



Research Data Management Policy

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Amendments	2022 V3.2. Simplified terminology and updated contact details for relevant support services. Added links to new SOPs and updated SharePoint links that have changed. 2021 V3.1. Text updated to incorporate additional references to MRC Gambia & Uganda processes.
Related Policies & Procedures	<p><i>LSHTM Data Classification and Handling Policy</i> https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security</p> <p><i>LSHTM Data Management Plan for research projects</i> https://doi.org/10.17037/PUBS.03716765</p> <p><i>LSHTM Data Management Plan for Research Students</i> https://doi.org/10.17037/PUBS.03750331</p> <p><i>LSHTM Data Protection Policy</i> https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security</p> <p><i>LSHTM Data Storage Options</i> https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security</p> <p><i>LSHTM Good Research Practice Policy</i> https://www.lshtm.ac.uk/sites/default/files/good-research-practice-policy.pdf</p> <p><i>LSHTM Information Management and Security Policy and supporting documents</i> https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security</p> <p><i>LSHTM Intellectual Property (IP) Policy</i> https://www.lshtm.ac.uk/sites/default/files/School_Intellectual_Property_Policy.pdf</p> <p><i>LSHTM Records Retention & Disposal Schedule</i> https://lshtm.sharepoint.com/sites/intranet-information-compliance/SitePages/Records-Retention-and-Disposal-Schedule.aspx</p> <p><i>LSHTM RDM Policy support document - Data Access Procedures</i> https://doi.org/10.17037/PUBS.00612422</p> <p><i>LSHTM Standard Operating Procedures (LSHTM-SOPs)</i> https://lshtm.sharepoint.com/sites/intranet-research-governance-and-integrity/SitePages/Standard-Operating-Procedures-(SOPs).aspx</p>

1 SCOPE

- 1.1** This policy applies to all individuals conducting research or carrying out related duties on behalf of the London School of Hygiene & Tropical Medicine (LSHTM), including those based at the MRC Unit The Gambia at LSHTM and the MRC/UVRI and LSHTM Uganda Research Unit. This includes, but is not limited to, employed and honorary staff, research students and visiting academics. It is expected that all collaborative research partners should be made aware of this policy. The group to whom the policy applies are referred to collectively in this document as 'Researchers'.
- 1.2** LSHTM expects the principles set out in this policy to be understood, observed, and followed by all researchers.
- 1.3** Where research is undertaken as part of a research project, primary responsibility for ensuring compliance rests with the senior researcher, typically the Principal Investigator (PI) or Supervisor. Responsibility may be delegated to a named researcher as necessary.
- 1.4** Where research is conducted with other institutions and/or external researchers, LSHTM researchers are responsible for the management of research data that are under their own control. If the senior researcher is not a member of LSHTM, LSHTM researchers should make their collaborators aware of the policy to facilitate compliance.
- 1.5** If all researchers associated with the research have left LSHTM, responsibility for compliance will devolve upwards, resting with the Head of Department in the first instance.
- 1.6** Exemption to specific principles may be granted in circumstances where compliance will breach legislative, regulatory, contractual, ethical, and/or other obligations. Such cases should be discussed with the Research Data Manager within Library, Archive & Open Research Services (LAORS) in the first instance. The decision will be escalated to the Research Governance Committee in more complex cases.

2 PURPOSE AND OVERVIEW

- 2.1** The London School of Hygiene & Tropical Medicine (LSHTM) recognises research data as a valuable asset that forms the basis for rigorous scientific enquiry, serves as evidence of research conduct, and has the potential to support equitable partnerships and enable new and innovative research in public health.
- 2.2** This Research Data Management Policy (henceforth RDM Policy) sets out expectations for how researchers should manage and share research data under their control in accordance with good research practice.
- 2.3** The RDM Policy forms a component of LSHTM's over-arching research governance framework, which regulates the research undertaken at LSHTM. It should be read in conjunction with institutional, national, international, and other requirements that apply to research data. This includes, but is not limited to, ethical and legal conditions that apply to the handling of human data.
- 2.4** The RDM Policy establishes LSHTM's commitment to complying with the Concordat on Open Research Data, a framework for best practice within UK HEIs with respect to research data

management. It forms a component of LSHTM's research governance framework and should be read in conjunction with the policies and procedures outlined in the References section.

3 POLICY

The London School of Hygiene & Tropical Medicine (LSHTM) defines the following principles to be followed by researchers in order to ensure research data are managed and disseminated in accordance with good research practice.

Guidance on addressing the principles can be found on ServiceDesk (<https://servicedesk.lshtm.ac.uk/>) and the intranet (<https://lshtm.sharepoint.com/>). One-to-one support is available from the Research Data Manager within the Library, Archive & Open Research Services.

3.1. LSHTM-led research projects working with research data must create a Data Management Plan

A Data Management Plan (DMP) is a formal document that outlines how research assets, such as data, code, and other support material, will be obtained, managed and shared during the research lifecycle and following its completion. It outlines how the researcher will address requirements that apply to the research and steps that will be taken to ensure it can be verified and reused.

LSHTM-led research projects working with research data must prepare a Data Management Plan (DMP) before the commencement of research, even if not required by their research funder.

A Data Management Plan should be written at the appropriate stage:

- Public/private funded research should prepare a Data Management Plan prior to submission of a research application or within the first 3 months of project funding, as required by the funder.
- PhD/DrPH students should agree a Data Management Plan with their Supervisor and submit it as part of their Upgrading or Review Report.
- Researchers that are unfunded, working with 3rd party data only, performing consultancy, or undertaking an MSc project solely in pursuit of a qualification are encouraged to prepare a Data Management Plan, but are not covered by this mandate.

It is advisable to develop a Data Management Plan in conjunction with other relevant documents, such as the research plan/protocol and Data Protection Impact Assessment (DPIA), where appropriate.

All researchers associated with a research project must be made aware of and abide by the Data Management Plan.

The Data Management Plan should be reviewed and updated at appropriate stages during the research lifecycle. It is recommended that it is reviewed and updated when significant changes are made to the project work plan or every six months, as a minimum.

Funder-specific templates and guidance for writing a Data Management Plan should be followed, where applicable. If no funder template exists, LSHTM provides templates that may be used (see Related Policies & Procedures).

3.2. Data management costs should be recovered from the research funder, where permitted

Costs associated with the capture, management, archiving, and sharing of research data during the project lifetime and following its completion should be considered at the earliest opportunity, preferably when preparing the research application, so that suitable arrangements can be made.

Researchers should review research funder guidelines on allowed costs and, where permitted, write these into the justification of resources and budget of the research application. Common examples of data management costs include hardware and software purchases, data-related training, staff time for data preparation, and use of third-party services.

Advice on research data costs may be obtained from the Research Data Manager.

3.3. Data rights should be recognised and agreed at the earliest opportunity

Researchers should clarify intellectual property rights and custodianship for research data and other research assets that are used in research at the earliest opportunity. This will ensure that it can be collected, stored, managed and shared in compliance with relevant conditions that apply to research. This includes ethical, legal, regulatory, contractual, and/or other requirements.

The rights of research participants to engage with decision-making is recognized as important for ensuring they benefit from work undertaken, in line with guidelines such as the CARE Principles for Indigenous Data Governance. Research participants must be provided with sufficient information to understand and influence how their information will be stored, analysed and shared as part of the research process. Guidance may be found in the LSHTM Standard Operating Procedure on Informed Consent (LSHTM-SOP-005) and relevant SOPs at the respective MRC Units in Gambia and Uganda.

Research partners should agree on a collaboration agreement that clearly indicates the rights they possess and permissions they provide to ensure research data can be used for current and future research. Rights will often be owned by the host institution(s) in which researchers are based, rather than the researcher themselves, therefore it is important that this agreement is reviewed and approved by the relevant institution's legal team. Advice on preparing collaboration agreements and sample templates can be obtained from the LSHTM Legal Services Office.

Exclusive rights to ownership or use of research data should not be handed over to a third party, unless it is a condition imposed by contractual or other obligations, without first consulting the Research Data Manager or LSHTM Legal Services Office for advice. Instead, researchers are encouraged to apply a non-exclusive licence that enables research data to be accessed and used by many parties.

Further information can be found in the LSHTM Good Research Practice Policy and LSHTM Intellectual Property Policy.

3.4. Research data must be securely stored and managed throughout the time period they are retained

Research data and other research assets must be securely stored and managed throughout the time period that they are held. This must ensure the confidentiality of information, protect against data loss and corruption, and comply with requirements that apply to the research. This includes ethical, legal, contractual, or other requirements, most notably the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018 (UK DPA 2018).

The managed storage environment may be operated by LSHTM and/or a trusted third party. Advice and guidance on classifying research data by its sensitivity level and selecting appropriate storage methods are available in the LSHTM Data Classification and Handling Policy and LSHTM Data Storage Options document.

In circumstances where a managed storage environment is not available (e.g. when working in the field), researchers must take all reasonable steps to ensure adequate measures are in place to protect research data and ensure they are not held in a jurisdiction that offers lower levels of protection than available in the UK. The research data must be transferred into a managed storage environment at the earliest opportunity.

Advice on LSHTM storage systems may be sought from LSHTM IT Services.

3.5. Documentation should be sufficient to access, understand, verify and reuse research data

The ability to access, understand and use research data for the purpose of research verification or new research, is dependent upon the existence and availability of documentation that is full, clear and accurate.

Researchers should ensure that they produce documentation that complies with research practices and reporting guidelines appropriate to the scientific domain(s) in which their research is conducted.

Research data that are made available should be supported by documentation that enable others to access, understand and use it, without the need to contact the study authors. Documentation that may be shared include: data collection tools, research protocols and procedures, participant informed consent forms, processing scripts, software code, data dictionaries and other outputs.

Further information on documentation practices can be found in the LSHTM Standard Operating Procedure on Good Documentation Practice (LSHTM-SOP-022).

3.6. Research data that contribute to research findings must be retained for the time period that they are needed

Researchers are responsible for ensuring research data necessary to verify and reproduce research findings are retained for the time period that they are needed.

Research data produced by a researcher must be kept in digital and/or physical form for a minimum of 10 years following funding completion, in accordance with LSHTM's Records Retention and Disposal Schedule.

A minimum retention period longer than 10 years may be specified by third parties for specific types of research. For instance, research data produced as part of a clinical trial must be kept for a minimum of 25 years. Similarly, research data that underpins published research findings must often be made available for a minimum of 10 years after the date that it was published, in accordance with journal requirements.

Data provided by a third party that contains a contractual condition that it is held for a shorter time period are exempt from this requirement.

A decision to dispose of research data or other research assets under the researcher's control may be made after the retention period has passed, in consultation with relevant staff. Appropriate documentation should be maintained on any research assets that are selected for disposal, in compliance with guidance outlined in the LSHTM Records Retention and Disposal Schedule and its supporting documents.

Further information can be found in the LSHTM Standard Operating Procedure on Data Destruction (LSHTM SOP 043) and the LSHTM Records Retention and Disposal Schedule. Advice on retention requirements that apply to research data may be sought from the Research Data Manager or the Archives & Records Manager within Library, Archive & Open Research Services.

3.7. Research data that substantiate research findings should be made available at the earliest opportunity, in accordance with conditions that apply to the research

Research data that substantiate research findings should be shared through a managed repository or enclave in a manner that is compatible with the ethical, legal, contractual, and/or other requirements that apply to research.

Research data suitable for sharing should be made available within 12 months of the grant closure or at the point when research findings based on the work are published, whichever is sooner. Funder policies and community practices that stipulate more rapid sharing supersede this requirement.

Access mechanisms applied to research data must comply with good research practice and conditions that apply to the research. Open access is encouraged where possible. However, controls upon access and use may be applied where necessary to fulfil ethical, legal, contractual or other requirements.

Researchers should take appropriate steps to identify and address barriers that may limit the ability to share research data. This may include ensuring that ethics and contractual documents recognise the need to share data with others, developing procedures and allocating resources to prepare data for sharing.

An exemption may be sought for research data covered by ethical, legal, contractual, or other conditions that prohibit sharing. Researchers that have not obtained explicit consent to share data within participant informed consent forms and/or collaboration agreements and who are subsequently required to make data available should seek advice from the Research Governance & Integrity Office and/or the Research Data Manager.

Further information can be found in the LSHTM Standard Operating Procedure on Informed Consent for Research (LSHTM SOP 005), LSHTM Standard Operating Procedure on Confidentiality and Anonymisation of Research Data (LSHTM-SOP-036) and LSHTM Data Access Procedures.

3.8. Research data that are made available for access must include details of institutional affiliation, funder, and author identifiers

Research data that are made available for access must provide the name and institutional affiliation of each author/contributor, as well as any research identifiers that are associated with the research.

Researchers must use the correct institutional affiliation when publishing research to which they have contributed so that it may be identified as an institutional output. This will be either 'London School of Hygiene & Tropical Medicine'; 'Medical Research Council Unit The Gambia at the London School of Hygiene & Tropical Medicine'; or 'Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit'.

Research data must clearly acknowledge the funding source(s) and grant or programme number(s) in order to ensure that grant conditions are met and to enable research assets to be clearly linked to funders.

Researchers should have an ORCID identifier to enable robust linking between research assets and their creators.

3.9. Research data must be registered with LSHTM, irrespective of whether it is hosted there or elsewhere

Research data intended for sharing must be registered with LSHTM on completion of funding or at the point when it is made available, whichever is sooner.

This requirement applies to all LSHTM-led research, research in which LSHTM has been assigned formal responsibility for data collection, management, or sharing in a contract or sub-contract, and research data that lists LSHTM researchers as a named contributor to the work.

Researchers undertaking consultancy work are encouraged to register research data that they produce if it does not breach confidentiality, contractual, or other obligations.

Library, Archive & Open Research Services maintains a digital repository, LSHTM Data Compass (<https://datacompass.lshtm.ac.uk/>), which may be used to register research data and other relevant research assets.

3.10. Published research should include information on how to access research data and other supporting material

Good research practice is built upon the recognition of all source material used in research. Researchers should ensure that all research assets that underpin research are cited in published research, following citation guidelines appropriate to their scientific domain.

Researchers must include a data access statement in published research where mandated by a research funder, sponsor, or publisher, even where there is no research data associated with the research or the research data cannot be shared.

An access statement should be included that outlines where research data may be obtained and any associated conditions for access and use. A persistent identifier, such as a Digital Object Identifier (DOI), should be included where one is available.

Advice is available from the Research Data Manager within Library, Archive & Open Research Services.

4 CONTACTS

Questions related to the Research Data Management Policy and its implementation should be directed to the Research Data Manager within Library, Archive & Open Research Services.

5 DEFINITIONS

- *Data Access Statement*: A statement provided in published research that describes where research assets that underpin the paper are hosted, how they may be accessed, and any conditions of access and use.
- *Data Management Plan (DMP)*: A document that describes how research data and/or other research assets will be obtained, managed and shared during the research lifecycle and following its completion.

- *Digital repository*: A system for storing, managing and sharing research assets, such as data and code. LSHTM Data Compass is an example of an institutional digital repository.
- *Metadata*: Information that describes one or more research assets. Metadata may describe the content of a research asset, how it was obtained, and how it may be accessed and used.
- *Non-Exclusive Licence*: A licence that grants the same rights to several licensees. This differs from an exclusive licence, which assigns rights to a specific licensee, to the exclusion of others.
- *Persistent Identifier (PID)*: A unique, stable, permanent reference to a digital object. Examples include the Open Researcher & Contributor ID (ORCID) system to identify authors, and Digital Object Identifier (DOIs) system applied to journal articles and datasets.
- *Principal Investigator*: The lead researcher or scientist for a project.
- *Researcher*: Any person conducting research or involved in the creation, collection, or generation of research data for or on behalf of LSHTM. This may include, but not be limited to, employed staff, research students, and honorary staff.
- *Research Asset*: A resource produced as part of the research process. This includes research data, code, scripts, collection tools, participant consent forms, and other resources.
- *Research Funder*: An agency responsible for the financial support of research activities.
- *Research Project*: A unit of work performed by one or more researchers that has been established for the purpose of addressing specific aims and objectives.
- *Retention Period*: The time period for which the research data must be kept. The LSHTM Records Retention & Disposal Schedule states research data must be retained for a minimum of 10 years following project completion, with the recognition that third-party requirements that have a longer retention period will take precedent.

6 REFERENCES

- Concordat on Open Research Data
<https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf>
- CARE Principles for Indigenous Data Governance
<https://www.gida-global.org/care>