

Data Management Planning

Simon Esling Centre for eResearch University of Auckland **July 2024**

Today's session

- What is a Data Management Plan (DMP)?
- Why create a DMP?
- What are the common sections of a DMP?
- Examples of Data Management Plans
- Questions?



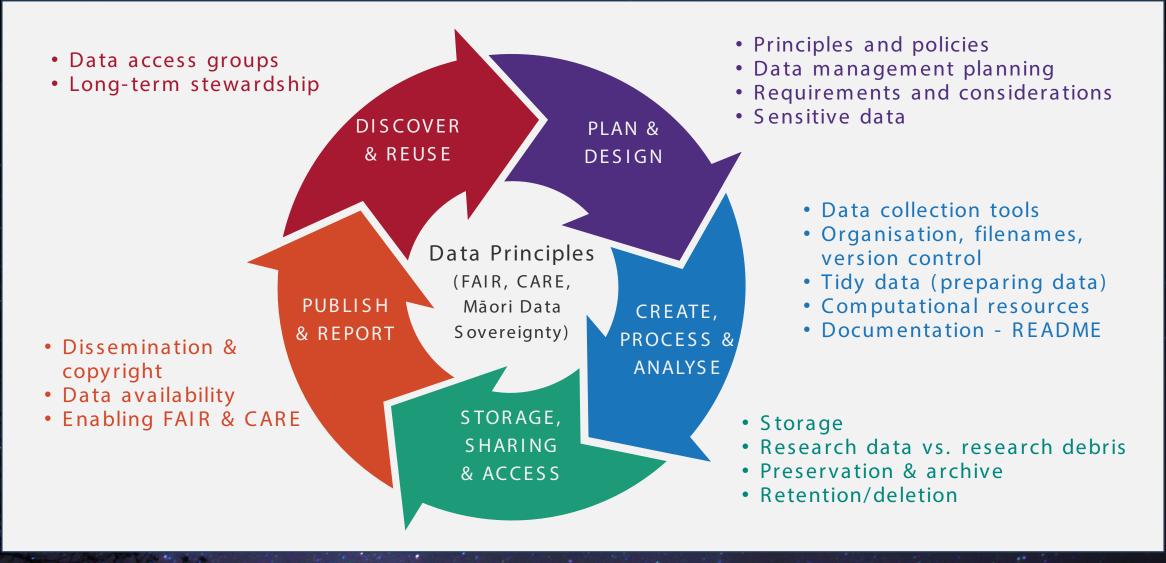
What is a Data Management Plan (DMP)?

Data management plans are <u>structured</u> documents that describe the important details and decisions relating to the data generated/gathered, stored and analysed during a research project.

DMPs include the project team members and their roles, outlining the requirements and considerations for the data and engaging with external stakeholders.



Research Data Management





Why create a DMP? For funders



National Institutes of Health















Why create a DMP? For Policy



There may be an institutional policy to ensure sensitive and restricted data is appropriately managed.

The DMP is a means of outlining where the data is stored, for how long, and who can access it.



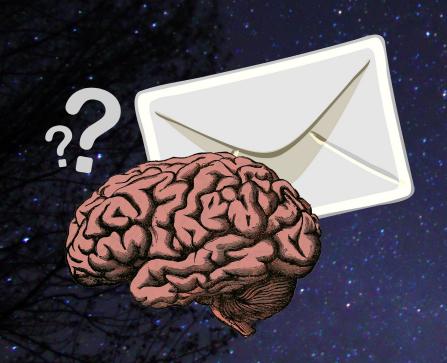
Why create a DMP? For Policy



- Data Governance Policy
- Intellectual Property Policy
- Research Data Management Policy
- Privacy Policy



Why create a DMP? For you







There are DMP tools online to help with templates













What are the common sections of a DMP?

Project information

Requirements and considerations

Data

Sharing and access

Publish



Title and description
Identifiers

Project
Information

Activity type
Research codes



Data Sovereignty Constraints Ethics Rights holders Intellectual Property Contracts and copyright

Requirements

and considerations



Data

Describe data creation/collection
 (Equipment/software/code)
 Non-digital/physical artefacts
 (Geospatial location)
 Data sources - e.g. databases
Metadata (+ any prescribed standards)
 Storage type/amount/location
Analysis - equipment/software/code
Analysis - standard(s)/schema(s)



Primary Data Owner
Stakeholder access
Data Manager
Access management
Data preservation
Minimum retention period

Sharing and access



Long-term data accessibility
Data publication(s)
Open Access/FAIR Publish
Licensing requirements
Creative Commons License

Findable, Accessible, Interoperable, Reusable



Examples of DMPs

DMPTool and DMPonline sites are run on the DMPRoadmap codebase



California Digital Library
USA



Queensland Cyber
Infrastructure Foundation
Australia



Digital Curation Centre
UK



University of Auckland

DMP template



HDEC
Data (and Tissue)
Management Plan
templates

https://ethics.health.govt.nz/
guides-templates-and-forms



University of Auckland (auckland.ac.nz)

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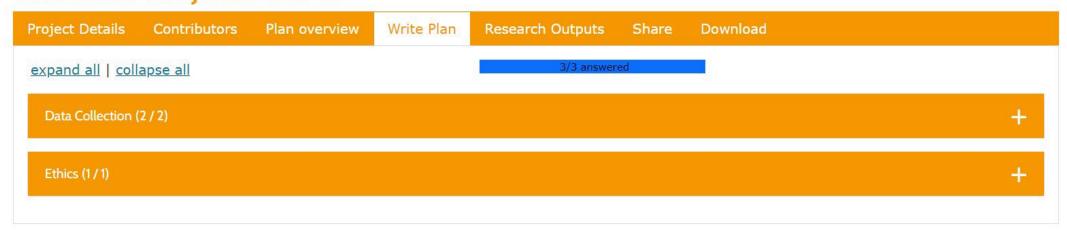
The Best Project Ever

Project Details	Collaborators	Write Plan	Research outputs	Finalize	Download	
This plan is based expand all collaps		lt DMSP" templa	ate provided by National	I Institutes of	Health (nih.gov)	
+ Data Type (2 / 3)						
+ Related Tools, Software and/or Code (1 / 1)						
+ Standards (1 / 1)						
+ Data Preservation, Access, and Associated Timelines (3 / 3)						
+ Access, Distribution, or Reuse Considerations (3 / 3)						
+ Oversight of Data Management and Sharing (1 / 1)						





The Best Project Ever 2









Data obligation considerations

Based on your selection above, note any considerations that might be important for the research project and data. For ethics, IP and indigenous/cultural constraints, detailed considerations can be listed in the subsequent fields.

Click or tap here to enter text.

Ethics

Ethics approval number

Enter the ethics approval number for this research project if you have one. If ethics is not required, put N/A.

Click or tap here to enter text.

Ethics type

Select an option(s) if your research will involve any of the following subjects or considerations.

Please select

Ethical considerations and management of data

Research ethics provide guidelines for the responsible conduct of research. At the university, all researchers are expected to maintain the highest standards of professional conduct when undertaking or supervising research in line with the Research Code of Conduct Policy. Consider all the ethical issues which may affect your project, including:

- How will you use and store data?
- Who is involved?
- Who can access the data?
- How long does it need to be kept?
- How will you secure or transfer sensitive data?
- How will you protect participant identity? What measures need to be implemented to ensure data is managed appropriately, such as data anonymisation, confidentiality, consent and privacy?
- What processes will you use to obtain consent for data sharing or reuse/optional secondary uses?

Click or tap here to enter text.

For more information, visit the ResearchHub:

- Research ethics Manage ethics and regulatory obligations
- Confidentiality and Non-Disclosure Agreements
- De-identifying data
- FAIR principles for research data
- Privacy and ethics in research (webinar).
- Privacy Act Changes Essential information for researchers

Consult with your Faculty-based Ethics Advisor and FIRST teams who can assist you in identifying and considering how to manage ethical requirements and issues which may arise from your research.

Rights holders

Owners/stakeholders/rights holders conversations

If there are other identified owners/stakeholders/rights holders to the data it is important to discuss and confirm data access expectations in both the short term and long term. For more information, visit the ResearchHub:

- Research Impact and Engagement
- CARF principles for indigenous data



Data sovereignty

Data sovereignty concerns the management of information in a way that aligns with the laws, practices and customs of the community in which it is located. In an Indigenous context, this may manifest at an individual or a community level. If the research involves Māori or Pacific people, language or culture, consideration must be given to the data access rights, ownership and governance entitled to indigenous nations and peoples. For more information and resources, visit the ResearchHub:

- CARE principles
- Māori data sovereignty
- Pacific data sovereignty

Click or tap here to enter text.

Contracts and copyright

Licenses/Agreements/Contracts

List any agreements, contracts or licences related to your project. If you require help sourcing your funding contract, reach out to your FIRST team.

Click or tap here to enter text.

Copyright and intellectual property (IP) owners

Copyright refers to the rights of ownership, reproduction, distribution and sale of work. In most cases, as an employee or student of the university, you own the copyright for your research work until such time as you transfer the rights. For more information on Copyright, visit the University Copyright Support pages or make contact with the Copyright Officer via the Research Hub.

Intellectual property refers to the ideas, inventions, and other creative works staff and students create through their research and other activities. Understanding how IP rights are derived is important for the commercialisation, collaboration, and future use of the research and data. For more information on IP, see:

- Intellectual Property Created by Staff and Students Policy
- Intellectual Property: A guide for students.
- Intellectual Property: An Overview
- Data sharing agreements

Choose an item.

Copyright and IP considerations

Based on your selection above, please note/detail any considerations that might be important for the research project and data. For example, if selected 'Joint Ownership' or 'Third Party data', state the relationships, agreements in place and rights permitted to use, store, publish or re-use the data. If you have selected 'Unknown', document the actions (and progress) that will be taken in order to find out the relevant owners. If your research is subject to a contractual funding agreement, indicate if there are any restrictions noted in relation to copyright or IP. If you require help sourcing your funding contract, reach out to your FIRST team.

For questions related to Copyright, contact the <u>Copyright Officer</u>. For questions related to IP, contact <u>UniServices</u> <u>Click or tap here to enter text.</u>

Data

This section details information about the organisation of the research data across the project life-cycle.



HDEC Data Management Plan

8 ACCESS TO AND USE OF DATA

Collected data will be used to answer the research questions and fulfil the study requirements described in the study protocol, and for the secondary purposes outlined in Sections 7.4 and 7.5.

8.1 IDENTIFIABLE DATA

Identifiable data may be accessed by the following groups: Add, modify, or delete as appropriate:

- The Investigator and designated study staff, to fulfil protocol requirements.
- Local radiology staff, to process, analyse and report images.
- Study monitor(s), for eligibility confirmation and source data verification purposes.
- The Sponsor and CRO, for audit purposes.
- The Sponsor and its authorised representatives, in the event of a compensation claim by a participant.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.
- The participant's GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

8.2 DE-IDENTIFIED DATA

De-identified data may be accessed and used by the following groups: *Add, modify, or delete as appropriate*:

- The Investigator and suitably trained and experienced study staff, to conduct the study.
- Spansor / CRO study manitar(s) for source data verification number

Add if applicable: De-identified data [may / will] be included in clinical trial registries and data banks (refer to Section 8.7).

8.3 [ANONYMOUS/ANONYMISED] DATA

Add if applicable: [Anonymous/Anonymised] data may be accessed and used by the groups described in Section 8.2.

Add if applicable: Anonymised data may also be made available to other researchers, as described in Section 8.5.

8.4 SENDING OF DATA OVERSEAS

Add if applicable: [Identifiable / de-identified / anonymised] data will be sent overseas to [state main countries].

Participants will be informed of the potential risks and cultural issues associated with sending [and storing] data overseas, and that there may be no New Zealand representation on overseas governance committees.

8.5 FUTURE USE OF DATA

Add if applicable: De-identified [and/or anonymised] data will be used by the Sponsor for future medical or scientific research as specified below: **select as appropriate**:

- unspecified purposes which are directly related to the study question(s)
- unspecified purposes which are related to the item and/or condition under study
- unspecified medical or scientific purposes which are not related to the study questions
- other unspecified research

Add if applicable: [If participants provide optional additional consent] De-identified [and/or anonymised] data will be made available to other researchers on request for future research as specified above and / or will be added to data from other sources to form larger datasets.



HDEC Data & Tissue Management Plan

8 Access to and Use of Data and Tissue

Collected data and tissue will be used to answer the research questions and fulfil the study requirements described in the study protocol, and for the secondary purposes outlined in Sections 7.4 and 7.5.

8.1 IDENTIFIABLE DATA AND TISSUE

Identifiable data and/or tissue may be accessed by the following groups: *Add, modify, or delete as appropriate:*

- The Investigator and designated study staff, to fulfil protocol requirements.
- Local laboratory staff, to process, analyse and report [insert type of samples] samples.
- Local radiology staff, to process, analyse and report images.
- Study monitor(s), for eligibility confirmation and source data verification purposes.
- The Sponsor and CRO, for audit purposes.
- The Sponsor and its authorised representatives, in the event of a compensation claim by a participant.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.
- The participant's GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.
- The Medical Office of Health, in the event of a positive result for a notifiable disease.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

Identifiable tissue will be used for analyses as described in the protocol [and laboratory manual].

8.2 DE-IDENTIFIED DATA AND TISSUE

De-identified data and tissue will be accessed and used by the following groups: *Add, modify, or delete as appropriate:*

- The Investigator and suitably trained and experienced study staff, to conduct the study.
- Sponsor / CRO study monitor(s), for source data verification purposes.
- The [New Zealand / overseas] laboratory, for sample processing, analysis, and reporting purposes.
- The imaging vendor, for analysis and reporting purposes.
- The CRO and Sponsor, for study conduct, data analysis and pharmacovigilance purposes, product registration and marketing, or as otherwise permitted by applicable local and international laws and regulations. Add if applicable: Third parties working with or for the Sponsor, including the Sponsor's subsidiaries and affiliates and third party researchers, may also have access for these purposes.
- The Health and Disability Ethics Committee, to comply with legal and regulatory duties.





HOME

PLAN *

MANAGE *

DATA RECORD *

PUBLISH *

ADMIN

keyword(s)

Search

Overview	This section details information about the regulatory and contractual obligations (if applicable) related research data as well as considerations around the ethical and sensitive nature of the research data.					
Project information	Considerations					
DMP Permissions	Select the constraints that apply (can select multiple) and then add comments in the considerations be					
Requirements and Considerations	Constraints					
Considerations	☐ Ecologically sensitive (e.g., endangered species)					
Data	☐ Ethics approval required					
Sharing and access	☐ Health or medical					
Sharing and access	☐ Indigenous/Cultural					
Publish and Report	☐ Industry partners					
Services	☐ Intellectual property (e.g. commercialisation, patent)					
Services	Personally Identifiable Information					
	Political					
	Protective security (e.g., International collaboration/export controls)					
	Other					



Questions?



