

FACULTY OF PHARMACY – RESEARCH DATA MANAGEMENT PROVISIONS 2016

1 Purpose and Application

- (1) These provisions give practical effect within the Faculty of Pharmacy (“the Faculty”) to the [Research Data Management Policy 2014](#) (“the Policy”) and the [Research Data Management Procedures 2015](#) (“the Procedures”).
- (2) These provisions apply to University staff, research students and affiliates in the Faculty.

2 Commencement

These provisions commence on 21 October 2016.

3 Definitions

Words and phrases used in these provisions and not otherwise defined in this document have the meanings they have in the Policy and Procedures.

Note: See clause 6 of the Policy and clause 3 of the Procedures.

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.

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

- (2) Across the Faculty, research data may include (but is not limited to):
 - (a) laboratory and field notebooks;
 - (b) primary research data (including machine data in hardcopy or computer readable form);
 - (c) databases;
 - (d) clinical data, including clinical records;
 - (e) questionnaires;
 - (f) photographs;
 - (g) audio-visual materials;
 - (h) test responses;
 - (i) physical collections of:
 - (i) slides;
 - (ii) artefacts;



- (iii) manuscripts;
 - (iv) specimens;
 - (v) samples;
 - (j) other forms, to be developed in the future.
- (3) When deciding which research data and primary materials to retain, chief investigators and research students (in consultation with their supervisors):
- (a) must determine which research data and primary 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, including (as appropriate):
 - (i) metadata;
Note: See also clause 8 of the Policy for a working definition of metadata.
 - (ii) script parameters;
 - (iii) databases and Excel tables;
 - (iv) survey questions and responses;
 - (v) recordings and transcripts of interviews;
 - (vi) unpublished materials (including online materials) which are liable to disappear over time: e.g. copies of speeches;
 - (vii) copies of archival materials which are not otherwise readily accessible to the public;
Note: Some archival materials (e.g. national archive) once copied are made available online, so would not need to be retained.
 - (viii) modelling software;
 - (ix) source data; and
 - (x) any other supplementary materials required to reproduce or verify the outcomes of the research, or enable researchers to re-analyse or use the data;
 - (d) must identify and record the instruments 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 8 and Schedule 2 of these provisions for retention periods.
- (4) Chief investigators and research students (in consultation with their supervisors) should retain physical data and primary materials in digital format, where possible, to minimise space and resources required to curate and store them.
- (5) Chief investigators and research students (in consultation with their supervisors) must document the types of research data and primary materials which will be retained in a Research Data Management Plan (RDMP).

5 Research data management plans (RDMPs)

- (1) 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) All research projects must be supported by an RDMP in the manner specified in the Research Data Management Procedures. Examples of research projects requiring RDMPs include, but are 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.
- (4) RDMPs must be prepared and registered with the Office of the Deputy Vice Chancellor (Research):
 - (a) by chief investigators 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;
 - (b) 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 [Progress Planning and Review for Higher Degree by Research Students Policy 2015](#).
- (5) RDMPs must be updated when the research data management needs of the research change significantly from those captured in the current RDMP.
- (6) 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 [Research Data Management Guidelines](#) for the [RDMP checklist](#) and [online RDMP Tool](#).
- (7) Chief investigators and research students (in consultation with their supervisors) should contact their Academic Liaison Librarian for assistance with research data management planning.
Note: See the [Library website](#) for contact details.

6 Contacts for research data management training and support

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

7 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 and research students in the faculty may be subject to an agreement with a third party. In such cases, chief investigators 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](#).

- (3) Chief investigators and research students (in consultation with their supervisors) should record the creator(s) or collector(s) of research data and materials, and note any applicable research collaboration agreements in their RDMP.

8 Retention of research data, primary materials and research records

- (1) All research data must be retained in accordance with clause 9 of the [Research Code of Conduct 2013](#).
- (2) All researchers are expected to familiarise themselves with these requirements.
- (3) Minimum applicable retention periods are listed in Schedule 2 of these provisions.
- (4) **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 [Research Agreements Policy 2011](#).

- (5) **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.
- (6) Chief investigators and research students should document the applicable minimum retention period(s) in their RDMP.

9 Storage of research data and primary materials

- (1) Research data must be stored in accordance with clause 6 of the Procedures.
- (2) Researchers should:
 - (a) 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 [Electronic Notebook \(eN\)](#) and [Research Data Store \(RDS\) website](#)
 - (b) store physical data, primary materials and research records in their laboratory or office, or in shared storage spaces within the faculty.
- (3) Researchers and research students 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.

- (4) Researchers and research students should contact the Faculty Research Manager to arrange storage space for physical data and materials that cannot be stored in individual researchers' office.
- (5) Chief investigators and research students (in consultation with their supervisors) should document the location of physical and digital research data and primary materials in their RDMP.

10 Preferred formats

- (1) Formats for data retention should be in accordance with clause 8 of the Procedures.
- (2) Chief investigators and research students (in consultation with their supervisors) should contact the Research Data Manager for advice on preferred digital file formats.
Note: See the [Research Data Management Guidelines](#) website or contact the Research Data Manager
- (3) Chief investigators and research students (in consultation with their supervisors) should document their choices of file format in their RDMP. The file format should be described in "ReadMe" docs or similar and kept with data in eN or on RDS.

11 Sharing research data and metadata

- (1) Chief investigators or research supervisors (with the consent of their research student(s) where required) should plan to make completed research data sets available for re-use 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 sub-clause 11(1) above, research data may be shared at any stage of a research project.
- (3) There are many ways to share research data, including (but not limited to):
 - (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.
- (4) When sharing data to support research publications, chief investigators or research students (in consultation with their research supervisors) 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.
Note: Depositing a data set in the University's open access repository and providing a persistent link to the publisher enables the researchers and the University to retain their rights to the dataset.

- (5) Chief investigators or research students (in consultation with their supervisors) should contact the Research Data Manager for advice on depositing supplementary datasets in the University's open access repository.

Note: See the [Sydney eScholarship](#) website

- (6) Chief investigators and research students (in consultation with their supervisors) should contact the Research Data Manager for assistance with sharing research data at any stage during or following their research project.
- (7) Chief investigators and research students (in consultation with their supervisors) should document decisions regarding data sharing in their RDMP.

12 Disposal of research data and primary materials

Chief investigators and research students (in consultation with their supervisors) 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.

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

(1) Research students:

- (a) At the end of their project, or when they leave the University, research students must:
 - (i) 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 [Library website](#) and clause 5(2) of these provisions

(2) Research supervisors must:

- (a) explain the requirements of these provisions to their research students;
- (b) arrange for access to or a copy 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);
- (d) 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..

(3) **Researchers:**

- (a) When a researcher leaves the University, they must:
- (i) ensure that data has been retained on the University's Research Data store, and
 - (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 Research Data Manager to create a record for their dataset(s) in the Research Data Registry.

Note: See the [Library website](#).

- (c) At the end of the retention period, the relevant Associate Dean must make a recommendation to the 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.

NOTES

Faculty of Pharmacy – Research Data Management Provisions 2016

Date adopted: 29 September 2016

Date commenced: 21 October 2016

Approved by: Professor Iqbal Ramzan, Dean, Faculty of Pharmacy

Signature:

Review date: 21 October 2021

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 LEGISLATION AND POLICIES

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

Information Security Policy 2010

Intellectual Property Policy 2016

Progress Planning and Review of Higher Degree by Research Students Policy 2015

Research Agreements Policy 2011

Research Code of Conduct 2013

Supervision of Research Higher Degree Students Policy 2013

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 Pharmacy	See the Library website
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 of Pharmacy website
Interpreting data ownership clauses in research grants, research collaboration agreements and contracts.	Director, Research Grants, Research Office	See Research Grants and Contracts
Selecting appropriate storage for digital data, materials and research records.	Faculty Research Manager	See the Faculty of Pharmacy 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.
Depositing completed digital datasets in the appropriate institutional repository; including setting the appropriate access permissions and restrictions.	Research Data Manager, University Library	See the Research Data Management Guidelines website



Requirement	Key contact	Addresses and links
General advice on copyright and IP in research data; selecting an appropriate University approved licence 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 licences 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 1

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 as per the provisions of the Policy, the Procedures and these provisions.
Data involving human research participants	5 years	<p>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.</p> <p>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.</p>
Data from clinical trials	15 years	<p>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.</p> <p>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.</p>
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).