Purpose:

To ensure that all materials associated with a research project are retained for appropriate periods of time, are stored securely and in such a manner that the research details can be reconstructed at any time and that disposal occurs securely and in line with legislative and contractual obligations.

Scope:

This procedure governs the storage, retention and destruction of information (data) in human research conducted at the Royal Victorian Eye and Ear Hospital (Eye and Ear).

It applies to all Eye and Ear staff involved in the conduct of research and Honorary Researchers with an appointment at the Eye and Ear. Data retention obligations may extend beyond the period of Honorary Researcher appointments.

Procedure / Method:

This procedure should be read in conjunction with the:

- NHMRC Australian Code for the Responsible Conduct of Research (The Code)
- NHMRC National Statement on Ethical Conduct in Human Research (National Statement)
- Royal Victorian Eye and Ear Hospital Research Policy

Retaining research data is important as it may be all that remains of the research work at the end of a research project. While it may not be practical to keep all primary material (including biological material, questionnaires or recordings), durable records derived from them (such as test results, transcripts, and laboratory and field notes) must be retained in an accessible format.

Research data should be considered as a shared resource by allowing other researchers to access the data where appropriate, unless this is prevented by ethical, privacy or confidentiality matters.

Secure Storage

Data must be stored securely and access restricted to those with the authority to access the research data. Wherever possible and appropriate, hard copy and electronic research data should be held in the researcher's department or other appropriate institutional repository. If research data or primary materials are held off site, the locations must be secure and the location of storage must be recorded in the research records.

If data and/or primary materials are to be relocated outside Australia, the Investigator(s) must ensure that the same minimum standards pertaining to confidentiality and privacy are maintained, as per the conditions of the ethics approval for the research project. As above, the location of the records must be clearly recorded and the records held securely.

If the circumstances under which the storage and/or use of research data or primary materials changes, an amendment must be submitted to the HREC for its review and approval.

Electronic records must also be held in a secure system with network security and access control.

Heads of Departments are responsible for ensuring that Databanks within their department are kept according to this procedure and must keep a register of Databanks that are held in their department.

Measures to maintain the confidentiality and privacy of all data should occur at all times. If the research is collaborative or sponsored, measures must be detailed in a written contract prior to the commencement of research. All parties must also be informed of relevant confidentiality agreements and restrictions on the use of research data. Similarly, ownership of the data should be agreed early in the research planning phase and reflected in research agreements.

Retention

It is the responsibility of the research team to determine what data and/or primary materials must be retained; however, such decisions must account for legislative and regulatory requirements, conditions of funding, contractual agreements or by convention of the applicable discipline.

The central aim is that sufficient materials and data are retained to justify the outcomes of the research and to build on research findings or defend them if they are challenged. The potential value of the material for further research should also be considered, particularly where the research would be difficult or impossible to repeat.

Minimum record retention periods are summarised below. (See Appendix 1 for Full schedule and source of retention requirements)

Record type	Retention period	Storage and Disposal condition
laboratory based research	5 years from the date of any publication(s) arising from funded research	secure storage and secure disposal
clinical research (adult)	15 years	secure storage and secure disposal
clinical research (child)	25 years	secure storage and secure disposal
clinical research involving gene therapy	permanent retention	secure storage
research with community or heritage value	permanent retention	secure storage

Note: If the study materials fall into more than one category above then the research records must be kept for the longest timeframe.

The duration of retention and the disposal of any primary materials for each study must be included within the Participant Information and Consent Form (PICF) to ensure participants are informed of the intended fate of research data and primary materials prior to providing informed consent.

The location of research data storage and/or disposal of primary materials must be clearly recorded and communicated, and must adhere to legislative requirements and local policy guidelines.

If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

Disposal

Researchers are obliged to keep records which confirm the time, date, method of disposal and the person responsible for the disposal.

The method of disposal must be secure so that records cannot be reconstructed following destruction.

Outcome:

To ensure responsible and compliant management of research data and primary materials.

Definitions:

Data is defined as information obtained directly or indirectly for research purposes and information that may be used for research purposes. For example, information obtained directly from a person in interview, questionnaire, focus groups, personal and medical histories, demographics, biographies, audiotape, audiovisual records, photographs; clinical, social or observation information from a source other than the person whose information it is, such as from medical history notes, doctors notes, surgical notes, carer or relative; information derived from human tissue such as blood, bone, muscle, organ and waster products, including genetic and radiological information.

Databank and database are considered to have the same meaning. A databank is a collection of data or information, as defined above. It may be stored on paper and kept in files or stored electronically and kept on a hard drive or on disk. A databank may be established with the intent to use the information contained within for a use other than research such as disease surveillance, trend identification and the stimulation of ideas for possible future research.

Standards:

National Statement on Ethical Conduct in Human Research (NHMRC 2007 and as amended)
Australian Code for the Responsible Conduct of Research (NHMRC 2007 and as amended)
Health Records Act 2000 (Vic)
Information Privacy Act 2002 (Vic)
Public Record Office Victoria (PROV) Schedules 12/05 (2012) and 07/01(2015)
National Standard 1 – Governance (NSQHS)

Linked Policy & Procedure:

Research Policy P18.0

Approval / Committees:

This procedure was approved by the Human Research Ethics Committee and the Executive Director Medical Services/Chief Medical Officer.

Responsible Executive:

Executive Director Medical Services/Chief Medical Officer

Evaluation:

This procedure will be reviewed to ensure adherence to the National Statement and The Code.

Procedure Review:

This policy/procedure will be reviewed triennially or earlier if legislative requirements change.

Key Words for Search:

research, retention, data storage, disposal

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Procedure Details:

Details		
Procedure Number:	RS1.20	
Section:	Research	
NSQHS Standard:	1 - Governance	
Legislation Section:	E – Patient's Rights	F - Privacy
Approval Date:	6/12/2012	
Review Date (s):	19/08/2016, 19/08/2018	2018 – no changes
Next Review Due:	19/08/2021	

Appendix 1

RECORD TYPE	DOCUMENT	RETENTION PERIOD	STORAGE	DISPOSAL
Research data Raw data Lab notebooks	NHMRC Code for the Responsible Conduct of Research (2007)	Generally at least 5 years from date of publication, with the exceptions of: • Clinical trials ≥ 15 years (European Union regulation no. 536/2014 requires clinical trial master files to be retained for at least 25 years after the end of the clinical trial) • Gene therapy permanently, e.g. patient record • Community or heritage value (NB covers ARC research also): permanent and preferably in a national collection Must account for contractual retention, professional standards and legal requirements (section 2.5)	• Requirement for safe, secure storage • Requirement for record of where data is stored (section 2.2)	Requirement for policy on secure and safe disposal once retention period expires (section 2.1.2)
	The Lancet Information for authors March 2015	May require access to raw data when under review and up to 10 years from date of publication	No info	No info
	NHMRC Deed (project and researcher schemes; checked December 2015) Section 8.3	As agreed by parties, or at least 5 years after the end of the funding period	No info	No info
Human research ethics: agendas/minutes	Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 12/05 (2012)	Indefinitely		
Equipment maintenance	Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 07/01 (2015) Category 4.5	7 years		
Financial management	Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 07/01 (2015) Category 5	7 years after financial year in which the record was created		
Intellectual property	Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 07/01 (2015) Category 10.3	7 years after the patent lapses For patent applications that are unsuccessful or attempts to establish IP have been abandoned – 2 years after administrative use has concluded		
Standard operating procedures and policies	Public Record Office Victoria (PROV) Public Record Office Standard (PROS) 07/01 (2015) Category 13.3	7 years after the procedure/policy has been superseded Records documenting the development of procedures – 2 years after procedures are superseded		

RECORD TYPE	DOCUMENT	RETENTION PERIOD	STORAGE	DISPOSAL
Animal Facility	Prevention of Cruelty to Animals Regulations 2008 "101 Return of Records: The holder of a scientific procedures premises licence, scientific procedures field work licence or specified animals breeding licence must keep all records required to be kept under the licence for 4 years and must send them to the Department Head if the licence holder ceases to hold the licence during that period"	4 years (University of Melbourne retains for 7 years)	No info	No info unless licence ceased mid approval period
Internal audit	University of Melbourne Records Retention and Disposal Authority v1.3 (2014) Category 0150/5100/1 and 2	10 years after audit completed if high-risk findings 5 years after audit completed if low-risk findings		
Poisons	Drugs and Poisons Control and Management	Hospital: • Paper records of transactions to be retained on-site by the Pharmacy for 12 months • Then secure off-site storage for an additional 2 years • Electronic records to be retained for 3 years for immediate viewing • Schedule 8 drugs: registers to be returned to Pharmacy and stored on-site for 12 months. Then placed in secure off-site storage for an additional 2 years Research: • Schedule 4 and 7 drugs: records to be retained for 3 years • Schedule 8 drugs: not listed (refer to hospital policy section)	Secure off-site storage for an additional 2 years (i.e. paper records: 1 year on-site + 2 years off-site = 3 years total)	
Commercial grants	Contracts between Eye and Ear/research partners and pharma (record-keeping clauses)	Individual contract dependent	Review individual contract for details	Review individual contract for details
Grant application records	University of Melbourne Records Retention and Disposal Authority v1.3 (2014) Categories 0200/4250/1-2	Successful: 7 years after last completed action Unsuccessful: 2 years after allocation of funds		
Grants management records: administration of research projects	University of Melbourne Records Retention and Disposal Authority v1.3 (2014) Categories 0200/4250/1-2	Successful: 7 years after last completed action Unsuccessful: 2 years after allocation of funds		
Reviews of research programs	University of Melbourne Records Retention and Disposal Authority v1.3 (2014) Category 0600/6950	5 years after date of last action		

Table modified from Peter MacCallum Cancer Centre, Office of Cancer Research Record Retention Schedule (Jan 2016)