

PROCEDURES

DISCUSSION DRAFT

Note: This template is suggested for use for drafting detailed procedures attached to a specific policy. It may be adapted to meet your needs.

TITLE: **Research Data and Materials Procedures**

**DATE APPROVED
(if different to the policy):**

POLICY RELATED TO: **Research Integrity Policy**

**MANAGER(S) RESPONSIBLE
FOR IMPLEMENTATION,
COMPLIANCE AND REVIEW:**

1 CONTEXT

This document covers the common research data and materials procedures to be adopted across Victoria University. It follows the Victoria University Research Integrity Policy developed in response to the Australian Code for the Responsible Conduct of Research.

In cases where variation, additional requirements or regulations, or other additional considerations are necessary the University encourages the development of addendums or guidelines. In particular there may be research project-specific data retention policies that should also be accommodated.

This procedure does not cover data and materials for assessment purposes only. For clarity the procedure does cover data and materials generated or used by PhDs, Masters by Research or any research activity resulting in or leading to a publication.

This document contains comments that are not intended to be part of the core procedures but can help provide clarity. These comments are indicated in italics such as this paragraph. The comments may form part of the final draft.

2 DEFINITIONS SPECIFIC TO THE PROCEDURE (If any)

2.1 Research Data and Materials / RDM (abbrev)

As defined in the Research Integrity Policy Item 4.1.1(a). This includes digital data, physical materials, and collections – those retained for compliance with the Research Integrity Policy and the Australian Code, those retained for ongoing value or other reasons, and externally maintained data and materials. RDM also includes any relevant records including: those containing essential information pertaining to the research or necessary in understanding or accessing the data and materials; records required to prove the integrity of the research, data or materials; and records detailing any ethical, privacy, confidentiality, intellectual property or other obligations surrounding data or materials.

Comment: It is good practice to keep relevant research records together with the data and materials. This supports better documentation and integrity, ensures appropriate long term retention of documentation and data, and ensures only appropriate future access and use. For these reasons all references to “Research Data and Materials” includes relevant records.

2.2 Research Data and Materials Plan / RDM Plan (abbrev)

A “RDM Plan” is the primary documentation for ensuring all researchers, project investigators and collaborators, and the institution are aware of issues pertaining to the management of research data and materials. The RDM Plan initially serves as a plan for how data and materials will be managed, and then as an ongoing plan for how data and materials are being maintained and accessed, then a post-activity plan for how data, materials and records will be retained. The RDM Plan must also cover access and use of externally maintained data and materials.

For the purpose of these procedures “RDM Plan” refers to the minimum information as required through the VU RDM Plan template. In a broader context a “RDM Plan” may refer to a well documented data management plan developed by institutions, departments, facilities, labs, groups or projects, that participating researchers adhere to.

2.3 Research Project / Research Activity

As defined by the Australian Code for the Responsible Conduct of Research “original investigation undertaken to gain knowledge, understanding and insight. It is a broad concept and there is no simple, single way to define research for all disciplines.” Further to this, Victoria University includes any activity involving or requiring research data and materials, particularly in use or management of data and materials. These include any research project (funded or unfunded), any Research Trainee project including higher degree research, general activities of a research group or operational unit (centre, institution, college, office, department), or any general activities of a research facility (laboratory, service centre, core facility, instrument).

3 PROCEDURES ADVISOR

The Office for Research, Associate Director is the initial point of contact for Research Data & Materials enquiries. Depending on the nature of the query further advice may be sought from the following referral network:

- Matters of ownership and IP – the college Research Development and Facilitation Managers (link?); Office for Research; Legal Services

- Matters of research integrity – Research Integrity Officer (RIO) or the Director, Office for Research (link?)
- Matters of ethics and privacy – Office for Research, Ethics team.
- Matters of infrastructure – College Directors for Research; Office for Research, eResearch team (IT related); ITS.
- Advice on Research Data & Materials practice – College Librarians; Office for Research, eResearch team.
- Advice on data and materials preservation – College Librarians and the Library Special Collections; VU Archives.
- Matters relating to the registry of RDM Plans – the Office for Research.

4 Responsibilities

4.1 Researcher

The primary responsibility for the responsible management and use of research data and materials, and the following of these procedures, lies with all researchers. Researchers are responsible for following the relevant procedures as outlined in the sections below.

Each research activity requires the registration of a Research Data and Materials Plan (RDM Plan). The registered RDM Plan must also be updated when circumstances change, as detailed in the sections below.

All RDM Plans must be approved by the immediate organisational unit leader (as defined in the Research Integrity Policy Item 2.14) or CI (as appropriate) and registered in the RDM Register in the University Office for Research.

Comments:

Chief investigators (CI) on a given project, college deans, or university research centre/institute directors, faculty or group managers, may choose to appoint a research data manager, professional staff member or equivalent role, to assist in responsible management and these procedures.

If a project CI or collaborator is not a VU staff member or affiliate, the VU researchers on the project are still responsible for ensuring that a RDM Plan is registered and updated. The RDM Plan should include data and materials that are not sourced, stored or retained at VU.

In the case where a research activity is under an ethics application the listed Chief Investigator (CI) is the primary person responsible for ensuring the integrity of the activity, including that the development, registration and implementation of a RDM plan occurs and that any updates are registered.

4.2 College Deans / Heads of Other Operational Units

Exit interviews for VU employees or students must confirm that any related RDM Plans be registered, up to date, and reflect the staff/student changes.

In the absence of any VU employed researchers on a registered RDM Plan, the head of the organisational unit (Dean of College) becomes the responsible owner of the RDM Plan.

All RDM Plans must be approved by the immediate organisational unit leader (as defined in the Research Integrity Policy Item 2.14) or CI (as appropriate) and registered in a RDM Register in the University Office for Research.

Comment [LJW1]: Consultation required as this may not be required. Not sure if practically this improves compliance. Perhaps necessary for supervisors of HDR students.

Comment [LJW2]: See above comments.

The head of the organisational unit (Dean of College) is responsible for reviewing and approving the disposal of data and materials that have fallen outside of the required retention period.

4.3 Office for Research

The Office for Research is responsible for providing the registry of Research Data and Materials Plans.

The Office for Research is responsible for notifying responsible Deans and Heads of impending review of RDM Plans and their retention periods.

4.4 University

The University is responsible for ensuring researchers have access to facilities for the safe and secure storage and retention of research data and materials, where practical. The university is responsible for providing facilities for maintaining records of where research data and materials are stored. The university is responsible for understanding responsibilities, issues and obligations for the security and access to data and materials, as informed by the responsible researchers.

The primary mechanism for researchers to document and inform the university of obligations, where data is being retained, retention periods, other requirements and issues is the registered RDM Plan.

5 THE PROCEDURES

5.1 Planning, Beginning and Conducting a research activity (Researchers responsibility)

An RDM Plan must be established prior to the commencement of a research activity.

The RDM Plan template can be downloaded from <http://research.vu.edu.au> .

Registered RDM Plans must be kept up to date throughout the activity. Specifically, a RDM Plan must be updated in the event of the below circumstances. In each circumstance, any agreement covering ownership, storage and access of data and materials should be reviewed before updating the RDM Plan. A RDM Plan must be updated:

- i. if there are significant changes to the researchers involved, any agreement involving data and materials, new or changed ethics applications involving data and materials, other requirements or obligations change or become apparent (including legal, privacy, contractual), or more generally how, where or what data and materials are to be maintained and retained;
- ii. when the activity is completed or ceases; (see "Ending the research activity" section)
- iii. prior to a researcher leaving the activity or project; or
- iv. prior to a researcher leaving the organisation unit or University.

An RDM Plan must cover primary records and analysed research data, any data/materials essential to the integrity of the research, generated at VU or externally owned, locally stored or externally maintained, including digital data, paper and other materials.

Comments:

*An RDM Plan *is not* necessary for short term projects for assessment purposes only, those identified with a minimum RDM retention period of 12 months as under section 5.6. An RDM Plan*

Comment [LJW3]: For feedback, should ownership be a requirement of planning? It does not necessarily negate the ability to appropriately manage data. It may potentially lead to misconceptions as claimed ownership may be incorrect.

Collaboration agreements require IP statements (similar) and how data will be managed but not necessarily ownership.

**is* necessary for PhDs, Masters by Research or any research activity resulting in or leading to a publication.*

It is expected that a RDM Plan will commence with only very brief information, prior to commencement of the research activity. Further detail should be added as the activity progresses.

The RDM Plan will contain the following information as outlined by the template:

- i. a complete high level record of proposed sources of data and materials;*
- ii. location of physical and/or digital data and materials, and location of copies, backups or digitised representations and records*
- iii. reference to, and location of, any other catalogue of data and materials;*
- iv. an identified minimum retention period;*
- v. additional procedures adopted to ensure safe and secure storage of, and access to data and materials;*
- vi. documented requirements for sharing and reuse, wider access to, or deposit in a subject repository and/or institutional repository (taking into account confidentiality requirements, privacy laws and any contractual obligations);*
- vii. any specific procedures to be adopted to re-evaluate and dispose of research data and materials (if necessary); and*
- viii. other information and processes necessary to locate and access research data and materials to validate or justify research outcomes and ensure the integrity of the activity.*

Comment [LJW4]: This list could stand to be removed. Seek comment on if this is useful here or not.

5.2 Using External Data and Materials (Researchers responsibility)

For using external data and materials, or data owned or curated by an external custodian, researcher must ensure an appropriate usage license or agreement is in place. (The agreement might be provided with the data and materials or be part of the access mechanism, such as a web-base license or "I agree" form.) The agreement should be checked for restrictions and any requirements on use must be formally documented in the RDM Plan.

If an agreement is not provided, permission must be obtained from the data/material custodians. The request for permission must seek written confirmation (letter, email) that the data/material owners allow the research activity and if any requirements must be met (eg. attribution, citation, restrictions, agreements).

Comment [LJW5]: Some boiler plate text might be good to advise students and/or staff. Needs to be carefully worded to not cause concern. Perhaps an appendix. Seeking feedback.

The RDM Plan for the activity must outline the custodian's retention plan for the used data and materials, if available, all restrictions and other important information. If the research activity involves copies, records or samples of the data and materials that can be retained, the Research Data and Materials Procedures apply to these to ensure they are responsibly maintained and retained. The written permission, information regarding restrictions and requirements must be stored together with any retained copies, records or samples.

Comment:

Copies and samples of externally maintained or owned data and materials may not be legally owned by VU, researcher staff or students. They may be subject to agreement or license. However, retention may be possible, with permission, and advisable if external retention of the data and materials cannot be guaranteed. Check that external custodians have a retention plan that extends past the research activity's minimum retention (see section 5.8), or that the custodians are a respected archive or repository. Ensure that durable records are kept as a minimum and the RDM Plan reflects where these are retained.

5.3 **Additional requirements and guidelines (Researchers Responsible)**

An RDM Plan should take into account, and include obligations under relevant laws, other codes of practice, professional and industry standards, contractual obligations and other University policies.

To assist in meeting additional requirements the VU Office for Research will provide access to common guidelines where possible. Please refer to the VU Office for Research website for a list of current guidelines. The Office for Research encourages groups, disciplines, organisation units and individuals to proposed, developed and/or externally sourced guidelines where appropriate. These may also include recommendations of local/specific services and advice for ease of data and materials management. Please contact the Office for Research if a guide is needed, known, or if you are proposing to develop one.

5.4 **Ending the research activity (Researcher Responsibility)**

When the research activity is completed or ceases researchers must ensure that the registered RDM plan is up to date and includes provision for the following tasks:

- i) Ensuring continued retention of the data and materials where required, including access, appropriate location, facilities and retention conditions;
- ii) Ensuring all essential information for access, use and evidence of data and materials is maintained and recorded;
- iii) Ensuring that researchers or data/material owners are clearly outlined in the RDM Plan (for retention), including local/external storage facilities and that the researchers/owners understand the requirement to update the RDM Plan if retention of data/materials changes; and
- iv) Ensuring that there is appropriate ethics and/or biosafety clearance for the prescribed handling/retention/access/destruction of the data and materials.

5.5 **Continued use or further use of Data and Materials (Researcher Responsibility)**

Some data and materials can be of significant value beyond specific research projects or as part of ongoing collections. Before using data outside of the intended research activity, consideration must be given to potential restrictions. Appropriate approvals may be required eg. ethics applications, further consent, biosafety, contractual requirements or changes, existing or amended agreements. Before using data and materials that could lead to commercial development seek commercialisation advice. This is a requirement for all research activity generated data and materials, even if generated by the same researcher.

Use of data and materials requires the registration of a separate RDM Plan for each research activity. For independent collections, archives or “banks” of data/materials a separate RDM Plan is required outlining how the collection is being managed.

For responsible reuse of another person’s data and materials (internally), if an appropriate usage license or agreement does not exist, permission must also be obtained from the VU data/material custodians. The request for permission must seek confirmation that the data/material owners allow the research activity and ask if any requirements must be met (eg. attribution, citation, restrictions, agreements). Internal custodians will need to update their RDM Plan to reflect subsequent use of data or materials to better inform later reviews of retention periods.

Comment [LJW6]: Seeking feedback.

Where data and materials will be made available, either in an open or restricted manner, to external parties, please refer to the VU Guidelines on Making Research Data Available.

5.6 **Exceptional data access requests (RIO responsibility)**

Comment [LJW7]: Seeking feedback.

A request for exceptional access is for access that would not normally fall under research or collaborative access within the research activity. It does not ordinarily cover new access for students or collaborators. It does cover enquiries made to or within the University, Freedom of Information, investigations, legal and regulatory requests, and any request where there is no longer an identifiable responsible owner of the RDM Plan.

The VU Research Integrity Officer is responsible for such requests. The process follows:

- RIO ensures that the requester has initially provided reasonable grounds for access.
- RIO sends notification of the request to the RDM Plan owner or identifies a head of operational unit appropriately responsible. This is another opportunity to identify if requests may be inappropriate.
- RIO assesses if the request seeks access to Confidential Information and identifies the nature of the confidential information. RDM could be identified as “confidential” within the registered RDM Plan for the activity, or if subject to ethics application that identifies the RDM as confidential, or if information is potentially protected by privacy act, or RDM includes commercially confidential information.
- RIO takes into account the nature of the confidential information, consulting with the RDM Plan owner or head of the operational unit, and consulting with the Office for Knowledge Exchange Industry, the university Human Research Ethics Committee (HREC), the university Animal Experimentation Ethics Committee (AEEC) or VU Legal Services as appropriate.
- RIO determines the process for gaining access to the data and materials, in consultation with the RDM Plan owner or head of the operational unit responsible.
- Access is facilitated by the operational unit responsible.

Note: The Australian Code for the Responsible Conduct of Research states under a researcher’s responsibilities “2.5.2 Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.” So it is important that an RDM Plan be up-to-date and reflect any ethical, privacy, confidentiality, intellectual property or other obligations around research data and materials.

5.7 **Storage and Retention (Researchers responsibility)**

All RDM storage must take into account ethics applications, security of materials and information, privacy, legal and contractual obligations. RDM must take into account relevant Institute, Centre or College procedures. An updated RDM Plan must be maintained outlining where all relevant RDM are retained and must refer to any requirements, restrictions or obligations around the data and materials.

University records must be stored and archived in accordance with the University Records Management Policy. Relevant copies of records pertaining to research data and materials should be stored with the research data and/or materials for integrity. (eg. contracts, agreements, ethic applications)

The VU R: drive (research data storage) has been established for the safe storage and retention of digital data, files and records. VU recommends the use the R: drive for storage of current research activities for easy transition to longer term retention. When a research activity is completed or ceases an R: drive project allocation must be used for the long-term retention of digital research data and records where possible. Each R: drive project allocation must have an associated registered RDM Plan indicating the allocation name (eg. R:\My Project Name) and the data retained there.

Where appropriate, VU encourages the contribution of research data to the wider discipline or to stakeholder communities. Researchers should consider promoting aspects of their data or collections for wider access, publishing data directly, or contributing data to a managed repository, archive or other organisation. These can include VU special collections, Research Data Australia, or recognised national and international discipline repositories. If data and materials are retained in a managed repository, archive or other organisation the registered RDM Plan must reflect this.

RDM must be retained in a durable and accessible form for a minimum retention period, the expiry of which must be explicitly stated in the RDM Plan. The following minimum retention guidelines must be adhered to:

- 5 years standard retention period
- 12 months for short term projects for assessment purposes only, and where there is no other requirement to retain for a longer period. This excludes PhDs, Masters by Research or any research activity resulting in or leading to a publication. A registered RDM Plan is not required for such data.
- 7 years for children and young persons under 18 years of age
- 7 years for psychological testing or intervention with adults
- 15 years for clinical trials
- 20 years for research under a commercial agreement
- 25 years after date of birth of participants for psychological testing, interventions or clinical trials involving children
- indefinitely, as the data, materials or project are likely to:
 - be controversial or of wide public interest
 - use an innovative technique for the first time
 - shift the paradigm in this field of research
 - be costly or impossible to reproduce
 - be of enduring value to researchers in this discipline, or other disciplines
 - support a patent application, innovation or invention, or other formal IP process
 - involve gene therapy
 - constitute a work that has community or heritage value (also should be retained in a national collection)

Where it is not practical to retain research data and materials in their original form, durable records derived from the data and materials must be retained. This may include photographs, recordings, measurements, or other evidential records.

Comments:

Researchers responsible for a RDM Plan or the responsible operational unit should review the retention period in the event of significant changes, continued use or subsequent activities, or if data becomes subject to external investigation or access request. RDM flagged for indefinite retention in particular will be reviewed and re-evaluated. Some RDM may be found of greater significance only after an initial period and may be reconsidered for longer or indefinite retention.

5.8 **Review, Disposal of Data and Material (head of operational unit responsibility)**

Comment [LJW8]: Seeking feedback.

Retained data, materials and records under a RDM Plan will be reviewed by the head of the operational unit, and researchers identified in the RDM Plan, after a 7 years retention period. Reviewers are responsible for ensuring that:

- the RDM Plan is up to date and includes any relevant agreements, contracts and obligations;
- the minimum retention period has been met;
- any associated research is not challenged and has no allegations of research misconduct (all relevant research data, materials and records must be retained until such matters are resolved);
- the research data and materials are re-evaluated, to determine if an extended period of retention is desirable or necessary; and
- all external retention and management obligations have been met (including agreements, commercial contracts, grant agreements, funding body statements, relevant research codes);
- submission to an appropriate research repository, archive or museum has been considered, in particular national and internationally recognised repositories, the VU library (special collections) and the VU archive;
- indefinite retention of durable/minimal digital records of the data and materials is considered (if not the data and materials themselves, and if practical); and
- if retention is no longer necessary, appropriate disposal and destruction is arranged for all data and materials.

Research Data, Materials and records **MUST NOT** be destroyed or removed apart from this procedure.

6 ACKNOWLEDGEMENT

Victoria University has drawn on the following sources of information in drafting this procedure:

- The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in [RFC 2119](#).
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