QIMR Berghofer Medical Research Institute	**Policy on the Management of Primary Materials, Research Data and Research Records**	Effective: 22/03/2022
		Version: 1.0
		Approved by: QIMRB Council

All Personnel are required to comply with the Institute's Code of Conduct, policies, procedures and guidelines, as amended from time to time. The Director and CEO will be responsible for approving all procedures and guidelines developed pursuant to this policy.

1 INTRODUCTION

In accordance with the Research Code, all Personnel must retain clear, accurate, secure and complete records of all research, including Primary Materials and Research Data. Should research findings be challenged, accurate research records are essential in assessing whether the research was conducted responsibly and whether the outcomes are accurate. The fundamental aim is that Primary Materials, Research Data and Research Records are owned, stored, retained, accessed, shared and disposed of appropriately. While it may not be practical or possible to keep all Primary Materials, records of them must be kept.

This Policy defines how Primary Materials, Research Data and Research Records must be managed in order to comply with statutory, ethical and funding body requirements, including the following or any subsequent revisions thereof:

a) *Australian Code for the Responsible Conduct of Research* (2018)
b) *Australian Code for the Care and Use of Animals for Scientific Purposes* (2013)
c) *National Statement on Ethical Conduct in Human Research* (2007, updated 2018)
d) NHMRC Funding Agreement;
e) *Information Privacy Act* 2009 (Qld);
f) *Privacy Act 1988* (Cth); and
g) *Public Records Act 2002* (Qld).

This Policy is complemented by the Institute's *Research Data Management Procedures* (Procedures) which provide more specific information to assist Personnel in complying with this Policy.

2 PURPOSE AND SCOPE

2.1 Purpose

This Policy sets out the requirements to ensure the appropriate management of Primary Materials, Research Data and Research Records in order to:

a) Comply with all statutory, ethical and funding body requirements;
b) Justify and verify the outcomes of research at the Institute;
c) Maintain a research environment of scientific rigour;
d) Protect the human rights and privacy of research participants;
e) Maximise the potential for future research; and
f) Minimise wastage of resources available to researchers and the wider community.

2.2 Scope

This Policy applies to all Personnel involved with primary materials, data and records arising from research under the auspices of the Institute. This Policy does not apply to the management of non-research organisational records within the Institute, such as records within Human Resources or Business Development units, which are covered by the Institute's *Information Management Policy*.

3 DEFINITIONS

Institute	QIMR Berghofer Medical Research Institute
Personnel	All Institute employees, volunteers, non-paid researchers, visitors, students, Council Members, Committee and Sub-committee members, Visiting Scientists, Honorary Scientists and Emeritus Scientists.
Personal Information	Information about an identified individual or information about an individual who is reasonably identifiable based on the associated information. This includes information or opinion/s which may or may not be true or recorded in material form. Personal Information includes health information and sensitive information.
Primary Materials	Objects in any format, including but not limited to samples, biological material, recordings and questionnaires from which Research Data and/or Research Records are generated.
Procedures	QIMR Berghofer Research Data Management Procedures
Research Activity	A formal or informal process undertaken by researchers that aims to discover new information or build on existing knowledge. This includes, but is not limited to, designing or performing experiments, collecting or analysing data, enrolling research participants and assessing participant eligibility.
Research Data	Data in any format that is collected or generated on which an argument, theory, test, hypothesis or any other research output is based. Research Data may include information in the form of measurements, sequencing, readings, facts, observations, images or Personal Information about human research participants. It can also include the software, algorithm or model used to arrive at the research outcome, in addition to the raw data that the software, algorithm or model is applied to.
Research Data Management Plan	A document that describes the type of Research Data or Personal Information that will be collected and how it will be managed, including access, use, storage, sharing and destruction. The Research Data Management Plan should also include licensing considerations, agreements with collaborators and information relating to meeting legislative requirements and Institute policies which apply to the data.

Research Records	Information in any format that is created or received for the purposes of recording research, for example animal monitoring sheets, consent forms, ethics approvals, grant applications and laboratory notebooks.
The Animal Code	*The Australian Code for the Care and Use of Animals for Scientific Purposes* (2013).
The Research Code	*The Australian Code for the Responsible Conduct of Research* (2018).
Vulnerable Person	A child under 18 years of age or an individual who is ≥18 years of age who is, or may be, unable to take care of themselves, or is unable to protect themselves against harm or exploitation by reason of age, illness, trauma, disability, or any other reason.
Vulnerable Persons Records	Provide corroborating evidence of interactions and contact with Vulnerable Persons that are, or may become, relevant to allegations and/or investigations of abuse. Examples include records relating to: a) Clinical research, including parental or carer consent; b) Education and training, including records relating to a vulnerable person's location, attendance, excursions and work experience placements; and c) Accidents, injuries, illnesses and any treatment provided.

4 OWNERSHIP AND CUSTODIANSHIP

With the exception of Personal Information, all Primary Materials, Research Data and Research Records collected, created or generated as part of QIMR Berghofer's Research Activities are the property of the Institute and must be managed as valuable assets of the Institute, unless otherwise specified in contract, funding, collaborative or other agreements.

The Institute's assertion of ownership does not impede the normal use of Primary Materials, Research Data and Research Records by Personnel for research and scholarly purposes.

If Personnel resign or transfer to a different institution, any Primary Materials, Research Data and Research Records that the Personnel created or curated whilst engaged at the Institute remains the property of the Institute. Primary Materials, Research Data and Research Records must not be transferred to a different institution unless there is an executed agreement between the Institute and the new institution and authorisation for the transfer has been obtained from the appropriate delegate.

To the extent that this Policy is inconsistent with the Institute *Intellectual Property Policy*, the latter policy will prevail to the extent of the inconsistency.

5 STORAGE, RETENTION, DISPOSAL AND DESTRUCTION

For the duration of the appropriate retention period, Primary Materials, Research Data and Research Records must be stored in a context and manner that preserves their integrity, ensures their security, allows access control and facilitates easy retrieval in the future.

Primary Materials, Research Data and Research Records must be retained for at least the minimum retention period as determined by prevailing standards for the specific type of research and any applicable state[1], national[2] and international[3] legislation, or applicable guidelines such as the Research Code. The minimum retention period will vary based on the research being undertaken. In all cases it will be at least five (5) years from publication or closing of a project (whichever is later) and in some cases it may be 15 years (e.g. clinical trials) or indefinitely.

Personal Information collected about human research participants must be stored securely on Institute managed storage. While some Personal Information may initially be collected on Institute devices such as laptops, this should be transferred as soon as practicable to Institute servers. Personal information should only be stored and used in accordance with the *Information Privacy Act 2009* (Qld). In addition, it should be noted that records of persons under 18 must be kept from the time collected until that person is 18 with the addition of the statutory retention period. In accordance with guidelines issued under the *Public Records Act 2002* (Qld), Vulnerable Persons' Records must be retained until 31 December 2028.

Primary Materials, Research Data and Research Records should only be destroyed or disposed of once the specified period of retention has ended and written authorisation has been granted by the Principal Investigator or the nominated custodian of the Primary Materials, Research Data and Research Records. In accordance with the *Public Records Act 2002* (Qld), laboratory notebooks (including electronic laboratory notebooks) are classed as permanent records and should never be destroyed.

Primary Materials, Research Data and Research Records that may be relevant to emerging or current legal, regulatory or disciplinary actions must not be destroyed, even if the minimum retention period has passed.

6 SECURITY AND CONFIDENTIALITY

Primary Materials, Research Data, Research Records, including Personal Information, must be stored securely to protect against theft, misuse, damage or loss. In determining the level of security, all Personnel must evaluate the need for confidentiality and sensitivity in accordance with relevant ethical and legal obligations, confidentiality and other agreements.

Inappropriate use of, access to or loss of data must be reported in accordance with applicable reporting schemes.

7 SHARING AND ACCESS FOR INTERESTED PARTIES

Primary Materials, Research Data and Research Records are to be made available to interested parties, both within and outside of the Institute, subject to compliance with:

a) NHMRC *Open Access Policy* (2018);
b) NHMRC *Principles for accessing and using publicly funded data for health research* (2016);
c) Research agreements, including material and data transfer agreements;
d) Legislative obligations;
e) Contractual requirements;
f) Ethical considerations; and
g) Commercial sensitivities.

[1] *University Sector Retention and Disposal Schedule* (QDAN601)
[2] *Therapeutic Goods Act 1989.*
[3] *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*

Personnel who wish to share Primary Materials, Research Data and Research Records with interested parties are responsible for determining whether it is suitable for the Primary Materials, Research Data and Research Records to be shared and obtain the appropriate authorisation to do so. This is to be done in accordance with processes and conditions outlined in the associated Procedures. Primary Materials, Research Data and Research Records involving Personal Information requires particular consideration of the *Privacy Act 1988* (Cth) and *Information Privacy Act 2009* (Qld) prior to disclosure.

Sharing of Personal Information must only take place with the approval of a relevant Human Research Ethics Committee and, where relevant, the valid consent of the individual whose information is to be shared.

8 RESPONSIBILITIES

8.1 Institutional

The Institute will provide facilities to safely store Research Records, Research Data and Personal Information, provided authorised users take reasonable steps to ensure security and comply with this Policy and the associated Procedures.

The Institute will make reasonable efforts to provide appropriate facilities for the storage of Primary Materials (e.g. walk-in cold and freezer rooms, cryogenic storage dewars, secure encrypted servers) as well as access to appropriate facilities for secure disposal or destruction of Research Records, Research Data and Primary Materials.

The Institute will develop, deploy and maintain Procedures and Guidelines to assist Personnel in fulfilling their obligations under this Policy and the Research Code.

8.2 Research and non-Research Personnel

All personnel are responsible for creating and retaining Research Data and Research Records that adequately document the research in which they take part, manage or support. Retention of records and data must meet the minimum timeframe specified in accordance with the *Public Records Act 2002* (Qld).

All personnel are responsible for managing the Primary Materials, Research Data, and Research Records that they collect, create, curate, generate, share, receive and/or use, irrespective of their work location, by following ownership, storage, retention and access guidance (during and beyond their use) and disposal or destruction (when the specified period of retention has passed).

Personnel conducting research that involves the use of Personal Information are required to complete a Research Data Management Plan prior to starting the Research Activity in order to document information relating to data acquisition, ownership, use, access, storage, sharing and disposal or destruction. A template to assist with the development of a Research Data Management Plan can be found in the associated Procedures.

All personnel are responsible for taking additional steps where required for the management of Primary Materials, Research Data, and Research Records in situations where privacy issues or commercial sensitivity are applicable. Information on de-identification and data protection is provided in the associated Procedures.

All personnel must maintain the security and confidentiality of Research Data, Research Records and Primary Materials (including where data may be shared or transferred) and ensure that all electronic Research Data and Records are stored on the Institute network, as appropriate.

Departing Personnel are responsible for updating relevant Research Data Management Plans and must nominate an Institute member who will be the custodian of all Research Data, Research

Records and Primary Materials retained within the Institute, or ensure that they are safely and securely disposed of provided the specified period of retention has ended and they are authorised to do so. Transfer of Primary Materials to Scientific Services must be undertaken in accordance with the *Public Records Act 2002* (Qld) and Institutional retention periods for Primary Materials, Research Data and Research Records specified in the Procedures.

9 RELATED DOCUMENTS

9.1 External References

Australian Code for the Care and Use of Animals for Scientific Purposes
Australian Code for the Responsible Conduct of Research
Guideline on Creating and Keeping Records for the Proactive Protection of Vulnerable Persons
Information Privacy Act 2009 (Qld)
Integrated Addendum to ICG E6(R1): Guideline for Good Clinical Practice E6(R2)
Management of Data and Information in Research, A guide supporting the Australian Code for the Responsible Conduct of Research
National Statement on Ethical Conduct in Human Research, National Health and Medical Research Council, Australian Research Council, 2007 (Updated 2018)
NHMRC Funding Agreement
Notifiable Data Breaches Scheme
Open Access Policy
Principles for accessing and using publicly funded data for health research
Privacy Act 1988
Public Records Act 2002 (Qld)
Therapeutic Goods Act 1989 (Cth)
General Retention and Disposal Schedule

9.2 Institute Policies and Procedures

Research Data Management Procedures (including Research Data Management Plan template)
Policy on the Responsible Conduct of Research and Research Misconduct
Information Management Policy
Intellectual Property Policy
Student Intellectual Property Policy
Assignment of Intellectual Property by Visiting Scientists Policy

10 RESPONSIBLE OFFICER

General Manager, Research Governance and Funding – Ext 3197

11 AMENDMENT HISTORY

Version	Date approved	Approved by/Scope of change	Date due for review
1.0	22 March 2022	New policy	March 2024