

Data Management Planning

NON-RCUK FUNDING APPLICANTS











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Document History

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1-1	20.02.2014	A. Burnham	Minor edit.
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Draft 3 \UoL_DMP_NonRCUKGuide_v0-3.docx	06.06.2013	A. Burnham	Third draft.
Draft 2 \UoL_DMP_NonRCUKGuide_v0-2.docx	07.06.2013	A. Burnham	Second draft for review by RCMG. Approved for release by PVC Research.
Draft 1 \UOL_DMP_NonRCUKGuide_v0-1.docx	04.062013	A. Burnham/University of Bristol	First draft.



A requirement for greater research transparency lies at the heart of several influential and recently published reports including the UK government's Innovation and Research Strategy for Growth¹.

Research funders encourage and expect fund-holders to follow policies and guidelines. This guide is designed to help applicants for non-RCUK funding, including Cancer Research UK (CRUK), the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), the National Institute for Health Research (NIHR), and the Wellcome Trust.

This document outlines expectations concerning the management and provision of access to research data and what applicants for funding and funded researchers will need to do in order to comply with those expectations.

1. Where to get help and information

Whatever your area of research and however it is to be funded there is support and advice available at the University.

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.

It is also recommended that you use the Digital Curation Centre (DCC) DMPOnline² resource to create a data management plan (DMP) using the EPSRC template and requirements. As and when University of Leicester templates and specific guidance are created this will be confirmed on the RDM website³.

¹ UK Government, Department for Business Innovation & Skills. Innovation and Research Strategy for Growth, www.bis.gov.uk/innovatingforgrowth

DMPOnline, https://dmponline.dcc.ac.uk/

³ Data Management Planning, http://www2.le.ac.uk/services/research-data/create-data/DMPlan

In 2014 the University agreed its **RDM Principles**⁴ which act to guide researchers and inform funders of the University approach. This can also be referred to:

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.

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.

⁴ RDM Principles, http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples

- 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 ongoing 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.

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)⁵.

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⁵ IT Services, http://www2.le.ac.uk/offices/ithelp/

University-based research also now needs to recognise the requirement to provide assurance through the Information Governance Toolkit where NHS patient data is handled⁶. Within the College of Medicine, Biological Sciences and Psychology there is an Information Governance improvement programme, with a web presence⁷.

General Information

University Research Data Management Website	www.le.ac.uk/researchdata
University Research Data Management Support	researchdata@le.ac.uk
University Research Data Management Principles	http://www2.le.ac.uk/services/research-data/documents/uol_rdmprinciples
University Information Governance	http://www2.le.ac.uk/colleges/medbiopsych/research/information-governance-igt
UK Data Archive – Managing and Sharing Data	http://www.data-archive.ac.uk/media/2894/managingsharing.pdf
Digital Curation Centre Funder's Data resource	http://www.dcc.ac.uk/resources/policy-and-legal/overview-funders-data-policies
Digital Curation Centre 'DMP Online' tool	https://dmponline.dcc.ac.uk/
Digital Curation Centre DMP Checklist	http://www.dcc.ac.uk/resources/data-management-plans/checklist
RCUK Joint Electronic Submission System (Je-S)	https://je-s.rcuk.ac.uk/JeS2WebLoginSite/Login.aspx

⁶ HSCIC IG Toolkit, <u>https://www.igt.hscic.gov.uk/</u>

⁷ University Information Governance, http://www2.le.ac.uk/colleges/medbiopsych/research/information-governance-igt



2. Requirements for Cancer Research UK (CRUK)

Since 1 April 2009 all those seeking funding from CRUK have been required to comply with its Data Sharing and Preservation Policy⁸.

CRUK Cancer Research UK regards it good research practice for all researchers to consider at the research proposal stage how they will manage and share the data they will generate.

CRUK requires that applicants applying for funding provide a data management and sharing plan as part of their application. This plan will be reviewed as part of the funding decision.

Plans should address eight points:

- 1. A description of the data
- 2. Standards to be used
- 3. Metadata
- 4. Methods of sharing
- 5. Timescale for release
- 6. Preservation
- 7. Data sharing agreements
- 8. Restrictions on sharing.

CRUK Data Sharing Guidelines9

Data Sharing - It is the policy of Cancer Research UK that all data generated as a result of its funding be considered for sharing and made as widely and freely accessible as possible whilst safeguarding intellectual property, the privacy of patients and confidential data

Data Management and Sharing Plan – All applicants are required to submit a plan, which should cover the following:

- The volume, type, content and format of the final dataset
- The standards that will be utilised for data collection and management
- The metadata, documentation or other supporting material that should accompany the data for it to be interpreted correctly
- The method used to share data
- The timescale for public release of data
- The long-term preservation plan for the dataset

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⁸ CRUK Data Sharing Policy, http://www.cancerresearchuk.org/sites/default/files/data-sharing-policy.pdf

⁹ CRUK Data Sharing Guidelines, http://www.cancerresearchuk.org/funding-for-researchers/applying-for-funding/policies-that-affect-your-grant/submission-of-a-data-sharing-and-preservation-strategy/data-sharing-guidelines

- Whether a data sharing agreement will be required
- Any reasons why there may be restrictions on data sharing, for example;
 - Development arrangements through Cancer Research Technology including intellectual property protection and commercialisation
 - Proprietary Data restrictions due to collaborations with for profit organisations
 International policies governing the sharing of data collected outside of the UK
 - Confidentiality, ethical or consent issues that may arise with the use of data involving human subjects.

Intellectual Property Rights and Proprietary Data - Data which might have the potential to be exploited commercially or otherwise to deliver patient benefit should be discussed with University Enterprise and Business Development and Cancer Research Technology prior to data sharing.

Standards, Metadata and Documentation - For data sharing to be a success it is important that data are prepared in such a way that those using the dataset have a clear understanding of what the data mean so that they can be used appropriately. To enable this, applicants are encouraged to include with the dataset all the necessary information (metadata) describing the data and their format

Methods for Data Sharing – Data can be shared under the auspices of the Principal Investigator, through a third party, using a data enclave, or through a combination of methods.

Timeframe for Data Sharing - Cancer Research UK expects data to be released no later than the acceptance for publication of the main findings from the final dataset.

Research involving human participants - Investigators carrying out research involving human participants must ensure that consent is obtained to share information.

Data Sharing Requests – You may ask the requestor to provide a brief research proposal on how they wish to use the data.

Data Sharing Agreements - To ensure that data are used appropriately investigators may consider implementing a data sharing agreement that indicates the criteria for data access and conditions for research use.

Data Acknowledgement - As a minimum, researchers using shared data are expected to acknowledge the investigators who generated the data upon which any published findings are based.

Data Preservation - Once the funding for a project has ceased researchers should preserve all data resulting from that grant to ensure that data can be used for follow-up or new studies. Cancer Research UK expects that data be preserved and available for sharing with the science community for a minimum period of five years following the end of a research grant.

CRUK does not run its own data centre or prescribe where or how researchers should preserve and share data. Publications are to be made freely accessible via PubMed Central¹⁰.

Open Access

CRUK released an Open Access Policy in March 2007¹¹ requiring that publications are made freely available via PubMed Central (PMC).

It is a condition of funding that Cancer Research UK funded researchers deposit in the Europe PMC database an electronic copy of the author's final version of papers accepted for publication. This should happen as soon as possible and no later than 6 months after publication. This requirement applies to research supported in whole, or in part, by Cancer Research UK which is published from 1 June 2007.

Information to support CRUK applications

CRUK Website	http://www.cancerresearchuk.org/home/
CRUK Data Sharing Policy	http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@fre/@gen/documents/generalcontent/cr_016308.pdf
CRUK Data Sharing Guidelines	http://www.cancerresearchuk.org/science/funding/terms- conditions/funding-policies/policy-data-sharing/data-sharing- guidelines/
CRUK Data Sharing FAQs	http://www.cancerresearchuk.org/funding-for- researchers/applying-for-funding/policies-that-affect-your- grant/submission-of-a-data-sharing-and-preservation- strategy/data-sharing-faqs
CRUK Open Access Policy	http://www.rcuk.ac.uk/RCUK- prod/assets/documents/documents/RCUKOpenAccessPolicy.pdf
CRUK Open Access Policy – FAQs (May 2013)	http://www.rcuk.ac.uk/RCUK- prod/assets/documents/documents/OpenaccessFAQs.pdf
National Cancer Research Institute Cancer Research Database	http://www.ncri.org.uk/what-we-do/research-database/
Europe PubMed Central	http://europepmc.org/
Digital Curation Centre CRUK page	http://www.dcc.ac.uk/resources/policy-and-legal/funders-data-policies/cancer-research-uk

¹⁰ Europe PubMed Central, http://europepmc.org/ (known as UK PubMed Central until 1 November 2012)

¹¹ CRUK Open Access Policy, http://www.rcuk.ac.uk/RCUK-prod/assets/documents/documents/RCUKOpenAccessPolicy.pdf



3. Requirements for the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)

The NC3Rs Guidance for Applicants confirms that all applications must be submitted via the RCUK joint electronic submission system (Je-S). Applicants should refer to the "Applicant and Grant Holder Handbook" ¹².

The NC3Rs has adopted the Medical Research Council (MRC) policy on Data Management and Research Data Sharing¹³ and so reference should be made to this policy and the University document supporting MRC applicants¹⁴.

All applications are required to include a Data Management Plan (DMP) as an attachment to their application on Je-S. The DMP should comply with the MRC's policy on research data sharing. The DMP should demonstrate how the applicant will meet, or already meets their responsibilities for research data quality, sharing and security. It should refer to any institutional and study data policies, systems and procedures and be regularly reviewed throughout the research cycle. The DMP is reviewed by peer reviewers alongside the Case for Support.

To produce a DMP to accompany a research proposal, applicants can use the MRC data management plan template¹⁵. If it is not used, then the applicant should ensure that all the topics listed on the template are addressed:

- Description of the data
- Data collection / generation
- Data management, documentation and curation
- Data security and confidentiality of potentially disclosive personal information
- Data sharing and access
- Responsibilities
- Relevant institutional, departmental or study policies on data sharing and data Security

The length of the DMP will be dependent on the complexity of the data collected, but should be between half a page and a maximum of 3 pages.

http://www.nc3rs.org.uk/sites/default/files/documents/Funding/Handbook.pdf

¹² NC3Rs Applicant and Grant Holder Handbook,

¹³ MRC policy on Data Management and Research Data Sharing, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/

¹⁴ Data Management Planning: MRC funding applicants, http://www2.le.ac.uk/services/research-data/documents/data-management-planning-mrc-funding-applicants-v1-1

¹⁵ MRC Template for a Data Management Plan, v01-00, 1 May 2012, http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/

Information to support NC3Rs applications

NC3Rs website	http://www.nc3rs.org.uk/
NC3Rs Project and Pilot Study Grant Schemes: Guidance for Applicants	https://www.nc3rs.org.uk/funding/pilot-study-grants
NC3Rs Applicant and Grant Holder Handbook 2014	http://www.nc3rs.org.uk/sites/default/files/documents/Funding/Handbook.pdf
MRC Policy on Research Data- sharing	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/policy/
MRC DMP template	http://www.mrc.ac.uk/research/research-policy-ethics/data-sharing/data-management-plans/
Digital Curation Centre MRC Funder's Data resource	http://www.dcc.ac.uk/resources/policy-and-legal/research-funding-policies/mrc
Digital Curation Centre guidance on MRC data planning	http://www.dcc.ac.uk/resources/policy-and-legal/mrc-data-plan-faqs
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4. Requirements for the National Institute for Health Research (NIHR)

The NIHR commissions and funds NHS, social care and public health research essential for delivering responsibilities in public, health and personal social services. Its role is to develop the research evidence to support decision making by professionals, policy makers and patients, make this evidence available, and encourage its uptake and use.

Its key objective is to improve the quality, relevance, and focus of research in the NHS and social care by distributing funds in a transparent way after open competition and peer review.

NIHR Applications

Since 1 April 2009, all applications to NHS Research Ethics Committees have been made using Integrated Research Application Service (IRAS)¹⁶ which was launched in January 2008.

IRAS is a single online system for applying for permissions and approvals for health and social care/community research in the UK. It streamlines the process for seeking relevant approvals, as researchers no longer need to enter the details for a single project in separate application forms.

The IRAS form can be accessed via the 'myresearchproject' website¹⁷.

The Integrated Research Application System (IRAS):

- Is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.
- Enables you to enter the information about your project once instead of duplicating information in separate application forms.
- Uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.
- Helps you to meet regulatory and governance requirements.
- Retains familiar aspects of the NRES form system.

Data issues within the IRAS form

Unsurprisingly management of confidential data is a critical theme of the IRAs form, issues including:

- Storage and use of personal data during the study.
- Physical security arrangements for storage of personal data during the study.
- Ensuring the confidentiality of personal data.

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¹⁶ Integrated Research Application Service (IRAS), http://www.hra.nhs.uk/resources/applying-for-reviews/integrated-research-application-system-iras/

¹⁷ IRAS form, https://www.myresearchproject.org.uk/

- Policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.
- Whether identifiers will be held in the same database as the clinical data, or in a separate database.
- Who will have access to participants' personal data during the study.
- Storage and use of data after the end of the study.
- Where the data generated by the study will be analysed and by whom.
- Who will have control of and act as the custodian for the data generated by the study.
- How long personal data will be stored or accessed after the study has ended.
- For how long research data generated by the study will be stored.
- Long term arrangements for storage of research data after the study has ended.
- Whether identifiable patient data will be accessed outside the care team without prior consent at any stage of the project.
- Review of the statistical aspects of the research.
- The methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.
- If using identifiable personal data, how anonymity will be maintained when publishing the results.
- Informing participants of results.

With such an emphasis on all aspects of data management it is advisable to create a data management plan early in order to inform the IRAS submission and for on-going support of the conduct of research.

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Medicines and Healthcare products Regulatory Agency (MHRA) for CTIMPs and devices
- NHS / HSC R&D offices across the UK
- NRES / NHS / HSC Research Ethics Committees
- 'National Information Governance Board (NIGB)' application now goes to the Confidentiality Advisory Group (CAG), part of the HRA
- National Offender Management Service (NOMS)
- National Social Care Research Ethics Committee

Open Access to research

NIHR encourages initiatives that increase the potential for quality research to be widely disseminated and freely accessed. They support the principle of Open Access to research as set out in its Policy on Open Access for funded research¹⁸.

Transparent and accurate reporting of research

The NIHR part-funds the EQUATOR Network¹⁹, which aims to enhance the reliability of medical research literature by promoting transparent and accurate reporting of health research.

¹⁸ NIHR Policy on Open Access for funded research, http://www.nihr.ac.uk/policy-and-standards/nihr-policy-on-open-access-for-its-funded-research.htm

¹⁹ EQUATOR Network, http://www.equator-network.org/

Information to support NIHR applications

NIHR Website	http://www.nihr.ac.uk/research
NIHR Policy on Open Access for funded research	http://www.nihr.ac.uk/policy-and-standards/nihr-policy- on-open-access-for-its-funded-research.htm
Integrated Research Application Service (IRAS)	http://www.hra.nhs.uk/resources/applying-for- reviews/integrated-research-application-system-iras/
IRAS form	https://www.myresearchproject.org.uk/



5. Requirements for the Wellcome Trust

The Wellcome Trust published a policy and policy statement on data management and sharing in January 2007 and this was revised in August 2010²⁰.

This states that all funded researchers should maximise access to their research data with as few restrictions as possible. It requires applicants whose proposed research will generate data that hold significant value as a resource for the wider research community to submit a data management and sharing plan as part of the application process.

The Wellcome Trust policy is aligned with others including MRC, BBSRC, the US National Institutes of Health and the NCRI Cancer Informatics initiative (refer to University data management guides regarding MRC and BBSRC²¹).

Data management and sharing plan

All applicants for funding should refer to the Trust's guidance on developing a data management and sharing plan²².

Wellcome Trust requires that all funded researchers maximise the availability of their research data with as few restrictions as possible. When applying via the biomedical sciences or medical humanities funding streams and the proposed research will result in data holding significant value as a resource for the wider research community, then you will be required to submit a data management and sharing plan *prior* to an award being made

When is a Data management and sharing plan required?

Plans are required in situations where the data outputs form a resource from which researchers and other users would be able to generate additional benefits, where the primary goal is to create a database resource and other research generating significant datasets that could be shared for added value e.g. where the data has clear utility for research questions beyond those that the data generators are seeking to address.

Examples of applications requiring a data management and sharing plan would include large-scale genetic association studies of common diseases; genome-wide or large-scale functional genomic studies in a specific organism; and longitudinal studies of patient and population cohorts.

For studies generating small-scale and limited data outputs, a data management and sharing plan will **not** normally be required

Data management and sharing plan content

There is **not** a set format for data management and sharing plans.

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Position statement on data management and sharing, http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm
 University Dtaa Planning documents, http://www2.le.ac.uk/services/research-data/advice-and-support/internal

University Dtaa Planning documents, http://www2.le.ac.uk/services/research-data/advice-and-support/interna
Guidance on developing a data management and sharing plan, http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Guidance-for-researchers/index.htm

They should be proportionate, both to the scale of the datasets generated and their likely level of value to the research community.

Questions to address concern how data outputs will be managed and shared:

 What data outputs will your research generate and what data will have value to other researchers?

Researchers should maximise access to research datasets of value to the wider research community in a timely and responsible manner in accordance with recognised data standards and providing appropriate metadata.

• When will you share the data?

All plans must state clearly the timescales over which datasets of value will be shared. Researchers have a right to a reasonable (but not unlimited) period of exclusive use for the research data that they produce but all grant holders must ensure as an absolute minimum that the data underpinning research papers are made available to other researchers on publication.

• Where will you make the data available?

Researchers should generally deposit data in recognised data repositories where these exist for particular data types.

How will other researchers be able to access the data?

Data should be made available to other researchers with as few restrictions as possible. Depending on the study, it may be appropriate to establish a graded access procedure in which less sensitive data e.g. anonymised and aggregate data, are made readily available, whereas applications to access to more sensitive datasets are subject to a more stringent assessment process.

- Are any limits to data sharing required for example, to either safeguard research participants or to gain appropriate intellectual property protection?
- How will you ensure that key datasets are preserved to ensure their long-term value?
 Researchers must consider how datasets that have long-term value will be preserved and curated beyond the lifetime of the grant.
- What resources will you require to deliver your plan?
 This includes people and skills, technical infrastructure and tools.

Information to support Wellcome Trust applications

Wellcome Trust Website	http://www.wellcome.ac.uk/index.htm	
Wellcome Trust Policy on data management and sharing	http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm	
Guidance for researchers: Developing a data management and sharing plan	http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Datasharing/Guidance-for-researchers/index.htm	
FAQs - Position on data management and sharing	http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Datasharing/Data-management-and-sharing/WTX035045.htm	
Open Access policy	http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002766.htm	
Policy on Intellectual property and patents	http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002762.htm	
Guidelines on good research practice	http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002757.htm	
Requirements for publishing Wellcome Trust-funded research papers	http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy _communications/documents/web_document/wtp053977.pdf	

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.

