University of Leicester

Data Management Planning

MRC FUNDING APPLICANTS

MRC Medical Research Council

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Document History

Version	Date	Author	Detail/Reason for Change
1-3	02.09.2015	A. Burnham	Inclusion of RDM Principles, updates and corrections
1-2	27.03.2014	A. Burnham	Minor edit.
1-1	20.02.2014	A. Burnham	Minor edit.
First published version (1-0) \UoL_DMP_MRCGuide_v1-0.docx (.pdf)	15.07.2013	A. Burnham	First published version.
Draft 5 \UoL_DMP_MRCGuide_v0-5.docx	08.07.2013	A. Burnham	Final draft with minor edits.
Draft 4 \UoL_DMP_MRCGuide_v0-4.docx	06.06.2013	A. Burnham	Fourth draft from review by RCMG. Approved for release by PVC Research
Draft 3 \UoL_DMP_MRCGuide_v0-3.docx	28.05.2013	A. Burnham	Third draft for review by RCMG.
Draft 2 \UoL_DMP_MRCGuide_v0-2.docx	10.04.2013	A. Burnham	Second draft.
Draft 1 \UoL_DMP_MRCGuide_v0-1.docx	10.04.2013	A. Burnham/University of Bristol	First draft using University of Bristol document as basis.

In common with most other major funders of biomedical research, the Medical Research Council (MRC) expects all research projects it funds to manage effectively and, where possible, share research data. The MRC's overall concern is to *"maximise the value of research data for human health in a timely and responsible manner, with as few restrictions as possible, consistently with the law, regulation and recognised good practice."*[1]

1. Introduction

Effective management of medical research data can:
- enable new research questions to be answered using existing data
- promote collaboration between different research teams and diverse disciplines
- allow the sharing of knowledge about the best methods for data collection, linkage and analysis
- help to ensure that collected data are clean and well documented, with value added
- support the independent verification of established research findings
- allow the development and testing of new research methods
- help to use the data produced by study participants to best effect

2. Summary of MRC data requirements

- *All* MRC-funded researchers have a responsibility to ensure that opportunities for data re-use are maximised, within the regulatory requirements of the law.

- All applicants submitting funding proposals to the MRC are required to submit a Data Management Plan (DMP) as an integral part of the application. A template is provided by the MRC[2] and a University of Leicester adapted version of this template is attached as **Appendix 1**.

  o A simple DMP could be fewer than 500 words long.
  o In cases where rich resources are to be created, a DMP should be between 1,000 and 1,500 words long.
  o Population or patient-based studies must meet twenty-one additional requirements.
  o Established population-or patient-based studies should already have a Policy on Data Sharing which can be referred to in your DMP.
  o Applicants proposing new population or patient-based studies should contact their College Research Management before submitting their application.
  o Once research is funded, DMPs should be updated annually by a designated member of the study team.

- It is the responsibility of the applicant to identify appropriate discipline-specific data repositories and then to deposit data in one of them to allow sharing. This should be done in

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[1] MRC guidance - data management plans, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/
[2] DMP template, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/

a timely manner.

- A limited *and defined* period of exclusive data use is reasonable.

- The MRC is willing to cover some of the costs associated with data sharing.

3. What you need to do – key data requirements

All applicants submitting funding proposals to the MRC are required to submit a Data Management Plan (DMP) as an attachment to the main Je-S Proposal form. This also applies to applications for the extension of current funding.

In your DMP you should demonstrate how you expect to fulfil your research data management responsibilities to the MRC (explained below), identify any obstacles to do so and describe the measures you will take to meet these challenges. Your DMP can also help to justify any funding required to fulfil the MRC's data management requirements.

Where research is only partly funded by the MRC, the MRC research data requirements still apply. If these requirements conflict with the policy of another part-funder, you should discuss this with the MRC[3] before your application is finalised.

Your DMP will be reviewed as an integral part of the application; a poor DMP can have a negative impact on an otherwise strong application. However, the MRC believes that data sharers should receive *"… full and appropriate recognition by funders, their academic institutions and new users for promoting secondary research"*[4].

4. Where to get help and information

Refer to the University research data website www.le.ac.uk/researchdata where specific funder related information and the latest data management advice will be included.

The range of appropriate contacts includes:

- IT Services
- Library
- Research Support Office

- Leicester Learning Institute
- Information Assurance Services
- Enterprise and Business Development

A single point of contact is also available: email researchdata@le.ac.uk at any time and as early as possible in the bid process. This will means specific queries or general request for assistance can be directed to the right place(s). You can also request assistance with development of a data management plan via this email address.

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[3] MRC Head Office Research Programmes Group, MRCdatasharing@headoffice.mrc.ac.uk
[4] MRC Policy on Research Data-sharing, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/

It is also recommended that you use the Digital Curation Centre (DCC) DMPOnline[5] resource to create a data management plan (DMP) using the MRC template and requirements. As and when University of Leicester templates and specific guidance are created this will be confirmed on the RDM website[6].

Specific research IT services available include Research File Storage, high performance computing, Wiki, 'LAMP' stack (a general purpose, Linux, relational database and web hosting service, based around open source software- Linux, Apache, MySQL and PHP), file transfer (FileDrop) and source code control (Subversion SVN)[7].

In 2014 the University agreed it's **RDM Principles**[8] which act to guide researchers and inform funders of the University approach (see 17. below).

MRC and general information

MRC Policy on Research Data-sharing	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/
MRC guidance - data management plans	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/
MRC DMP template	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/
MRC "What is a Data Management Plan"	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/
MRC Head Office Research Programmes Group	MRCdatasharing@headoffice.mrc.ac.uk
MRC Open Access Position Statement	http://www.mrc.ac.uk/research/research-policy-ethics/open-access-policy/
MRC Good Research Practice Guidance	http://www.mrc.ac.uk/research/research-policy-ethics/good-research-practice/
MRC Information Security Policy	http://www.mrc.ac.uk/documents/pdf/mrc-information-security-policy/
RCUK Open Access Policy	http://www.rcuk.ac.uk/research/openaccess/
Public Health Research Data Forum	http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Public-health-and-epidemiology/WTDV030689.htm
Digital Curation Centre MRC Funder's Data resource	http://www.dcc.ac.uk/resources/policy-and-legal/research-funding-policies/mrc
Digital Curation Centre 'DMP Online'	https://dmponline.dcc.ac.uk/

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[5] DMPOnline, https://dmponline.dcc.ac.uk/
[6] Data Management Planning, http://www2.le.ac.uk/services/research-data/create-data/DMPlan
[7] IT Services, http://www2.le.ac.uk/offices/ithelp/
[8] RDM Principles, http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples

tool	
Digital Curation Centre DMP Checklist	http://www.dcc.ac.uk/resources/data-management-plans/checklist
University Research Data Management website	www.le.ac.uk/researchdata
University Research Data Management Principles	http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples
University Research Data Management Support	researchdata@le.ac.uk
RCUK Joint Electronic Submission System (Je-S)	https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx
HSCIC Information Governance Toolkit	https://www.igt.hscic.gov.uk/
University Information Governance web	http://www2.le.ac.uk/colleges/medbiopsych/research/information-governance-igt
HSCIC Information Governance Toolkit	https://www.igt.hscic.gov.uk/

5. DMP format

Your DMP should be written with two distinct audiences in mind: fellow scientists in your own field and data managers. Avoid generalisations and be concise. Before you write anything, consider the complexity of the data you intend to create and how much long-term value your data is likely to offer to the wider research community.

If the scale, complexity and cost of managing your data are low, your DMP could be less than 500 words long. In the case of population cohorts, genetic and omic data, bio banks and other datasets that are potentially rich resources for the wider community, your DMP should be between 1,000 and 1,500 words long.

If your research will form part of an established population or patient-based study, your DMP will be significantly longer, as it must indicate how you will meet twenty-one additional requirements[9]. If this is the case, much of the information you will need to provide to the MRC should already be included in your study's existing Policy on Data Sharing. This should be available on your study's project website.

If you intend to establish a *new* population or patient-based study, you should seek advice on how to work towards meeting the MRC's twenty-one data sharing requirements.

It is highly recommended that applicants make use of the DMP template provided by the MRC[10]. If applicants choose *not* to use the template, the issues raised below must still be addressed. If the funding application is successful, your DMP should be reviewed and updated annually by a designated member of your study team.

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[9] MRC Policy on Sharing of Research Data From Population and Patient Studies, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-sharing-population-and-patient-studies/
[10] DMP template, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/

6. The nature of your research data

As part of your DMP, you should state the nature of your data (for example, qualitative, statistical, interview, imaging) and in which format/s your data will be collected, analysed and stored (for example, Open Document Format, CSV file or Excel spread sheet). The key aim here is to explain how your research data will support not only your own immediate research needs but also future secondary analysis and long-term use.

If you find you need to use a non-standard data format (for example for data from a unique, in-house system that would be unsuitable for wider use), you should consider converting your data to a more widely used format once you are ready to share it. Explain this intention in your DMP.

If you're unsure which file formats to use, the UK Data Archive maintains a list of recommended deposit formats[11] which may be suitable.

You should also try to estimate the size of the data you expect to generate. This can be difficult to do before a study begins; if necessary, use quantities generated by similar past studies as a basis for your estimate.

7. Re-using existing data

The MRC recognises that scientists use existing data in increasingly diverse ways: for instance, by using data linking or meta-analysis. Your Case for Support should identify existing datasets you expect to draw on. If you intend to generate new data, your Case for Support should also explain why this is necessary.

Studies that make use of existing datasets should meet the same high standards as all MRC research in regards to scientific quality, ethical requirements and value for money. They should also add recognisable value to the original datasets. The MRC suggests that such research is often most fruitful when it is a collaboration between a new user and the original data creators.

If you have previously collected or generated research data of your own which you intend to use as part of new research, you should ensure that your DMP describes procedures for managing both existing and any newly generated data.

8. Copyright

Unless stated otherwise, the ownership of intellectual property lies with the organisation carrying out the research. If you plan to work collaboratively on a new study with an external partner, copyright and other IPR (Intellectual Property Rights) issues may need to be clarified in a Consortium Agreement or Memorandum of Understanding. This is not required as part of your application, but you should say that if the application is successful such an agreement will be created. All research partner institutions should then be made aware that a Consortium Agreement

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[11] UK Data Archive File Formats Table, http://www.data-archive.ac.uk/create-manage/format/formats-table

will be forthcoming. Enterprise and Business Development[12] can provide advice on research IPR issues. Ultimately, however, it is the responsibility of the applicant to ensure that IPR issues do not unnecessarily prohibit data sharing.

9. Ensuring the quality of your data

Your DMP should describe how you will ensure the quality of your research data. Quality should be considered whenever data is created or altered, for instance at the time of data collection or data entry. Procedures you may wish to carry out to ensure that data quality is maintained include:

- putting time aside to validate data manually
- regular calibration
- repeating samples
- standardised data capture, or
- recording and entering values into prepared databases or transcription templates.

You should mention in your DMP any data standards you intend to use at the data collection/generation stage (see 12. Metadata).

10. Data storage

You should explain where your data will be stored, how it will be organised in the short term and who will back it up.

If you do not have existing data storage arrangements, it is recommended that when you create data you store it in the University's Research File Storage facility (RFS), managed by IT Services. All those with research storage needs are able to register for this service in order to be allocated a storage allocation appropriate to the project[13].

Researchers are not charged for this service (unless requirements are extremely large), it offers peace of mind (for the researcher and research funder) and reduces researcher IT responsibilities, being managed by IT Services as a secure service, backed-up daily.

If you do not make use of the RFS, your storage provider's back-up security standards and procedures should be described instead. If you will be working collaboratively with other institutions, make sure that the security and back-up procedures of each data-holding partner are described in your DMP.

Your DMP should also outline how you will keep your data safe *before* it's deposited in a storage facility such as the RFS. This is particularly important if you are conducting field research. As a minimum requirement, try to ensure that at all times at least two copies of the data exist and that every copy can easily be accounted for and located if required. Mobile devices such as laptops, external disc drives and voice recorders should be encrypted and you should plan for data transfer (to RFS for example) to be secure and as early as possible.

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[12] University Enterprise and Business Development, http://www2.le.ac.uk/offices/ebd
[13] Research File Storage, http://www2.le.ac.uk/offices/ithelp/services/rfs

11. Personal information

If your research is part of an established study, data security measures will already be in place and these should be summarised in your DMP. *All* MRC-funded researchers however, have a responsibility to ensure that opportunities for data re-use are maximised, within the regulatory requirements of the law. MRC adopts the view that the potential benefits to patients and the public should outweigh identified risks. The MRC's guide to using Personal Information in Medical Research[14] states:

> *"Principal investigators must take personal responsibility for ensuring (as far as is reasonably practical) that training, procedures, supervision, and data security arrangements are sufficient to prevent unauthorised breaches of confidentiality."*

The need for information confidentiality, integrity and availability is recognised through the MRC Information Security Policy[15].

If you are planning to make use of a data storage facility that complies with a recognised information security standard (such as ISO 27001), explain this in your DMP. If not, describe the main risks to the security of any data relating to human participants and how these risks will be addressed, such as by access control or encryption. The information you provide must correspond to that provided in the plan made as part of your ethical review.

Since 2011 there has been an expectation[16] that where organisations such as Universities (in the conduct of research as secondary users of data) access NHS patient information they should use the **Information Governance Toolkit** and all staff should undertake annual IG training. For support and advice refer to the University IG web presence and contact IGT@le.ac.uk

12. Metadata

Metadata[17] is 'data about data' or 'cataloguing information' that enables data users to find or use a dataset. In your DMP you should outline plans for documenting your research data to meet both your own needs and those of later users. It is generally best to use established and shared metadata standards, rather than create new ones. This helps with consistency and saves effort.

For example, ICD-10[18] (International Statistical Classification of Diseases and Related Health, 10th Revision) is a medical classification from the World Health Organisation that *"codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases".* ICD-10 provides 14,400 unambiguous codes.

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[14] Personal Information in Medical Research, www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002452
[15] MRC Information Security Policy, http://www.mrc.ac.uk/about/information-standards/information-security/
[16] NHS England & ICO letter,
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215445/dh_130134.pdf
[17] Metadata, http://www2.le.ac.uk/services/research-data/organise-data/metadata
[18] International Classification of Diseases, www.who.int/classifications/icd/en/

The Data Documentation Initiative[19] (DDI) is an international standard for describing data from the social, behavioural and economic sciences. DDI uses XML to allow metadata to be encoded in a standardised way, simplifying data sharing and subsequent re-use.

Metadata can be kept in a separate, dedicated database or spread sheet. If you are planning to use data analysis software, such as a qualitative analysis package, you will have the option of adding documentation within the software itself, in the form of notes.

In attempting to organise and document your data, it may help to imagine another data user trying to make sense of your data in your absence, after your project has concluded. If no metadata were provided, this other user would be faced with the difficult task of 'unpicking' your data. How, for instance, would they make sense of your file and folder names? Or your methodology or approach to data processing? What extra information would they need to make the most of your data?

13. Providing long term access to data

If your research is part of an established study, the existing Study Policy on Data Sharing should contain much of the information you need to provide about current data governance procedures and existing data-sharing agreements. If your study has an established history of data sharing, your DMP should include a brief evaluation of these activities (for further information, see the MRC's guide to Reporting on Data Sharing[20]).

If there is not an established history of data sharing, it is the responsibility of the applicant to identify appropriate discipline-specific data repositories. The Wellcome Trust maintains a list of major biomedical data repositories that preserve and provide access to research data. Researchers may choose to share their data by depositing it in a repository such as the UK Data Archive[21].

The University requires that all research publications are deposited with the Leicester Research Archive (LRA)[22].

Data must be shared in a timely and responsible manner. The MRC recognises however that on-going research contributing to the completion of datasets must not be compromised by premature sharing and analysis. A limited *and defined* period of exclusive data use is therefore reasonable. Access to data may also be delayed for a short period to allow time for the preparation and filing of patent applications. You should indicate which data cannot be retained and/or shared, and explain why this is necessary.

14. Roles and responsibilities

Data management responsibilities should be clearly assigned to named individuals within your DMP. The Principal Investigator (or Research Director for larger studies) is usually responsible for

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[19] Data Documentation Initiative, www.ddialliance.org/getting-started
[20] MRC data sharing policy, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/
[21] UK Data Archive, www.data-archive.ac.uk
[22] Leicester Research Archive, http://www2.le.ac.uk/library/for/researchers/publish/open-access

research data sharing. The person responsible for maintaining and updating the DMP (if this is different) should also be named in your DMP.

Support services are in place at the University to help you manage and share your research data (see 3. Where to get help and information above) and any such services you plan to use should be mentioned in your DMP to demonstrate the role played by data specialists.

15. The cost of managing research data

If any costs are involved in meeting the MRC's data management requirements (for example, the cost of dedicated effort, equipment or software tools for managing, storing or providing access to your data), these should be mentioned in your application. If the costs are substantial, you should differentiate between:

- Costs associated with collecting and/or processing new data
- Your own research on newly acquired and legacy data
- On-going data curation and preservation
- Providing access and data sharing

16. Citing research data in research outputs

From 1 April 2013 all the UK's Research Funding Councils, as part of RCUK, required research outputs i.e. journal articles to provide a means by which third parties can access any underpinning research datasets. This may be a reference (such as a unique URL or DOI) printed in a paper which will lead an enquirer to a specific web page where the data is available. Alternatively the enquirer might be directed to a page which displays the contact details of a custodian of the data and asked to email them in order to gain access to the data.

Given the extended timescales involved in publication, it is strongly recommended that the authors of published academic outputs *do not provide their current contact details* as a means of accessing underpinning research data, as these will change over time. If you plan to use an established data repository service, ask it for a unique reference identifier which could be included in the publication instead.

17. University RDM Principles

In 2014 the University agreed its **RDM Principles**[23] which act to guide researchers and inform funders of the University approach and should be referred to in funding proposals.

Research data are defined as any material created or collected for the purposes of analysis to generate and validate original research results, irrespective of the format of data. Research data may be digital, paper based or in other forms. Examples of different types of research data include datasets, images, text (such as transcripts of interviews), audio and video recordings, and computer scripts.

Scope

1. *These principles apply to all research conducted at the University, regardless of funding source. They do not imply additional compliance where good practice and relevant research funders' requirements are already being followed.*

Research inception and planning

2. *Data management planning is an integral, essential and dynamic component of the research process from inception and should include provision for the selective long term custodianship of research data.*
3. *Research proposals should include all possible recovery of direct costs of research data management where the funder allows this.*

During the research: management and storage of data

4. *During the research process, data are an asset which needs to be appropriately managed and stored: to meet legislative, funder, information governance and University requirements; to facilitate data security (confidentiality, integrity, availability); to facilitate appropriate access, collaboration and sharing of data and results.*
5. *Data can be actively managed throughout, following and updating the data plan, recognising that storage and its funding is not infinite, with ongoing decisions regarding retention and destruction.*

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[23] RDM Principles, http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples

After the research: retention, sharing, publishing, citation, re-use

6. *When the research has been completed, research data (including websites) of long term value, or data required by funders or the University must be selected for retention, then preserved and curated for as long as appropriate.*

7. *Data retained in these circumstances must be offered to funder or discipline repositories and/or to the UK Web Archive as appropriate. If such repositories are unavailable or unsuitable, data must be stored in a University repository. Data deposited with external repositories or unsuitable for making open access must be registered with the University.*

8. *There is a presumption of open access to data held in a University or other public repository. However, access may be restricted, subject to a time embargo or not permitted for legal (i.e. intellectual property, data protection, confidentiality, contractual requirements), ethical or commercial reasons.*

9. *Data should not be deposited with any organisation that does not commit to appropriate access and availability for re-use and exclusive rights to re-use or publish research should not be handed to commercial publishers, unless this is a condition of funding.*

10. *The re-use or sharing of data that are made available should not be unnecessarily restricted by licences or terms of use.*

11. *All research outputs must cite data produced and/or used during research as appropriate, detailing access to that data.*
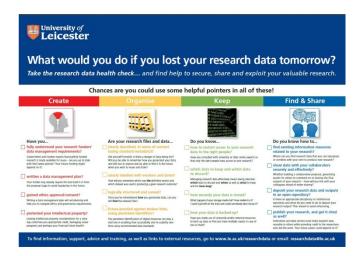
Responsibilities

12. *Primary accountability for research data management lies with the most senior University researcher associated with the work or project. Responsibility for research data management may be delegated.*

13. *During the research process, researchers are responsible for adherence to legal requirements such as Data Protection and for the creation of metadata and other documentation that enables data to be discoverable, understandable and re-useable.*

14. *After the deposit of data with a repository, the repository is responsible for the on-going management of that data in accordance with legal, technical and other requirements.*

15. *The University will be responsible for providing a Research Data Management service led by the Library to include training, advice, guidance and data curation.*

16. *The University will secure sustainable solutions that meet the requirements for long term data storage and re-use as set out in these principles.*

The Managing Research Data guide series comprises:

- An Introduction to Managing Research Data – For Researchers and Students
- Data Management Planning – AHRC funding applicants
- Data Management Planning – BBSRC funding applicants
- Data Management Planning – EPSRC funding applicants
- Data Management Planning – ESRC funding applicants
- Data Management Planning – MRC funding applicants
- Data Management Planning – NERC funding applicants
- Data Management Planning – STFC funding applicants
- Data Management Planning – Non-RCUK funding applicants

They are part of a range of RDM material produced by the University, all available via www.le.ac.uk/researchdata.

Appendix 1 – MRC Template for a Data Management Plan

TEMPLATE FOR A DATA MANAGEMENT PLAN

(University of Leicester adaptation of MRC Data Management Plan

The following **template** can be used to develop a Data Management Plan to accompany a research proposal. The notes (*in italics*) provide further context and guidance for its completion.

If you opt NOT to use the template the topics listed in the template must be addressed.

0. Proposal name
Exactly as in the proposal that the DMP accompanies

1. Description of the data

1.1   Type of study

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

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, genotypic data, images, tissue samples,…

1.3   Format and scale of the data

File formats, software used, number of records, databases, sweeps, repetitions,… (in terms that are meaningful in your field of research). Do formats and software enable sharing and long-term validity of data?

Explain how your research data will support not only your own immediate research needs but also future secondary analysis and long-term use.

If you need to use a non-standard data format (for example for data from a unique, in-house system that would be unsuitable for wider use), consider converting your data to a more widely used format once you are ready to share it. Explain this intention.

If unsure which file formats to use, the UK Data Archive maintains a list of recommended deposit formats[24] which may be suitable.

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[24] UK Data Archive File Formats Table, www.data-archive.ac.uk/create-manage/format/formats-table

Estimate the size of the data you expect to generate. This can be difficult to do before a study begins; if necessary, use quantities generated by similar past studies as a basis for your estimate.

2. Data collection / generation

Make sure you justify why <u>new</u> data collection or long term management is needed in your Case for Support. Focus in this template on the good practice and standards for ensuring new data are of high quality and processing is well documented.

2.1   Methodologies for data collection / generation

How the data will be collected/generated and which community data standards (if any) will be used at this stage.

2.2   Data quality and standards

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.

3. Data management, documentation and curation

Keep this section concise and accessible to readers who are not data-management experts. Focus on principles, systems and major standards. Focus on the main kind(s) of study data. Give brief examples and avoid long lists.

3.1   Managing, storing and curating data.

Briefly, 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). [Enter data security standards in Section 4].

Insert detail of use of IT Services managed central Research File Storage, use of central daily back-up facility. Use of encrypted mobile devices, and appropriate secure file transfer processes.

Use of logical, consistent data structures, folder and file naming.

3.2   Metadata standards and data documentation

Plans for documenting, annotating and describing data so that research data are usable by others than 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.

==Use of logical, consistent data structures, folder and file naming.==

3.3   Data preservation strategy and standards

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

==Leicester Research Archive – publications.==

4. Data security and confidentiality of potentially disclosive personal information

*Complete this section only if your research data include **personal data relating to human participants in research**. Information provided will be in line with you ethical review.*

4.1   Formal information/data security standards

Identify formal information standards with which your study is or will be compliant. An example is ISO 27001.

4.2   Main risks to data security

If not *using* formal *standards, summarise the main risks to the confidentiality and security of information related to* human participants, *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 and security conditions.*

MRC guidance on the categories of data availability is provided.

==Insert detail of use of IT Services managed central Research File Storage, use of central daily back-up facility. Use of encrypted mobile devices, and appropriate secure file transfer processes.==

5. Data sharing and access

Identify any data repository (-ies) that are, or will be, entrusted with storing, curating and/or sharing data from your study, where they exist for particular disciplinary domains or data types. Information on repositories is available here.

5.1   Suitability for sharing

Indicate whether the data you propose to collect (or existing data you propose to use) in the study will be suitable for sharing. ("Yes" or "No")

If "No," indicate why they will not be suitable for sharing and then go to Section 6.

5.2 Discovery by potential users of the research data

Indicate how potential new users can find out about your data and identify whether they could be suitable for their research purposes, e.g. through summary information (metadata) being readily available on the study website, in the MRC gateway for population and patient research data, or in other databases or catalogues.

Indicate whether your policy or approach to data sharing is (or will be) published on your study website (or by other means).

5.3 Governance of access

Identify <u>who</u> makes or will make the decision on whether to supply research data to a potential new user.

For population health and patient-based research, indicate how <u>independent oversight of data access and sharing</u> works (or will work) in compliance with MRC policy.

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

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.

Summarize the principles of your current/intended policy.

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

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

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

6. Responsibilities

Specify who, alongside the PI, is responsible for ensuring the study-wide data

management, as well as for specific roles such as metadata creation, data security and quality assurance of data.

<mark>Insert IT Services, Research Data Management input</mark>

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

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

Add any others that are relevant

Policy	URL or Reference
Data Management Policy & Procedures	University Research Data Management Principles: http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples
Data Security Policy	University Information Security Policy: http://www2.le.ac.uk/offices/ias/resources/policies/ispolicy/Information%20Security%20Policies%20Combined.pdf
Data Sharing Policy	*a)* University Research Data Management Principles: http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples *b) study policy for sharing research data*
Institutional Information Policy	University Information Security Policy: *http://www2.le.ac.uk/offices/ias/resources/policies/ispolicy/Information%20Security%20Policies%20Combined.pdf*
Other:	University Research Data Roadmap: http://www2.le.ac.uk/services/research-data/documents/UoL_RDRoadmap_v01.pdf University Data Protection Code of Practice: http://www2.le.ac.uk/offices/ias/resources/policies/dpp/dp_codeofpractice.pdf
Other	

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