clause 5(2) of these provisions

(3) Research supervisors must:

- (a) ensure the requirements of these provisions are communicated and explained to their research students;
- (b) arrange for access to or copies of their research students' research data, research records and any primary materials (retained physical materials) at the end of the project, or when the research student leaves the University;
- (c) direct their research students to create a record in the University's Research Data Registry (providing assistance and resources as required);
- retain their research students' research data research records and any primary materials for the minimum retention period; and



(e) at the end of the required retention period, make a recommendation to their Head of School to share, retain, archive or destroy the research data, research records and primary materials. This recommendation must be based upon the record within the University's Research Data Registry and comply with the requirements of legislation, University policy, and any applicable ethical, contractual, or confidentiality obligations.

Note: See clause 10 (5) of the *policy* and clause 5 (2) of these provisions.

13 Contacts for research data management training and support

Contacts for research data management training and support are listed in Schedule 1 of these provisions.

NOTES

Sydney Medical School Research Data Management Provisions 2017

Date adopted: 3 February 2017

Date commenced: 1 March 2017

Approved by: Professor Arthur Conigrave, Dean, Faculty of Medicine

Signature:

Review date:

Related documents:

LEGISLATION

Copyright Act 1968 (Cth)

Electronic Transactions Act 1999 (Cth) Privacy Act 1988 (Cth)

Therapeutic Goods Act 1989 (Cth)

Government Information (Public Access) Act 2009 (NSW)

Privacy and Personal Information Protection Act 1998 (NSW)

Protection of the Environment Operations Act 1997(NSW)

State Records Act 1998 (NSW)

University of Sydney Act 1989

University of Sydney By-Law 1999 (NSW) (as amended)

UNIVERSITY REQUIREMENTS

University of Sydney (Higher Degree by Research) Rule 2011 (as amended)

Research Code of Conduct 2013

Information Security Policy 2010



Research Agreements Policy 2011

Supervision of Research Higher Degree Students Policy 2013

Intellectual Property Policy 2016

University Privacy Policy 2013

University Recordkeeping Policy

University Recordkeeping Manual

EXTERNAL DOCUMENTS

Australian Code for the Responsible Conduct of Research 2007 (NHMRC/ARC)

NHMRC Revised Policy on the Dissemination of Research Findings

NHMRC Statement on Consumer and Community Participation in Health and Medical Research

AMENDMENT HISTORY

Provision Amendment

Commencing



SCHEDULE 1 – CONTACTS FOR RESEARCH DATA MANAGEMENT TRAINING AND SUPPORT

Chief investigators and research students (having first consulted with their supervisors) are encouraged to contact the following for advice and assistance with research data management training and support.

Requirement	Key contact	Addresses and links
Research data management training and support, including individual assistance with research data management plans.	Academic Liaison Librarians for Faculty of Medicine	See the <u>Library Website</u>
Identifying which research data and primary materials are to be retained, or other advice on the interpretation of the provisions in this document or the Policy and Procedures.	Associate Dean Research	See the Faculty website
Interpreting data ownership clauses in research grants, research collaboration agreements and contracts.	Director, Research Grants and Contracts, Research Office	See Research Grants and Contracts
Selecting appropriate storage for digital data, materials and research records.	Faculty Research Manager	See the Faculty website
Transferring data and materials (including physical materials) into the University from another institution or out of the University to another institution.	Commercial Development and Industry Partnerships	See the Commercial Development and Industry Partnerships website
Describing and documenting research data collections.	Research Data Manager, University Library	See the Research Data Management Guidelines website
		See also clause 8 of the Research Data Management Policy 2014, concerning Metadata and documentation.



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Requirement	Key contact	Addresses and links
Depositing completed digital datasets in the appropriate institutional repository; including setting the appropriate access permissions or restrictions.	Research Data Manager, University Library	See the Research Data Management Guidelines website
General advice on copyright and IP in research data; selecting an appropriate University approved license for open access datasets.	Manager, Copyright Services, University Library	See the Copyright website
Advice on patents and other registered IP rights; commercialisation of research; advice on selecting alternative licenses and/or terms of use to enable open access to research datasets.	Commercial Development and Industry Partnerships	See the Commercial Development and Industry Partnerships website



SCHEDULE 2 – RETENTION PERIODS FOR RESEARCH DATA

All research data must be retained in accordance with clause 9 of the Research Code of Conduct 2013. The following retention periods apply to the management of research data and materials within the Faculty.

Data type	Retention	Notes
Machine, instrument or sensor generated data	5 years	The standard <i>minimum</i> retention period for non-human data is five years.
Source code and computational data, such as binary or ASCII data, software generated data including input parameters, scripts, software versions and samples of output data	5 years	Source code and computational data, such as binary or ASCII data, software generated data including input parameters, scripts, software versions and samples of output data are considered research data within the Faculty, and must be retained consistently with the <i>policy</i> , the <i>procedures</i> and these provisions.
Data involving human research participants	5 years	The minimum retention period for non- clinical research data collected from human participants is normally 5 years or as otherwise specified in the University of Sydney Human Research Ethics Application. For a list of minimum retention periods for other types of data collected from human participants, refer to clause 9 (6) of the Research Code of Conduct 2013.
Data from clinical trials	15 years	The minimum retention period for research data collected during clinical trials is 15 years or otherwise in accordance with the applicable requirements of the Therapeutic Goods Administration (TGA), or Department of Health and Ageing.



Data type	Retention	Notes
		Data relating to research subjects who were children at the time it was collected must be retained for the longer of 20 years or until the subject(s) reaches the age of 25.
Data relating to patent applications	20 years or the life of the patent	Data that relates to any patent applications must be retained for the life of the patent (generally 20 years);