

Institutional Underpinnings – Ethics and Data Discussion Paper. Version 1.0

Testing the Data Sharing and Publication element of the Institutional Underpinnings Framework

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Introduction

Background

As part of the Australian Research Data Commons (ARDC) National Data Assets program, the ARDC partnered with 25 universities to create a jointly agreed <u>Research Data Management (RDM) Framework</u>. The first draft of this framework was developed through a co-design process and was released on April 1, 2022. The framework is intended to inform institutions' design of policy, procedures, infrastructure and services, and improve coordination of RDM within and between institutions. Sixteen priority elements were identified and eight of those are receiving immediate focus. This discussion paper deals with the element *Open Research and Data Publication*.

Open Research and Data Publication Element

The Open Research and Data Publication element of the framework aims to provide institutions with guidance to improve research data discoverability and impact, in line with funders and governments increasing demand for greater openness and data re-use to ensure a greater return on investment. Importantly, the element acknowledges that barriers exist to adopting open research and data publication approaches. The element also deals with infrastructure considerations and repositories. The final component of the element contains future proofing suggestions that aim to enable institutions to respond to the movement towards increasingly open research data.

Testing of Framework

This phase of the project aims to test the Open Research and Data Publication Element by examining what would be required to implement Recommendation 5 – Future Proofing recommendations. In particular, the specific recommendation to embed sharing practice in ethics applications to foster future data sharing. Other related future-proofing aspects from the element are addressed as part of this project as listed here:

- Embed sharing practice in institutional RDM policy
 related aspect, as sharing is already embedded in the University's new research data policy, so the project explores embedding sharing practices around ethics processes
- Embed sharing practice in ethics applications to foster future data sharing
 the focus of this project
- Teach greater awareness of data licensing and the different licences
 - related aspect, this project explores current knowledge and use of licences and the effect on data sharing
- Negotiate data sharing agreements early in the project as these are critical to resolving ownership / IP / right to publish and re-use
 - related aspect, explored opportunistically as part of the project related to ethics procedures
- Take appropriate measures to protect data from inappropriate access loss, theft, misuse
 - related aspect, explored by the project related to ethics process opportunities

Specifically, we focus on how to embed data sharing practice in the ethics process and trying to understand how an institution could go about this in a concrete, practical manner. How much of a barrier to data sharing are ethics processes? What are the current processes and how do they impact on data sharing? What current training supports researchers and ethics committees that enable data sharing? What specific changes to ethics processes and associated support material could be recommended?

Ethics applications are a major touchpoint for researchers when planning the collection of confidential or sensitive data. Ethics processes focus on the risks associated with collecting, storing, analysing and publishing sensitive data concerning human participants or animal research. Researchers are required to understand and balance the requirements for managing confidential and sensitive research data against an ever-changing research technology landscape. This includes deciding on appropriate storage, data protection and platforms. To help navigate this complexity, researchers seek advice from many different areas including ethics staff and committees, Institutional and research IT, the library, and other research support units.

Researchers are also being encouraged by funders and government¹ to make their data available to other researchers to verify and facilitate sharing of research data. Any sharing of data needs to consider the character of the consent provided and the requirements of privacy laws.

This project aimed to discover how data sharing at the University of Melbourne is impacted by ethics processes. It sought input from stakeholders from different areas and looked to see if there are common patterns of data sharing by researchers. It highlights any barriers and recommends opportunities that the ethics related processes can bring to future sharing of research data. It will work with key institutional stakeholders with a view to addressing the opportunities and commencing change.

Methods

Discovery: Review of Training, Support and Policies

One of the key aspects of the project methodology was a Discovery phase, which included an overview of training, support, policies and frameworks related to ethics processes and research data sharing for researchers at the university.

This initially involved a scan of relevant principles and frameworks related to research data sharing, from an institutional, national and global perspective. These included: the FAIR Principles; the Sorbonne Declaration on research data rights; the *Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research*, the code under which research at Australian Universities (and other organisations) operates; and the University of Melbourne's *Principles for Open Access to Research Outputs*.

Throughout the project, also examined were the policies, training and support related to research data sharing, which are provided to researchers at the University. This was undertaken initially through a desktop scan of relevant University policies and the institution's RIOT (Research Integrity Online Training) content, where data sharing is engaged with or mentioned in relation to or apart from research ethics processes. These were explored further during the workshop and case studies discussed below.

In this phase, we also began a mapping of the ethics process and its various stages.

Discovery: Mapping the Ethics Process

The mapping resulted from a three-pronged approach. Firstly, by obtaining a map of the ethics process from the Office of Research Ethics and Integrity (OREI) at the University. This examines the process from an administrative perspective from the point of creation of the online human research ethics application in the online Infonetica portal used to submit these applications. Secondly, our own ethics application for the workshop phase of the project not only allowed us to begin to map the process from an applied perspective but also allowed us to begin to understand opportunities for and barriers to the data sharing in the ethics process and thus informed the development of questions for the workshops themselves. Later, the researchers at the workshop contributed their perspective of the ethics application process, which built up a fuller picture.

Workshop

A second major phase of the project was a workshop, held with researchers from the University who had included data sharing in their human research ethics application as an intended outcome of their project. This included those that had already shared data and others who were still in the process of completing projects with data yet to be shared.

The participants were asked a series of questions (see appendix 1) surrounding their experiences with aspects of the ethics process, including the applications themselves, their interactions with the ethics committees, training and

¹ For example, Australian Research Council, *Open Access Policy*, Version 2017.1 (2017), https://www.arc.gov.au/sites/default/files/2022-06/Open%20Access%20Policy%20Version%202017.1.pdf; Australian Research Council, *Research Data Management* (n.d.) https://www.arc.gov.au/about-arc/strategies/research-data-management; National Health and Medical Research Council, *Open Access Policy* (2018); https://www.nhmrc.gov.au/about-us/resources/open-access-policy; Department of Prime Minister and Government, *Open Access* (n.d.), https://www.pmc.gov.au/public-data/open-data. See also discussions of Australian Code below.

support received, how the process did or did not facilitate the sharing of research data, and what aspects of the process might be improved.

During the workshops, the participants also explored their own ethics application process, assisting us to flesh out the ethics mapping already sketched out during the discovery process and to gain an on-the-ground understanding of how researchers themselves undertook and experienced the process.

This human centred approach allowed us to investigate some of the on-the-ground impacts of the ethics processes at the university including policies and training, and the application process, which we had already explored through our desktop scan and review.

Scan of Ethics Applications

Another principal method for the project was a benchmarking aspect, in which we examined a sample of historic ethics applications across a range of disciplines, project types and researchers at various career stages, and looked at how data has or has not been shared at the completion of those. This included ethics application forms, participant consent forms, interview/survey questions, plain language statements, data management plans and project proposals/overviews. We also examined projects that had not been completed, and data not yet shared, but which still gave an insight into the ethics process at various stages of a projects' research lifecycles.

The ethics applications initially were supplied by interested researchers approached by the IU project team and, later, were also provided by several researchers involved in the workshop.

Project Governance

The project was overseen by a steering committee made up of representatives from ethics, research and data support, clinical trials expertise and academic leadership. A 'terms of reference' was drawn up and agreed to clarify the role of the reference committee – with the role of the committee being to provide advice and input into the project and sign off on key deliverables.

The project itself was subject to an ethics application (University of Melbourne Ethics ID 24262) that addressed issues of data sharing and privacy of participants. This application process also provided an additional case study that provided input into this report.

Results

Review of Training, Support and Policies Discussion

FAIR Data Principles

The <u>FAIR Data principles</u> were published in 2016 and provide a useful framework for assessing how data are published and how they can be made discovered and reused. These are a set of guiding principles to make data Findable, Accessible, Interoperable, and Reusable. While some institutional training, support and policy documents mention the FAIR principles explicitly, the principles themselves are embedded within most related resources.

The RIOT training does not explicitly mention the FAIR principles, but expresses the principles in the language of reproducibility and integrity while also making extensive reference to the Australian Code for the Responsible Conduct of Research principles (see below). In particular, Module 4 'Managing and Recording Your Research' talks about allowing others to replicate your work. While this focus comes from an integrity perspective, it is equally applicable to all the FAIR principles but especially the Reusable principle.

Principles for Open Access to Research Outputs at Melbourne

The University of Melbourne has a <u>set of principles</u> relating to open access for research outputs and commits the University and its researchers to sharing research as widely as possible: "<u>to encourage the uptake of open access</u> <u>because of the wide-ranging benefits of removing access barriers to research</u>." While the principles chiefly focus on research outputs, Principle 8 specifically addresses data sharing, stating: "The sharing of research data is supported by the University, while taking into consideration regulatory responsibilities, ethical, legal, cultural and other guidelines."

At the time of writing, the FAQs on the Principles only address data sharing in two questions. The first 'I don't want to share my data' indicates that researchers are supported in but are not required to share their data. The second questions 'Where can I register metadata about my research data' lists some relevant data and metadata repositories, including the University's data repository, melbourne.figshare.com. Overall, the FAQ questions, particularly the first, provide little encouragement, support and advice to the researcher on how and why they might share their data and no mention is made of ethics processes.

The University's <u>Open Scholarship</u> "site is a hub to support University of Melbourne students and academics in exploring the ways in which they can apply open practice to their teaching and research." This provides further support for and suggestions about data sharing in one section. It suggests reasons for data sharing and directs researchers to specific resources in order to support data sharing, including the <u>Managing Data @Melbourne</u> online training modules, the Open Research Library Guide and the Digital Stewardship team.

While the Principles stated aim is to encourage data sharing, there is no mention or link to them in relevant training programs and policies at the University of Melbourne. This includes the RIOT training, which has a module on Module on Managing and Recording Your Research, with a subsection on Data ownership, protection and sharing (and which has a specific 'UoM Context' popup, which provides relevant links to University of Melbourne sources and support. The Managing Data @ Melbourne training, Module 6 'Sharing & Preserving Data' also makes no mention of the Principles. It should be noted, however, that this module does go into significant detail on data sharing best practice, providing support and encouragement for data sharing in general, as well as examining data sharing policies of various funding agencies, such as the ARC and NHMRC.

In the human research ethics application form, where researchers are required to disclose intended sharing of data, neither the Open Scholarship Principles nor the Open Scholarship site are listed are listed as documents to which researchers should refer, nor is the University's Research Data Management Policy (MPF1242). The set of Principles is not specifically referred to in the University's Research Data Management Policy (MPF1242) (updated 9 June 2022), which addresses data sharing in §§5.15–5.18. However, the main tenet of the Principles related to data sharing are reflected in these sections, particularly 5.18 which states 'Researchers are encouraged to publish research data and records to disciplinary, institutional or other established repositories to allow reuse by other researchers and maximise the value of research, unless prevented by ethical or legal obligations.'

If the Principles on Open Access, including Data Sharing are to be made known and the practice encourages, links to them must be including in training and support materials, ethics applications and policies. Likewise, the FAQs on the Principles themselves should give better information on Data Sharing, it's opportunities and link to where researchers can find further information and support. However, as the training modules are not compulsory for all researchers, many may not discover the Principles through this avenue in any case.

Australian Code for the Responsible Conduct of Research & The National Statement National Statement on Ethical Conduct in Human Research (2007)

The <u>Australian Code for the Responsible Conduct of Research</u> (NHMRC/ARC, 2018. Henceforth, the Code) is a series of principles under which research in Australia operates. The Code is embedded in the research policy framework at the University of Melbourne, including research ethics and training.

The code is supported by several guides, including *Management of Data and Information in Research*: (NHMRC/ARC 2019) and *Publication and Dissemination of Research* (NHMRC/ARC 2020), which both include information that unpacks the code in relation to the sharing of research data.

The code 'includes within its scope the appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information' (NHMRC/ARC 2019, 1), including specific institutional responsibilities.

Principle 3 of the Code – Transparency in declaring interests and reporting research methodology, data and findings – specifically advocates the sharing of data, encouraging researchers to 'share and communicate research methodology, data and findings openly, responsibly and accurately' (NHMRC/ARC 2018, 2).

The *Management of Data* document specifies institutional responsibility regarding data sharing. This includes policy development relevant to access by interested parties (NHMRC/ARC 2019, §2.5), where it notes that 'Institutional

policies should address options for sharing data via open access and via mediated access (i.e., access to data or information with the assistance of a data custodian or other authorised person).' This includes provision of facilities to safely store and manage research data 'and, where possible and appropriate, allow access and reference' (NHMRC/ARC 2019, 4).

Likewise, the Code specifies that a responsibility of researchers is 'where possible and appropriate, allow access to research data and primary materials, in particular, to enable to facilitate the sharing of research data' (NHMRC/ARC 2019, 4). Researchers should also manage, retain and store their data in a manner that facilitates its sharing, subject to legislation, other codes and frameworks, and with relevant consent, including the use of a Data Management Plan (NHMRC/ARC 2019, 6–7).

Acting alongside the Code to promote sound research governance, is the <u>National Statement on Ethical Conduct in Human Research</u>: 2007 Updated 2018) (NHMRC/ARC 2007/2018. Henceforth the National Statement) 'a series of guidelines made in accordance with the <u>National Health and Medical Research Council Act 1992.</u>' It includes a series of guidelines related to data management, including retention and sharing, including sections on informed consent, archiving/retention, sharing and future use/re-use of data (Chapters 2.2.14–20; 3.1.27; 3.1.31; 3.1.36–7; 3.1.50; 3.1.73–74. pp.32–38).

The Statement provides excellent detailed information on ethical data management to a great extent, which can be followed by those developing, considering and approving research ethics applications.

Of particular importance to the data retention and sharing practice is the discussion of informed consent in Chapter 2.2: General Requirements for Consent. It notes that 'consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it'. Guidelines in the chapter include specific requirements that must be conveyed to participants and are detailed in Plain Language Statement and on consent forms provided to them (2.2.6).

With regard to data sharing and informed consent, Chapter 2.2.14, 'Future use of data and tissue in research' is of particular importance to those considering retention and sharing of data. It notes that:

Consent may be:

- (a) 'specific': limited to the specific project under consideration;
- (b) 'extended': given for the use of data or tissue in future research projects that are:
 - (i) an extension of, or closely related to, the original project; or
 - (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
- (c) 'unspecified': given for the use of data or tissue in any future research. The necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent (see paragraph 2.2.2).

For those wishing to share their data (whether in open or mediated forms), decisions must be made about these types of consent and ensure that consent obtained aligns with future uses. Researchers may also give more in depth detail about how the participants' data will be used (for example, noting that data will be shared on a project website, shared with other researchers in the field, provided on an open access website, stored in a repository, details of identification or de-identification of data). This relates to:

- 2.2.15 Extended or unspecified consent may sometimes need to include permission to enter the original data or tissue into a databank or tissuebank (see paragraph 3.2.9).
- 2.2.16 When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.

Ensuring that appropriate consent is obtained either during or after the project, facilitates the practices of data sharing for researchers. Those researchers that participated in the data sharing workshop (see below) applied different levels of consent to their research, both specified and extended, with relevant information provided to their participants.

The National Statement does not give detailed information for discipline specific practices and methodologies, nor is it a platform for encouraging data sharing to a great extent. It does however discuss the topic in its guidelines and mention benefits of the practice.

The statement notes that 'It is also increasingly common for funding agencies to require the sharing of research data either via open access arrangements or via forms of mediated access controlled by licenses' (p.37). It does mentions potential value of data retention, sharing and future use in one place (3.1.74):

Data and information may be of cultural, historical or other significance such that they should be retained beyond the minimum retention period. Disposing of these data or information without consideration of these factors violates the ethical principle of respect. These matters should be appropriately addressed in the research plan and in consent processes and documentation.

It also notes that data storage and retention should be the practice, rather than the exception:

3.1.50 In the absence of justifiable ethical reasons (such as respect for cultural ownership or unmanageable risks to the privacy of research participants) and to promote access to the benefits of research, researchers should collect and store data or information generated by research projects in such a way that they can be used in future research projects. Where a researcher believes there are valid reasons for not making data or information accessible, this must be justified.

While benefits of data retention and sharing are thus discussed in the document but no further detail is provided for researchers, with the main purpose being protection of data and people, rather than the benefits of data retention and sharing.

Ethics processes at the University, including the ethics application form are aligned with the National Statement to ensure compliance with the requirements of the latter and these are referenced in the online human research ethics application form.

The Code, the National Statement & University of Melbourne Research Policies

The Code and Statement underpin research and ethical policies at the University, including those relevant to data sharing. The Research Data Management Policy (MPF1242) (2022) is one of these and is the chief policy dealing with data sharing.

Regarding data management and data sharing, MPF1242 addresses the topic to some extent. It notes that Research Students should develop a Data Management Plan with their supervisor (§5.19 (b)). A formal data management plan is not required for any other researchers, although it is a part of the Code (see above), but 5.1 notes 'Researchers must ensure that ownership of and responsibility for research data and records is identified and documented at the start of a research project and reviewed and updated as appropriate, with consideration given to' a number of factors, including 'storage, retention, disposal, publication or licensing of research data or records' (§§5.1(a)). The policy further engages with the Code's aspect of data sharing in 5.16, where it states: 'Researchers must make available any research data and records substantiating research findings to enable academic discussion or evaluation of research outputs, unless prevented by ethical or legal obligations.'

The policy is supported by the <u>Research and Research Training Processes</u>, which includes Research Data Management, including Retain Research Data and Share Research Data processes that provide a framework and workflow for research data management and sharing.

The Code & University of Melbourne Research Training

The Code is also embedded in the formal research training processes at the University. The Code is referred to regularly in the RIOT training, discussed elsewhere in the report, which is compulsory for Research Students only. This includes Module 1, which gives an overview of the Responsibilities of the Code, including those related to data management and sharing such as

- R22 Research Records 'Retain clear, accurate, secure and complete records of all research including research
 data and primary materials. Where possible and appropriate, allow access and reference to these by
 interested parties.'
- R23 Responsible dissemination

Module 3, Planning your Research, includes more information on data management and sharing to ensure compliance with the Code. While this module does go into some detail about data management and sharing, it is not comprehensive in directing participants on where to go to gain further information about how they would go about sharing data. Although it does treats data sharing as opportunity, it emphasises the risk aversion aspect rather than encouraging the practice.

The Code, the National Statement & University of Melbourne Ethics Processes

As with Policies and Research Training, the human research ethics application process encompasses requirements of the Code. In the current online application form, Section E specifically addresses data management and sharing, and several subsections reference the National Statement and the Australian Code.

Section E refers applicants to the National Statement 2.2.15, on consent for future use of data, and 3.1.56, which notes that users must create a data management plan when intending to store and share data. It does not however mention the sections of the Code nor the statement regarding the responsibility of researchers to make their data available where possible and the benefits and importance of data sharing. Inclusion of reference to further relevant sections of the Code and Statement here might further encourage researchers to consider data sharing.

The Code, the Statement & Practice at the University of Melbourne

While the Code specifies researcher responsibility to create a data management plan in order to guide and facilitate data sharing, there is no overarching mechanism or policy that requires all researchers to create data management plans across the University when undertaking research projects. It is only compulsory for research students, where funding bodies require a such a plan, and at the discretion of individual faculties and departments. The requirement to create a data management plan and update this through the life of a project, when necessary, inclusive of advice on support for data sharing (available through several avenues, summarised below), has the potential to increase data sharing on a wider scale.

Although the University provides a platform for data storage and sharing (or researchers are guided to utilise industry relevant repositories that facilitate sharing), uptake on the use of melbourne.figshare.com is quite low, with only 1677 items at the time of writing. It is likely that much of university project data is stored on the secure university servers and share drives with little to no facility for sharing either data or the related metadata to researchers outside the project teams. Another ARDC project dealing with data retention sought to address this by increasing the 'FAIRness' of these data sets resulting in additional metadata enabling findability of these high value collections. Anecdotally and from discussions with workshop participants, it seems as though there may be lack of knowledge of melbourne.figshare.com, as well as encouragement or support for researchers to store their research data there and potentially facilitate sharing where possible. We understand that that a melbourne.figshare.com communications plan is under development.

Although policies and training and ethics applications at the University do link to or mention relevant sections of the Code, outlining researcher responsibilities regarding data management and sharing, the Code itself is not detailed enough to encourage and support researchers in how to share data and make it safe for sharing.

Other University Sources and Support Related to Data Sharing

The University provides several training and support options to assist researchers with data management and sharing. This includes Managing Data@Melbourne, developed by Scholarly Services and the Digital Stewardship team, assisting with 'resource, training and data management planning, data focused advice on tools, resources, policy, effective process, and grant applications'. The Managing Data @ Melbourne training program (available on the LMS), aimed at graduate researchers and is open to all staff, includes information and advice on data preservation and sharing. Module 6 specifically addresses data sharing, discussing its benefits, funding body requirements, best practise for sharing and long-term preservation. The Managing Data @Melbourne training program is generally not compulsory although some departments and faculties do require their graduate researchers to complete this as part of their induction program. Because this is left up to individual unit, we do not know the extent of this requirement at present and further work would be worthwhile.

The Digital Stewardship team has a wider range of support services and resources related to data sharing on its website. This includes links to melbourne.figshare.com (the University's repository and sharing platform for research data) and information on the types of assistance the Digital Stewardship team provides such as data retention and sharing.

Further support and advice on data sharing can be found through the University <u>Open Scholarship</u> website and the <u>Research Data Management</u> section of the Research Gateway website. The sites include information and advice on open data and data sharing and the team provide regular training and events on these topics. Additionally, the Library has a <u>guide</u> on open research practises in its guides for Advanced Researchers, which provides some information on making data open and links to the Open Scholarship resources. It should be noted though that further information on potential repositories for the retention and sharing of data could be included in these guides (e.g., no mention is made of one of the most reliable repositories for sharing data, the Australian Data Archive [ADA])

Research Integrity training at the University also encompasses discussion of data management and sharing, and relates this to the Code, as discussed above. RIOT (<u>Research Integrity Online Training</u>) is compulsory for all graduate research students, and available to but not compulsory for other staff. 'The University of Melbourne [also] has a peer network of <u>Research Integrity Advisors</u> who provide advice about the responsible conduct of research and the University processes for managing concerns or complaints about research conduct.'

Recently the University has implemented a Research Data Classification Framework, which will likely in future be embedded in the ethics application process. The Managing Sensitive Data pages on the University's Research Gateway site provide information on managing sensitive data in line with this Framework. This includes the Framework, an assessment tool, information about suitable repositories for sensitive data, and FAQs with further resources. While advice is given on data sharing on this site, particularly in the FAQs, including links to support services such as the Research Data Services directory and RIOT Training, there are no direct links to specific information on data sharing, such as the Library pages on Open Data, the Open Access Principles or specific advice on data sharing and its advantages. While a useful tool, the Classification Framework focuses chiefly on risk aversion, with lack of information on data sharing potentially discouraging the practice.

Currently there is no specific self-serve training that addresses detailed aspects of data sharing, its benefits and specific applicability to various disciplines and types of data (e.g., structured/unstructured/qualitative/quantitative). While some discussion of data sharing is included in training (RIOT, MD@M) above, this is not compulsory for all researchers. Uptake on the programs by non RHD researchers has not been examined here and would be worth investigating.

Workshop & Ethics Application Process

On 19 July 2022, the IU Phase 2 team from the University held a two-hour workshop to explore researchers' experiences of the ethics application process, perceived barriers to data sharing or actual barriers that they have encountered, and how the process has resulted (or not) in their data being shared.

The sample size for the workshop was relatively small, with four researchers participating, either in response to the <u>call</u> for participants or being invited by the IU Phase 2 team. The researchers involved were already interested in and/or have some experience in data sharing or have future plans to share their data. Thus, the responses were from participants already socialised in the benefits and some processes of data sharing. It should be noted that this is the experience of only four researchers and that different experiences might be revealed with a larger sample size.

The researchers noted several benefits arising from data sharing. These included:

- Transparency (both academic and public)
- Critical evaluation and ethical scrutiny
- · Replication and error checking
- Value for money
- Promotes research: speeding up, answering new questions of old data
- Co-creation with and agency of research participants

• Allowing public engagement with/scrutiny of research

Participants came from a variety of disciplines and all four might be considered interdisciplinary researchers and work with both quantitative and qualitative data to varying degrees. Participants 1 and 2 are involved in history and philosophy of science research and, in addition, have a background in and continue to research in STEM, including medical research, research methods and ethics. Their research also focuses on replication of research data and the practise of data sharing. Participant 3 works at the intersection of human rights, political science and utilises oral interviews and significant amounts of qualitative data in their research. Participant 4 is trained and works in the fields of classics, archaeology, research data stewardship and data visualisation. Researchers were involved in both Closed Sharing with select collaborators, and more open sharing, including providing open access to research data.

Follow-up questions to gain a deeper understanding of the participant responses were developed and circulated to all four participants, with responses received from Participant 2 and Participant 3.

During the workshop, participants were asked to explore and discuss two overarching aspects of the ethics application process (full topics/areas of discussion can be found in Appendix 1 below):

- 1. Mapping the current state of data sharing and the impact of ethical considerations / processes. This was intended to:
 - a. establish process from researchers' perspectives;
 - b. examine their perspectives on data sharing;
 - c. discuss the impact of disciplinary norms in methodologies surrounding data sharing
 - d. explore how current university ethics application processes facilitate or restrict data sharing
- 2. Mapping the ideal future state of data sharing:
 - a. what data sharing should look like in the future;
 - b. what ethics processes should look like in the future;
 - c. what is and isn't working in ethics processes at the University; and
 - d. opportunities and desires for ethics processes to facilitate data sharing in future.

The resulting discussion centred around two major aspects of the broader ethics application process (see below):

1. Data management planning and training, including data retention and sharing and Data Management Plans

While a Data Management Plan (DMP) is not compulsory for all researchers and is not always a formal requirement for the ethics application process, each of the participants both had written DMPs for their research and found them a useful tool. The DMP has a section on intended data sharing was seen as potentially contributing significantly to the decision-making surrounding the practice prior to the submission of the ethics application. Likewise, other aspects of data retention and sharing, which might or not be explored through a DMP were considered by the researchers as important to the practice of data sharing and an extended part of the ethics process. This included training, support, infrastructure and other resources for researchers to facilitate data retention and sharing.

Participants noted some main points about data management (including the DMP process):

- a. Navigating the DMP process with regards to data retention and sharing could be challenging for some researchers.
- b. Great support, training, resources were needed for completing a DMP and making decisions around data retention and sharing, including discipline-specific norms and practices. This included for one researcher, cross regional data sharing requirements and for another, greater detailed information about requirements of the DMP form.

- c. One researcher noted that the DMP form was more geared toward qualitative, rather than quantitative, data.
- d. There was a perceived lack of centralised space at the University for storage of data and lack of availability of platforms to share data.
- e. During the DMP process and in general information provided, there was not enough advice on systems for storing and sharing data, including repositories.
- f. During the DMP process and in general, there is a lack of encouragement for longer-term retention and data sharing amongst researchers who may not even realise that this is an option.
- g. Disciplinary norms or lack of understanding and uptake of data sharing in various disciplines may discourage data retention and sharing. One researcher noted that they saw value in retention in perpetuity including for future researchers, included it in their data management plan but were advised to remove it by their supervisor, who didn't believe this was practiced in their HASS-related discipline.

While, arguably, there is the support, training and infrastructure (both internal and external) for those developing a DMP and/or considering retaining, storing and sharing their data (as noted above), these participants *perceived* this was lacking and did not feel sufficient support and information was provided during the various points in the research process.

There was a perception that, in practice, decisions were often discussed with a supervisor or colleagues to establish treatment of the data but would benefit from more information provided on the practice during the DMP training, ethics application, and support process and discussions with a data management/sharing experts (perhaps with discipline-specific training in the practice).

This possibly reflects a lack of detailed information provided during the various processes involved in the ethics application process and at other points of the research process, including research training, data management training and other points as discussed in the previous section. This was noted by one researcher, who observed that while these services and support are likely available to them, there was a lack of awareness around the topic of data retention and sharing, as well as training and support available to researchers in this sphere. It is also likely due to a lack of interaction points related to data sharing that are not researcher initiated. It is very much on the researcher to identify the need for data sharing and navigated the University information ecosystem to find out what resources are available.

Participants had a number of potential places where better processes could facilitate data sharing during the development of a project and when they are making decisions about data management. These mainly focused on improvement of DMP guidance and support surrounding data sharing options, as well as general concerns surrounding data management at the university:

- a. A how-to-guide for researchers who wish to make their data open. For example, template DMPs, PISCFs, how to aggregate data, protocols, data repositories, meta-data standards, de-identification procedures etc.
- b. Have much more information provided on the DMP form, including detailed information about what information is required on the form.
- c. Improve consistency around DMPs, i.e., who needs to do one.
- d. Build more detailed data management training into a statistics and research methods courses including ethics training.
- e. More inclusion of information (such as FAQs) on data sharing and retention through the research process (including but not limited to) RIOT, Ethics training, DMP forms, ethics application form and other resources where data retention and sharing is mentioned but not explored in detail.
- f. Better promotion and socialisation of the benefits of data storage, long-term retention and sharing at all levels of the university, not just in training for graduate students.

2. Ethics application process

Participants discussed in some depth the broader ethics application process (see below), including planning, pre-submission discussions, completion of the form, consent forms and PLSs, training, support, and ethics committees. They noted significant blockages to data sharing and even data retention for future use at all stages of the process but particularly on the application form and related materials and at the point of ethics committee assessment.

- a. Ethics application forms/documentation/templates
 - Defaults in ethics process (including the branching of the online application form and defaults in the associated documents) restrict and prove barriers to data sharing. This includes:
 - Data Sharing is only addressed in Section E on Data in the subsection related to the question 'Are data to be stored in a databank for future research?'. Questions related to data sharing only appear if the user selects 'Yes'. This includes the open text questions 'Purpose of Future Use' and 'How will restrictions on use of data be recorded to ensure future adherence?'. This is drawn from the process/requirements in the National Statement (NS 2.2.14-18, NS 3.1.55-62).

The potential for data sharing is never flagged in the application form unless this initial question is selected. This contrasts with earlier versions of the application form in Word format, examined by the IU Phase 2 team. In these, 4.3 Future use of Data, Materials or Tissues' was a separate question to other issues of data management, retention and storage.

- There is no longer a methodology section on the form, in contrast to earlier versions in Word format. For many researchers, data retention and sharing are an integral part of their methodology, and this is another point in the application process where they might be prompted to consider data retention and sharing.
- A DMP is not a requirement of all ethics applications. DMPs are a point where a researcher might be flagged to consider data sharing as this is a process that specifically asks questions (albeit brief) about planned data retention and sharing.
- In the Ethics application form, Consent forms and PLS, certain defaults do not encourage data retention and sharing. For instance, the ethics application form offers seven options regarding retention of data, ranging from perpetuity to destruction after five years (and other). Five years is the standard minimum required period for retention of research data, but required minimum periods may be shorter or longer and may depend on state and federal legislation.² While not all data should be kept in perpetuity, more in-depth consideration of how and why data should or should not be obtained is needed, particularly as this is supported by the National Statement 3.1.50.
- Further, despite these options, the default on the participant consent form for retention of records is: 'I understand that the data from this research will be stored at the University of Melbourne and will be destroyed 5 years after publication.'
- On the PLS, the question about potential data sharing and retention is open ended 'What will happen to the information about me?' – again, with no guidance for the researcher on where to explore potential data retention and sharing.
- There is not a significant amount of detail on the benefits of and how to retain and share data sharing during the entire ethics application process. Where data retention and sharing are addressed, researchers are only guided to the National Statement, University retention and disposal of records policies and relevant legislation (and not the Code) – a range of

² NHMRC/ARC, Management of Data and Information in Research (2019), 2.3. https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf

policies and frameworks that actually provide little concrete or useful guidance on the topic.

- As noted above, this research training/advice on data retention and sharing seems to often
 come from supervisors and peers rather than data management experts. Researchers
 suggested better information might be given during the process, such as links to an FAQ on
 data sharing and where support services and training on the topic, including discipline
 specific advice, might be found.
- More guidance, training and support on completing the ethics application is needed. Where
 these supports and resources are available, this should be flagged somewhere during the
 process and appropriate links provided.
- Overall, these blockages were also perceived by participants as potentially discouraging
 research that incorporates sensitive data overall, with the potential perception by
 researchers that this type of research is too difficult to navigate safely.

b. Ethics Committee

The workshop participants also made considerable mention of the ethics committees that assessed and approved the human research ethics applications. They saw the aspects of the committee system as a barrier to data retention and sharing. Some of the main issues identified included:

- A lack of understanding of research data retention and sharing as a practice and the benefits that arose from it, including, at times, disciplinary norms where data sharing was usually acceptable. This could lead to refusal by the committee of intents to share data.
- One participant noted they were discouraged from sharing oral interview transcripts with their participants unless the participant requested it. This was despite best practice in oral history being to send interviewees transcripts for checking. The researcher felt that this decision was made to protect the researcher and the University in a cross-border data transfer situation. However, this researcher viewed sharing data with their interviewees as a methodological concern, not only for co-creation of the research but also for future use by the interviewees to enact change from a human rights perspective in their nation. This was included in the original research methodology and the researcher removed it at the request of the committee.
- On the other hand, another workshop participant noted that two different human research ethics committees approved several projects where data sharing, including the sharing of un-anonymised data, as well as permanent retention of the data, was approved with no pushback. The researcher noted that the only pushback was a lack of understanding about why a researcher wished to retain the data permanently, demonstrating potential lack of engagement with discussions of potential for future research through re-use of older data and FAIR practices.
- Workshop participants felt that ethics committees don't necessarily have fine-grained knowledge and/or training about context of research (for example, they don't have the country/regional specific knowledge) nor about data sharing and long-term data retention itself (and as a methodology) so are uncertain when it is proposed.
- They commented that this might be dependent sometimes on the committee and their composition and expertise.
- Another participant commented that the avoidance of commenting on methodology by HRE Committees was also problematic as data retention and sharing are often part of a researcher's methodology.
- A further comment was that committees are focused on 'protecting' participants and data, and that finding ways to safely share data is not a priority or consideration.

- It was also suggested by workshop participants that the time taken going back and forth between HRE Committees and researchers, sometimes multiple times, and the delays in commencing research that this caused, could discourage researchers from suggesting data sharing and retention outside what committees might be comfortable with.
- Workshop participants suggested that committee members should receive training in the benefits and opportunities of data retention and sharing and that a committee should contain at least one or two members that were trained or had experience in data retention and sharing.

Ethics Processes & Review of Ethics Applications

A section of the workshop was concerned with mapping the ethics processes from the researchers' points of view and comparing with a high-level map of the process from the University's Office of Research Ethics & Integrity (OREI).

From the perspective of the *OREI* (Figure 1) and the administrative point of view, researcher's ethics application process begins with the creation of the application and loading of supporting documents in Infonetica, followed by pre-submission review and feedback. This is followed by formal submission of the application, review by the ethics committee and an outcome (either approval or request for further amendments). A step-by-step guide for researchers on this process can be found on the Research Gateway website.

Further amendments may require the researcher to return one or more times to the application and resubmit. As noted by workshop participants above, this can often significantly delay the start of a research project, particularly with HRE Committees often only meeting once a month.

Researcher ethics application process



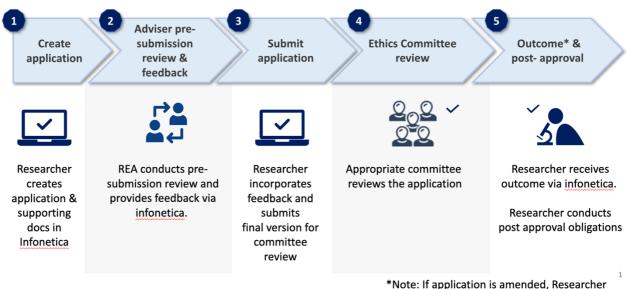


Figure 1: Basic mapping of ethics application process from researcher perspective. University of Melbourne, OREI.

For workshop participants, the researcher journey, from their perspective the process includes extra steps: at the beginning, the drafting stage (Figure 3), and 'potentially multiple rounds back to committee'.

needs to go back to 'submit application' stage

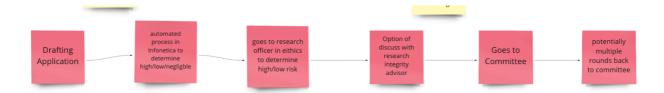


Figure 3: Journey of ethics application process from perspective of workshop participants. From MIRO board at workshop.

In addition to the basic steps, researchers viewed the process more holistically, identifying the development of the research project and methodology, discussions with supervisors and peers, and the creation of a data management plan as key points contributing to the ethics application process, including with regard to data sharing and retention. These pre-application discussions and considerations were vital to what they might include in their ethics application. As discussed above though, this might not involve a strong understanding of the possibilities and benefits of sharing data. Indeed, workshop participants noted that prior to the ethics application and even the research development/data management process, researchers would benefit from further information and training on the topic of data sharing, as well as engagement with experts on data retention and sharing throughout research lifecycle. Research Ethics Advisers are available for consultation prior to submission and in some schools (e.g., Melbourne Law School), this is a compulsory step prior to submission. Advising this on the Human Research Ethics website or at the beginning of the application form could prove useful for researchers.

With respect to data sharing in the above mapping of the ethics application process, researchers might benefit from an extra step being added to this process. For example, the provision of information and one-one-one discussions with someone trained in data management including sharing but who also is involved in the ethics processes, such as an REA, during the course of development of the research, data management strategy and ethics application. Overall, researchers might benefit from discussing their application with an REA (not only supervisors and peers/colleagues) prior to submission to Infonetica to ensure a smoother and more rapid process.

Conclusion

The Institutional Underpinnings Phase 2 research program for the University of Melbourne found a number of main points that revealed both opportunities for and barriers to data sharing (including long-term retention of data) through the broader human ethics processes and related areas in the research lifecycle at the University.

Key barriers to data sharing and long-term data retention

Researchers are not provided with sufficient direction or support they need to make decisions about data sharing including:

- Lack of information and training on the topic at points where researchers could be informed (e.g., data management planning, ethics application forms and associated documentation, University policies, research training modules).
- Limited discoverability of existing relevant information on the topic.
- Lack of discipline specific advice on data sharing.

Overall, while there is support for data sharing and retention on University platforms, including relevant web pages, the Infonetica platform and training modules, as well as policies that encourage data sharing, there is a lack of promotion, training and encouragement for data sharing through the University platforms and processes where researchers might be exposed to it.

The ethics and data management processes, including policies and training, at the University by and large emphasise risk aversion and protection of people and data, rather than exploring the potential benefits of the sharing and retention of that data.

Areas of improvement/consideration

Ethics processes play only one key intervention point for changing researcher perceptions and behaviours around data sharing. More broadly, University-wide culture change, through socialisation, training, encouragement and support is necessary to impactfully increase data sharing at the University. This project has revealed some areas for improvement at both these scales.

University-wide recommendations:

- Improving information resources about data sharing, including:
 - Better discoverability of existing University information about data sharing by embedding it in research administration processes, such as the ethics application process or research training modules.
 - Creating more detailed information about the benefits of data sharing and retention, including appropriate discipline-specific practices, to which researchers can refer/be referred.
- Improving the training environment around data sharing, including:
 - o Building data management training into a more integrated research methods training package.
 - Ensuring information is delivered in onboarding and ongoing training packages, rather than as oneoff prompts
- Broad promotion and encouragement of data sharing, including:
 - Better communication of the benefits of sharing and retaining data along FAIR principles
 - o Promoting and encouraging use of data archives/repositories (including figshare) with the ability for publicly sharing data and/or metadata.
 - Support of and advice with discipline-based practices through staff knowledgeable about data sharing in specific fields.

Ethics process recommendations

- Linking researchers to existing information, support and training in current ethics resources (including the application form, consent and PLS templates). These might include links to Open Data and Managing Data @ Melbourne, as well as to the Principles for Open Data or the Code.
- Conducting a terminology review of the ethics application form as pertains to data sharing. For example: what is a databank? Does 'Sharing data' mean within project, or more openly with others (e.g., data publishing). Provide an institutional understanding of terms. Hover over or link to terms. Use the NS terminology plus explain.
- Revising specific blockages in the ethics application process, including default responses on the forms. This
 might include reconsidering some of the branching, providing dropdowns in associated documents (e.g.,
 consent forms, PLS) that provide options and links to information on data retention and sharing.
- Inclusion of reference to further relevant sections of the Code and Statement in the ethics application form might further encourage researchers to consider data sharing.
- Build feedback or comments on the process into ethics application forms.
- Create a step-by-step guide or 'What to do before you submit and ethics form' guide for researchers (including advice on where and how they can get information on aspects of this, including data sharing) would be useful.
- Discuss with Ethics Committee to ascertain their understanding of data sharing and their perspective.
- Continue to meet Reference group and prioritise actions.

Some of the above suggestions could be implemented relatively rapidly (e.g., providing links to information on the relevant forms). Other aspects, such as revising ethics processes and greater promotion of data retention and sharing across the University would require more time. This discussion paper also suggests that the University needs to do

further work to gain a more detailed understanding of current researcher practices, understanding of and enthusiasm for data sharing, as well as what researchers require for this to become part of their research process.

As a next step, the Reference group will reconvene to prioritise recommendations, including consideration of:

- Desirability, feasibility and viability (e.g., financial viability) of all recommendations
- Required resourcing and most appropriate operational area to action a recommendation
- More detailed planning of specific actions required
- Any co-dependencies between recommendations or against other programs of work

These findings concur with some aspects found by two similar projects: one at Edith Cowan University and another by a Go8 team of librarians tasked with investigating barriers to data sharing in Australian universities. Both found that it was a combination of processes, training, communication and socialisation that might assist with increased uptake of the practice. The ECU experience underscores this multi-pronged approach. In addition to reviewing policy and procedures they 'will identify data sharing champions and provide improved support material for researchers and skills development for support staff'.³

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³ Edith Cowan University is also participating in the Institutional Underpinnings project, examining ethics processes and data sharing. Once the resulting report is made public, it may be included in a later version of this document.

Appendix 1

Institutional Underpinnings Workshop & Post-workshop Questions and Discussion Points

Workshop Discussion Points

Workshop Objectives

Examine:

- Do disciplinary norms impact data sharing?
- Does the current ethics process impact data sharing?
- What would make you share data more regularly and effectively?
- Are we missing anything?
- How do we capture this additional information?
- How do we implement changes that will have a significant impact?

Three Sections/Sets of Activities

Pre-Activity: exploring participants' research backgrounds

Activity 1: Mapping the current state of data sharing and impact of ethical considerations/processes

Activity 2: Mapping the ideal future state

Activity 3: Planning for next steps [This section was absorbed into Activity 2 due to time constraints but also as participants covered this in the previous activity when mapping their ideal future state.]

Activity 1 Mapping the current state of data sharing and the impact of ethical considerations / processes

1a: Using a post-it note from the tab on the left-hand side, describe your current ethics application process.

[Created a researcher viewpoint of the ethics journey]

1b: Participants were asked to consider three ideas and rate them as positives or negatives [some also fell in between the two]

- 1. What is your opinion on data sharing?
- 2. Is your opinion influenced by any disciplinary norms or considerations?
- 3. How does the current ethics process impact your opinion or ability to share data?

Activity 2 Mapping the ideal future state

Participants were asked to consider:

- 1. What should data sharing in the future look like?
- 2. What should the ethics process in the future look like?

By placing ideas into four categories:

- 1. Delights: what's working?
- 2. Challenges: what's not working

- 3. Opportunities: what can be improved
- 4. Wishlist: What doesn't yet exist

Post-workshop Discussion Points

Following the workshop, two participants were asked to explore their observations in further detail. These questions formed the basis of that discussion.

- 1. A number of participants mentioned that the human research ethics application (including the form itself and templates of documents such as PLS and consent forms) was potentially discouraging to or not encouraging of data sharing.
 - What specific points in the application process discourage data sharing? What do you think could be provided to or done for researchers/what changes could be made to forms and templates etc to encourage data sharing.
- 2. Are you aware of University of Melbourne Open Access Principles and the Open Scholarship site and have you used it, specifically with regard to data sharing? Please feel free to elaborate on how you have found it useful/not useful or have any other comments
- 3. Are you aware of the University Data Management policies at Melbourne with regards to data sharing? Please feel free to elaborate.
- 4. Are you aware of and have you utilised any support services or training (internal or external/formal or informal) to provide assistance with sharing data for research projects? Please feel free to elaborate.
- 5. Are you aware of suitable repositories to share your data (including University repositories?)
- 6. Which HRE committee did your project go to?
- 7. Did you have any issues with the committee questions/requests etc that affected or may have affected your capacity or eagerness to share your data?
- 8. Did you specifically have pushback from the committee on data sharing of identified or de-identified data or about the length of time that you wanted to keep your data?
- 9. Do you feel that the University promotes or provides adequate support for data sharing throughout the ethics process?