Medical Research Council (MRC): MRC Template - Initial Phase

0. Proposal name

0. Enter the proposal name

Guidance:

Exactly as in the proposal that the DMP accompanies

1. Description of the data

1.1 Type of study

Guidance:

Up to three lines of text that summarise the type of study (or studies) for which the data are being collected.

1.2 Types of data

Guidance:

Types of research data to be managed in the following terms: quantitative, qualitative; generated from surveys, clinical measurements, interviews, medical records, electronic health records, administrative records, genetic and genomic data, images, tissue samples, code, software and workflows etc.

1.3 Format and scale of the data

Guidance:

File formats, software used, number of records, databases, sweeps, repetitions, etc. (in terms that are meaningful in your field of research). Indicate the size of data to be stored and made available.

Do formats and software enable sharing and long-term validity of data?

2. Data collection / generation

2.1 Sources of data

Guidance:

Will you be collecting/generating new data or re-using existing data? How will you achieve this?

2.2 Data quality and standards

Guidance:

Which community data standards (if any) will be used at this stage? How consistency and quality of data collection / generation will be controlled and documented, through processes of calibration, repeat samples or measurements, standardised data capture or recording, data entry validation, peer review of data or representation with controlled vocabularies.

2.3 Consent for data sharing and re-use

Guidance:

If you are obtaining consent or consent has been obtained previously, please explain how this allows data sharing and re-use.

3. Data management, documentation and curation

3.1 Managing, storing and curating data

Guidance:

Briefly describe how data will be stored, backed-up, managed and curated in the short to medium term. Specify any community agreed or other formal data standards used (with URL references) to enable interoperability. [Please note that data security standards should be included in Section 4].

3.2 Metadata standards and data documentation

Guidance:

What metadata is produced about the data generated from the research? For example, descriptions of data that enable research data to be used by others outside of your own team. This may include documenting the methods used to generate the data, analytical and procedural information, capturing instrument metadata alongside data, documenting provenance of data and their coding, detailed descriptions for variables, records, etc.

3.3 Data preservation strategy and standards

Guidance:

Plans and place for long-term storage, preservation and planned retention period for the research data. Include formal preservation standards, if any. Indicate which data may not be retained, if any.

4. Data security and confidentiality of potentially disclosive personal information

4.1 Formal information/data security standards

Guidance:

Identify formal information standards with which your study is or will be compliant. An example is ISO 27001. If your organisation is ISO compliant, please state the registration number.

4.2 Main risks to data security and how they will be managed

Guidance:

Please summarise the risks specific to your research that would require data security measures to be implemented. This should include:

- risks to the confidentiality and security of data and information
- risks of misuse

and describe the level of risk and how these risks will be managed.

Cover the main processes or facilities for storage and processing of personal data, data access, with controls put in place and any auditing of user compliance with consent (where applicable) and security conditions.

It is not sufficient to write not applicable under this heading.

If you intend to work with overseas collaborators or data users, describe how your approach ensures that the team has a robust cyber-security culture and a process to identify and protect any sensitive data and information. Further guidance is available on the MRC Data Management and Sharing page and the UKRI principles and guidance on trusted research and innovation.

5. Data sharing and access

5.1 Suitability for sharing

Guidance:

Is the data you propose to collect in the study suitable for sharing within the team and with external users (including international)? If yes, briefly state why it is suitable and explain how risks, such as re-identification will be managed.

If you are re-using data, what steps will you take to ensure further sharing of the data? If no, indicate why the data will not be suitable for sharing and then go to Section 6.

5.2 Discovery by potential users of the research data

Guidance:

Indicate how potential new users (outside of your organisation) can find out about your data and identify whether it could be suitable for their research purposes. This can be done through making summary information (metadata) readily available on the study website, in the HDRUK Gateway, or in other recognised databases or catalogues. How widely accessible is this repository? How will you make your data FAIR, including sharing necessary methods or software tools to access it?

Indicate where your policy or approach to data sharing is (or will be) published on your study website or otherwise accessible. Will unique and persistent identifiers be attributed to your data, methods, or software to allow data users to cite them and data generators to track them?

5.3 Governance of access

Guidance:

Identify **who** makes or will make the decision on whether to supply or grant access to research data to a potential new user.

For population health and patient-based research, indicate how independent oversight of data access and sharing works (or will work) in compliance with MRC policy and guidance. Explain whether you will have a public data release register with information about sharing. Indicate whether the research data will be deposited in and available from an identified community database, repository, archive or other infrastructure established to curate and share data.

5.4 The study team's exclusive use of the data

Guidance:

MRC's requirement is for timely data sharing, with the understanding that a limited, defined period of exclusive use of data for primary research is reasonable according to the nature and value of the data, and that this restriction on sharing should be based on simple, clear principles. What are the timescales/ dependencies for when data will be accessible to others outside of your team? Summarise the principles of your current or intended policy.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Guidance:

Restriction to data sharing may be due to participant confidentiality, consent agreements or IPR. Strategies to limit restrictions may include data being anonymised or aggregated; gaining participant consent for data sharing; gaining copyright permissions. For prospective studies, consent procedures should include provision for data sharing to maximise the value of the data for wider research use, while providing adequate safeguards for participants. As part of the consent process, proposed procedures for data sharing should be set out clearly, and current and potential future risks associated with this explained to research participants.

5.6 Regulation of responsibilities of users

Guidance:

Indicate whether external users are (will be) bound by data sharing agreements, setting out their main responsibilities.

5.7 Working with overseas collaborators or data users

Guidance:

Please indicate how sensitive data will be shared with international collaborators and/or accessed by overseas data users. Describe measures to manage associated risks.

Have you considered legislation of overseas partners that might permit authorities to access sensitive information without consent from all parties? If yes, please comment on how you will respond to this potential risk.

If applicable, describe what measures you will put in place when sharing data, and how you will comply with UK's export control legislation and any other legal requirements, as per <u>UKRI's Trusted Research and Innovation Principles</u> and UK government guidance (<u>National Protective Security Authority's Trusted Research Guidance for Academia and Industry</u>). For more information from UKRI visit page on <u>Trusted research and innovation</u>.

6. Responsibilities

6. Responsibilities

Guidance:

Apart from the PI, who is responsible at your organisation/within your consortia for:

- data management
- metadata creation
- data security
- quality assurance of data
- implementation and maintenance/ revision of DMP

7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security

Guidance:

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.

Add any others that are relevant.

8. Author

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Guidance:

You can also use the Download plan function and select option to include 'project details coversheet'. This will download plan details, including author and contributors. Please remember to select an editable format when downloading plan, e.g. Word doc or text.

Medical Research Council (MRC): MRC Template - Detailed Phase

0. Proposal name

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7. Relevant policies

7. Relevant institutional, departmental or study policies on data sharing and data security Default value

Policy	URL or reference
Data Management Policy and Procedures	
Data Security Policy	
Data Sharing Policy	e.g. a study policy of sharing research data
Institutional Information Policy	
Other	
Other	

Guidance:

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.

Add any others that are relevant.

8. Author

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Guidance:

You can also use the Download plan function and select option to include 'project details coversheet'. This will download plan details, including author and contributors. Please remember to select an editable format when downloading plan, e.g. Word doc or text.