

Research Data Management Policy

Section 1 - Background and Purpose

(1) Research data and primary materials, and registers of those materials, are University records and must be stored and disposed of in accordance with University Records and Archives Policies and Procedures, <u>Privacy Act 1988</u> and the <u>Privacy and Data Protection Act 2014</u>.

(2) This Policy sets out the responsibilities of the University staff and students, academic units and central administrative units involved in research data management according to:

- a. The Australian Code for the Responsible Conduct of Research (2018) (the Code);
- b. The <u>Management of Data and Information in Research A Guide Supporting the Australian Code for the</u> <u>Responsible Conduct of Research;</u>
- c. The Open Access Policy of the Australian Research Council (ARC);
- d. The Open Access Policy National Health and Medical Research Council (NHMRC); and
- e. Established University governance.

Section 2 - Scope

(3) This Policy applies to:

- a. All La Trobe campuses and facilities;
- b. All La Trobe staff and students who engage in research;
- c. All La Trobe research, including research conducted under any arrangements with third parties and/or conducted external to the University, but under the University's auspices;
- d. All Research activities involving collection, storage, retention, import/export, accessibility, disposal, breaches and curation of data management systems and research data management.
- (4) This Policy does not apply to:
 - a. Administrative records.

Section 3 - Policy Statement

(5) The University is responsible for:

- a. Ensuring compliance of the University with current legislation, funding requirements, and other relevant codes and guidelines.
- b. Informing and training research support staff, students and researchers about how to manage research data.
- c. Establishing governance and management practices for research data and communicating the processes to

manage research data and primary materials in accordance with the relevant statutory requirements, ethical/regulatory requirements, funding agency guidelines or contractual arrangements with research partners.

- d. Providing and operationalising storage options and governance processes.
- e. Providing a mechanism to make research data available for use by other researchers, except where the sharing of data is prevented by privacy, confidentiality, ethical/regulatory restrictions, legal or other contractual obligations.
- f. Maintaining the University's open access repository.

(6) Research data and primary materials must be managed systematically according to this Policy and the <u>Guide</u> to enable good research practice to:

- a. Promote quality research
- b. Enable verification of research outcomes
- c. Support future research
- d. Ensure research data and primary materials are made available to others as soon as it is available subject to any contractual or other legal restriction, and appropriate ethical, defence related, data sharing and open access principles
- e. Enable researchers to conduct their research more efficiently
- f. Allow for better management of research resources
- g. Help to keep data safe and compliant with legal and ethics requirements
- h. Increase potential exposure and citations
- i. Ensure data confidentiality is preserved as per ethical and privacy requirements for human research participants
- j. Enhance the reputation of researchers and the University

(7) The FAIR (Findable, Accessible, Interoperable, Reusable) data principles below should also be considered:

- a. Findable: The date should have identifiers (and appropriate metadata that allow the data to be findable through disciplinary discovery portals (local and international);
- b. Accessible: The data should be open unless there are privacy, national security or commercial interest concerns. There should be clarity and transparency around the conditions governing access and reuse;
- c. Interoperable: To be interoperable the data will need to be in appropriate formats, to allow sharing;
- d. Reusable: The data should have appropriate metadata that will allow for reuse.

(8) The <u>Australian Code for the Responsible Conduct of Research (2018)</u> (the Code) and the <u>National Statement on</u> <u>Ethical Conduct in Human Research (2007)- Updated 2018</u> outline expectations for the proper management and retention of research data and primary materials. The procedures stated in this Policy ensure the University meets its continuing role in the management of research materials, and researchers retain sufficient research data and primary materials to justify the outcomes of their research and to defend them if challenged.

Section 4 - Procedures

Part A - Governance

(9) The Research and Graduate Studies Committee (RGSC) will oversee the direction and implementation of research data management across the University. The RGSC can choose to appoint a working group. The membership of the working group may include the following stakeholders and will be chaired by the Senior Deputy Vice-Chancellor (Research and Industry Engagement) (SDVC(R&IE)) or delegate:

- a. Associate Dean, Research & Industry Engagement from each School
- b. Research Office
- c. Library
- d. Digital Records
- e. Information Services
- f. Research Infrastructure
- g. Additional members as required: Graduate Research School or Infrastructure and Operations

Part B - Responsibilities

(10) The Senior Deputy Vice-Chancellor (Research and Industry Engagement) will:

- a. Oversee research data and primary materials management planning activities across the University, and where appropriate, on an inter-institutional basis.
- b. Review and approve facilities, infrastructure and online repository for the storage of research data and primary materials in accordance with this Policy.
- c. Review and approve new facilities, infrastructure and expansion of online repository for the storage of research data and primary materials to ensure legislative compliance.
- (11) The Associate Dean, Research & Industry Engagement from each School will:
 - a. Oversee research data management planning within their School
 - b. Ensure compliance with the Policy within their School
- (12) Deans or equivalent organisational units or delegates will:
 - a. Ensure researchers are aware of their responsibilities under this Policy.
 - b. Assist with the identification of local storage facility options in their school/departments for physical research data and primary materials that meet security, confidentiality and safety requirements.
 - c. Maintain clear and accurate records that help locate, retrieve and dispose of, in a timely and appropriate manner, stored data and materials.
 - d. Ensure researchers who leave the University have adequately planned for the ongoing custodial responsibilities for the research data and primary materials in compliance with this Policy.
 - e. Approve reasonable requests by researchers to take copies of data with them when leaving the University. Any arrangements should be documented, and the documentation stored with the data.

(13) The University Research Ethics Committee will:

- a. Review and approve Research Data Management Plans for compliance with the <u>National Statement on Ethical</u> <u>Conduct in Human Research (2007)- Updated 2018</u> and relevant ethical guidelines.
- b. Review and approve informed consent processes and/or waiver of consent processes to ensure appropriate consent is sought in accordance with the relevant Privacy Laws of the country/state, and/or any other applicable laws and regulation relating to research data and primary materials.
- c. Maintain and review Research Data Management Plans for compliance with the <u>National Statement on Ethical</u> <u>Conduct in Human Research (2007)- Updated 2018</u>.

(14) The Research Office will:

a. Review research ethics, research grant and contract funding applications for compliance with this policy, and

advise applicants, relevant committees and other groups on compliance.

- b. Ensure or recommend contracts outlining roles and responsibilities to transfer and/or receive research data and primary materials for research conducted in collaboration with other organisations, commissioned research and outsourced research gathering.
- c. Ensure researchers are informed and supported in complying with this Policy.
- (15) The University Library will:
 - a. Provide advice to stakeholders on the Research Data Management Plans or refer to the relevant area/s.
 - b. Provide feedback and advice regarding appropriate metadata repositories for publication of research data.
 - c. Refer stakeholders to the relevant area/s for appropriate help/advice regarding La Trobe research data storage infrastructure.
- (16) Digital Records will:
 - a. Develop and provide training and support for University Research and Administrative Units involved in research data and primary materials management.
- (17) Information Services (IS) will:
 - a. Develop, implement and maintain centrally supported and secure digital storage for research data so that researchers can comply with this Policy.
 - b. Ensure that stakeholders are consulted as appropriate prior to procurement of systems that impact on other areas that are subject to compliance with legislation, policies and guidelines.
 - c. Ensure guidelines around the use of research systems are written in consultation with all stakeholders listed in this Policy.
 - d. Provide accurate capability and security information about tools, programs and systems available to researchers for collection, sharing and storage of research data.
 - e. Review and make recommendations in consultation with relevant stakeholders on appropriate secure digital storage.
 - f. Monitor the capabilities of tools, programs and systems used in the collection, use, sharing and storage of research data to provide expert advice regarding appropriate storage of research data.
- (18) Research Infrastructure will:
 - a. Advocate for appropriate research data storage solutions. Guidance can be found on the Office of Research Infrastructure <u>website</u>.
 - b. Build awareness of the various research data storage options available to researchers.
- (19) Researchers will:
 - a. Be expected to understand and abide by the <u>Privacy Health Information Policy</u> and the <u>Privacy Policy</u> to comply with any applicable state, territory or national legislation.
 - b. Retain clear, accurate, secure and complete records of all research including research data and primary materials within Schools or equivalent and as detailed in Part D of this Policy. Where possible and appropriate, allow access and reference to these by interested parties and for audit and monitoring purposes including investigation of research misconduct allegations.
 - c. Be responsible for ensuring appropriate security for any confidential material, including that held in computing systems. Where computing systems are accessible through networks, attention to security of confidential data is required.

- d. Maintain adequate records of the source of research material, experimental data and authorship in a secure place after publication and in a recoverable format should questions arise.
- e. Maintain an up-to-date Research Data Management Plan/s.
- f. Report any inappropriate use of or access to or loss of data, in accordance with applicable institutional policies and, where relevant, other reporting schemes such as <u>the Notifiable Data Breaches scheme</u> and relevant funding bodies.
- g. Ensure that the timing and the modality of the disposal of research data and primary materials within their School, Research Centre, or Institute is consistent with the Code, University policies, procedures and guidelines, current legislation, as well as ethical and contractual requirements.
- h. If conducting research involving Indigenous people:
 - i. Apply the <u>AIATIS Code of Ethics for Aboriginal and Torres Strait Islander Research</u> and <u>AIATSIS Collection</u> <u>Access and Use Policy</u> in local jurisdictions when formulating a research data management plan.
 - ii. Consult with research participants and communities regarding the methods of collecting, storing and accessing the data and sharing the results, and further steps or the learnings from the research at the end of the research project.
- i. When leaving the University and as part of the exit planning, researchers must ensure custodianship of their data is transferred to an appropriate researcher as determined by the Dean or other organisational unit. All original data must remain at La Trobe, unless otherwise agreed with the researcher or the researcher's new organisation (if any) covering ownership and storage of the materials

Part C - Ownership of Research Data and Primary Materials

(20) La Trobe owns or has rights to use primary materials and research data created by University staff in accordance with the La Trobe University <u>Intellectual Property Statute 2009</u> and <u>Intellectual Property Policy</u>, subject to any third party agreements in relation to that data.

(21) Students and honorary staff of the University will normally own research data they create in accordance with La Trobe University Intellectual Property Statute 2009 and Intellectual Property Policy, but the University may from time to time request students or honorary staff of the University to assign or licence certain rights to their research data on agreed terms.

(22) At the end of a research project which has been hosted by La Trobe, research data and primary materials remain the property of La Trobe, unless subject to a third-party agreement.

Part D - Curation and Research Data Infrastructure

(23) Digital and physical curation must ensure research data and primary materials remain available for the applicable retention period, with appropriate data security, data back-up (where applicable), data archiving and data destruction arrangements. This is the responsibility of the relevant data custodian managing the use, disclosure and protection of source data.

Part E - Data Storage, Retention, Transfer and Disposal

(24) Research data and primary materials, and registers of that material and data are University Records and must be kept in a format, and for a period, that conforms to the requirements of the relevant state, territory or national Privacy Laws, funding agency or publisher guidelines or in accordance with discipline norms, whichever is the longer period. As per the <u>Guide</u>, in general the minimum period for retention of research data is 5 years from the date of publication. When the specified period of retention has finished they must be disposed of in a secure and safe manner in accordance with the University <u>Records Management Policy</u>, and relevant state, territory or national Privacy Laws and Regulations. All Disposal of research data is coordinated by the University's Records and Archives Services (R&AS).

(25) The period for which the data should be retained should be determined by the specific type of research, subject to any applicable state, territory or national legislation:

- a. For most clinical trials, retaining research data for 15 years or more may be necessary.
- b. For research involving young people (<18 years of age), the data must be kept for the required period from the time they become an adult.
- c. For gene therapy, research data must be retained permanently (e.g. data in the form of patient records).
- d. If the work has community, cultural or historical value, research data should be kept permanently, preferably within a national collection.

(26) Wherever possible, original data (hardcopy data, electronic data and, where relevant, materials, specimens or samples) should be retained in the School or research unit in which they were generated. If required, individual researchers can hold copies of the data for their own use, however retention solely by the individual researcher is not permitted. When data are collected by external bodies they must abide by the minimum data retention requirements outlined above.

(27) The following statements are applicable for transfer of research data and primary materials:

- a. If the original data are retained by the researcher, the Dean or Research Centre Director must be formally advised of its location and can access the data.
- b. Researchers should also give consideration as to whether specimens or samples should be retained in research repositories.
- c. In accordance with section 3.3.42 of the <u>Australian Code for the Care and Use of Animals for Scientific Purposes</u>, when animal specimens, they must be appropriately documented and lodged with an institution that manages a publicly accessible reference collection.
- d. Where primary material is not kept within the School, a written record of the location of data must be retained by the researcher and School.

(28) When a researcher moves from La Trobe, original data must remain with La Trobe, otherwise written agreement must be reached with the researcher and with the new organisation covering ownership and storage of research data.

(29) When research is carried out by staff and students at multiple organisations, agreement must be reached in writing and these must clearly specify the principles of storage and retention of research data within each organisation.

(30) When the data are obtained from limited access databases (or an external database), or via a contractual arrangement, written indication of the location of the original data, or key/information regarding the database from which it was collected, must be retained by the researcher or School.

Part F - Confidential and Sensitive Data

(31) Researchers must exercise care in handling confidential or other sensitive information used in or arising from a research project. Research data and information to which obligations of confidentiality or other sensitivities may apply commonly fall into one of the following categories:

- a. Data or information that is commercial-in-confidence or that is inherently confidential and which has been provided in confidence (e.g. secret and sacred religious or cultural practices, or information on the location of vulnerable species).
- b. Sensitive data or information subject to privacy legislation (e.g. identifiable human medical/health and personal data or information).

- c. Data or information subject to classification regimes and other controls (e.g. national security).
- d. Information, police records or information and primary materials subject to export controls).

(32) Researchers must ensure that the security and privacy measures that are used for research data and primary materials are proportional to the risks associated with the confidentiality or sensitivities of these data and materials. These measures relate to storage, access and sharing of the data and information and should be recorded in the data management plan. Researchers have the responsibility to seek advice from the relevant area/s if unsure.

(33) Regarding the use and storage of audio-recorded and video-recorded data, audio-recorded data should be deleted from the recording device as soon as transcribed.

Part G - Importation and Exportation of Research Data

(34) Researchers must ensure that they meet the relevant Customs, Australian Quarantine Inspection Service (AQIS), or other legal or regulatory requirements for the import and export of research material. Where applicable, a Materials Transfer Agreement must be executed when receiving, giving, or receiving and giving research materials. All transborder and international border dataflow must be compliant with Privacy Laws across all jurisdictions. Unless absolutely required by the terms of the research project/collaboration, research data should not be stored or otherwise transferred in non-Australian jurisdictions to ensure compliance with all relevant regulations.

(35) Research, correspondence, and informal scientific exchanges must comply with the Department of Defence requirements when sharing Defence Strategic Goods.

Part H - Research Data Accessibility

(36) Data related to publications should be deposited in the <u>University's open access repository</u> to ensure they are available to other researchers unless not appropriate and it does not comply with the relevant ethics approvals, University policies and national, state or territory regulations.

(37) Where confidentiality provisions apply (for example, where the researchers or the institution have given undertakings to third parties, such as the subjects of the research), it is desirable for data to be kept in a way such that reference to them by third parties can occur without breaching such confidentiality.

Part I - Non-Compliance and Breach of the Research Data Management Policy

(38) Breaches of this policy will be handled in accordance with the <u>Research Misconduct Procedure</u> or <u>Research -</u> <u>Higher Degree Student Misconduct Procedure</u>.

(39) The Senior Deputy Vice-Chancellor (Research and Industry Engagement) or their delegate may determine that a breach of this procedure may be dealt with as a Breach of the <u>Australian Code for the Responsible Conduct of</u> <u>Research (2018)</u>.

(40) Data breaches will be reported as per the <u>Compliance Management Policy</u> and the <u>Notifiable Data Breach (NDB)</u> <u>Scheme</u>.

Section 5 - Definitions

(41) For the purpose of this Policy and Procedure:

a. Curation: Curation of digital materials involves active interference to mitigate digital obsolescence, for example

by migrating data to ensure compliance with evolving industry standards to ensure it continues be accessible. This may require migration from one storage technology to another, or data manipulation to meet new standards for data recording and presentation in human or machine-readable forms

- b. Data custodian: Data custodians are responsible for managing the use, disclosure and protection of source data. Data custodians collect and hold information on behalf of a data provider. The role of data custodians may also extend to producing source data, in addition to their role as a holder of datasets.
- c. Data Management: Data Management is those activities that control how data is collected, organised, used, disseminated and disposed of. It includes measurement, monitoring, and auditing of all these activities. Data Management excludes the use of data in research, but includes recording entities and processes involved in producing and influencing the data in order to assist reproducibility
- d. Disposal: A range of processes associated with implementing records destruction or transfer decisions which are documented in retention authorities
- e. Defence Strategic Goods: Goods, software or technology that is regulated when exported, supplied, brokered or published. A permit is required when exporting, supplying, brokering or publishing DSGL items, unless there is an exemption
- f. Metadata: is information or facts about research data for the purpose of attribution, description, management and discovery
- g. Preservation: Preservation of digital materials refers to the retention of digital materials in the format in which they were generated. Preservation is a precondition for later curation
- h. Primary Materials: Data, materials, specimens, samples or information generated or collected by the researcher in its raw, unanalysed state as part of their research
- i. Records: (AS ISO 15489.1-2002, s.3.15): Information created, received, and maintained as evidence and information by an organisation or person, in pursuance of legal obligations, or in the transaction of business
- j. Research Data: Data or information collected, generated, created or observed which is be used to validate research findings
- k. Researcher: anyone undertaking or piloting research in association or affiliation with La Trobe including but not limited to academics, students, higher degree by research candidates, professional staff and third-party associates
- I. Research repositories: A research repository is an archive for collecting, preserving, and disseminating digital copies of the University intellectual output. Deposit of physical materials should be considered. Researchers should also submit datasets to an appropriate public data repository.
- m. Samples: A sample of material, such as urine, blood, tissue, cells, DNA, RNA, or protein, from humans, animals, or plants.
- n. Sensitive data: Sensitive data are personal information, Health and Genetic data relevant to an individual, ecological data relating to sensitive ecological communities, animal or plant species, data generated or used under a restrictive commercial research funding agreement, and data likely to have significant negative public and/or personal impact if released. Ecological data may be considered sensitive for reasons of:
 - i. conservation e.g the locations of threatened species;
 - ii. biosecurity e.g unverified sightings of pests not previously recorded in Australia;
 - iii. privacy e.g specimens collected on private property, collectors names etc.
- Staff: All employees of the University or affiliated enterprises with which the University has a formal agreement and includes casual employees, clinical staff and unpaid members of the University such as Honorary and Adjunct appointments, all of which are registered on the HR system.

Status and Details

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