Research Data Management Policy

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Related Policies & Procedures	*LSHTM Data Classification and Handling Policy* https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security *LSHTM Data Management Plan for research projects* https://doi.org/10.17037/PUBS.03716765 *LSHTM Data Management Plan for Research Students* https://doi.org/10.17037/PUBS.03750331 *LSHTM Data Protection Policy* https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security *LSHTM Data Storage Options* https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security *LSHTM Good Research Practice Policy* https://www.lshtm.ac.uk/sites/default/files/Good_Research_Practice_Policy.pdf *LSHTM Information Management and Security Policy and supporting documents* https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security *LSHTM Records Retention & Disposal Schedule* https://lshtm.sharepoint.com/Services/Information-Management/Pages/-records-retention-and-disposal-schedule.aspx *LSHTM RDM Policy support document - Data Access Procedures* https://doi.org/10.17037/PUBS.00612422 *LSHTM Standard Operating Procedures* https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-%28sops%29.aspx *LSHTM Standard Operating Procedure: Informed Consent for Research (LSHTM-SOP-005)* https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-%28sops%29.aspx *LSHTM Standard Operating Procedure: Good Documentation Practice (LSHTM-SOP-022)* https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-%28sops%29.aspx *LSHTM Standard Operating Procedure: Confidentiality and Anonymisation of Research Data (LSHTM-SOP-036)* https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-%28sops%29.aspx

	LSHTM Standard Operating Procedure: Data Management (LSHTM-SOP-037) https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-%28sops%29.aspx

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. Exemption to specific expectations may be granted in circumstances where compliance will breach external obligations. Advice should be sought from the Research Data Manager based within the Library & Archives Service in the first instance. The decision will be escalated to the Research Governance Committee at LSHTM or the relevant MRC Unit in more complex cases.

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.

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.

2. PURPOSE AND OVERVIEW

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 enable new and innovative research in public health and elsewhere.

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.

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.

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.

3. POLICY

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 the LSHTM ServiceDesk (http://servicedesk.lshtm.ac.uk/) and intranet (https://lshtm.sharepoint.com/Research/Research-data-management/). One-to-one support is available from the Research Data Manager based within the LSHTM Library & Archives Service.

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

Data management should be considered when planning research to ensure adequate resources are allocated to achieve the designated objectives.

LSHTM-led research projects working with research data are expected to prepare a Data Management Plan (DMP) before the commencement of research, even if not required by their research funder. This should provide details of the research data and other assets to be acquired, how they will be managed in accordance with ethical, legal, and other requirements, procedures to ensure they can be accessed, verified and reused, resources needed, and other relevant information.

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

- Public/private funded research: prepare a Data Management Plan prior to submission of a funding application (if required by the funder) or within the first 3 months of project funding.

- PhD/DrPH students: agree a Data Management Plan with the Supervisor and submit it as part of the 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.

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

To ensure adherence and continued relevance to the research, the Data Management Plan should be reviewed and updated at appropriate stages during the research. The review and approval process should be tailored to the project, influenced by factors such as its research milestones and duration. 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. Significant events that may necessitate a DMP review include: changes to project objectives, data handling workflow, project budget, or legal/ethical framework in which the project operates. Amendments should be approved by the Principal Investigator and/or other project members with an understanding of the association between the research and data management process.

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.

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 course attendance, staff time needed to prepare data for analysis and sharing, and use of third-party web 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

Research data are produced with input from multiple groups, including research participants, research partners, host institutions, country governments, and others. To ensure the Data Management Plan can be implemented, it is essential that the contribution provided by each rights holder are recognised and appropriate permission obtained at the earliest opportunity.

Research participants must be provided with sufficient information to understand and influence how their information will be stored and used during the study lifetime and following its completion so that they can provide explicit consent. Information on data ethics can 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 institution's legal team. Advice on preparing collaboration agreements and sample templates can be obtained from the relevant Legal Services Office at LSHTM and the MRC Units in Gambia and Uganda.

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 in the first instance. Instead, Researchers are encouraged to apply a non-exclusive licence that enables research data to be accessed and used by many parties.

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

Research data and other outputs must be securely stored and managed throughout the time period that they are held, in compliance with legal, regulatory, contractual, and other obligations, most notably the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. The managed storage environment may be operated by LSHTM and/or a trusted third party.

In circumstances where a managed storage environment is not available (e.g. when working in the field), the researcher must take all reasonable steps to ensure adequate measures are in place to protect research data from unauthorised access and use, and 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.

Guidance on classifying research data by its sensitivity level and selecting appropriate storage methods may be found in the LSHTM Data Classification and Handling Policy and LSHTM Data Storage Options document.

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

Researchers must create documentation sufficient to access, understand, analyse and reuse research data.

Documentation may be contained in many research outputs, including survey questionnaires, codebooks, Standard Operating Procedures, informed consent forms, processing scripts, software code, workflows and other research outputs.

Documentation should comply with reporting standard and guidelines appropriate to the scientific domain(s) in which the research is performed, the type of research data produced, and other relevant factors.

Key information to include in the documentation is the content of the research data (e.g. the number of research participants covered, the purpose of each variable and how it is measured), actions performed to acquire and process research data prior to performing analysis, and any procedures that must be applied to enable independent verification of research findings and/or use in new research.

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 validate and reproduce research findings are retained for the time period that they are needed.

Research data generated by LSHTM must be kept in an appropriate form (e.g. digital, paper, physical samples) for a minimum of 10 years following funding completion, in accordance with LSHTM's Records Retention and Disposal Schedule. 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 minimum retention period longer than 10 years may be specified by third parties for specific types of research output. For instance, research data that underpins research findings which is published following project completion often need to be available for 10 years after the date that the journal paper was published.

A decision to dispose of research data under the researcher's control may be made after the retention period has passed, in consultation with relevant staff. However, the researcher should be aware that other versions of the research data may continue to exist. For instance, an anonymised derivative held in a research data repository.

Appropriate documentation should be maintained on any research data selected for disposal. This should clear indicate what information is to be deleted, justification for the action, responsibility for the decision, when it was performed, and by whom.

Advice on retention requirements for research data is available from the Research Data Manager. Guidance on exemptions to the LSHTM Records Retention and Disposal Schedule are available from the Archives & Records Management team based within the Library & Archives Service.

3.7. Research data that underpins findings should be made available at the earliest opportunity

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

Access mechanisms should be appropriate to the research data being made available. Prior to release, an impact assessment should be performed to identify and assess risks associated with data release (e.g. participant identification) and steps taken to minimise these risks. Further information can be found in the LSHTM Standard Operating Procedure on Confidentiality and Anonymisation of Research Data (LSHTM-SOP-036) and LSHTM Data Access Procedures.

An exemption may be granted 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

3.8. When making research data available, metadata describing research data should be sufficient to aid discovery and linkage

Researchers should ensure metadata that describes research data made available is sufficiently descriptive to understand its content, the context in which it was produced, and individuals and/or organisations that should be credited for its production. This will ensure that the research data can be discovered and linked to other resources.

Descriptive metadata created should comply with documentation standards and guidelines applicable to the subject domain and system in which it is held.

The correct institutional affiliation must be used to ensure it is recognised as an institutional output and included in relevant bibliometric measurements. This will be:

- 'London School of Hygiene & Tropical Medicine' for researchers associated with LSHTM in the UK. LSHTM's International Standard Name Identifier (ISNI) is '000000040425469X'.
- 'Medical Research Council Unit The Gambia at the London School of Hygiene & Tropical Medicine' for researchers associated with the research unit in The Gambia
- 'Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit' for researchers associated with the research unit in Uganda

The funding source(s) and grant/programme number(s) must be clearly acknowledged to demonstrate grant conditions have been met and enable research data to be clearly linked to the appropriate project(s) and funder(s).

Researchers are strongly encouraged to create and use an ORCID identifier to enable robust linking between research data and their creators. Support on the creation and management of an ORCID identifier is available from the Library & Archives Service (library@lshtm.ac.uk).

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 research data are 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.

The LSHTM Library & Archives Service maintains a research data repository, LSHTM Data Compass (https://datacompass.lshtm.ac.uk/), which may be used to register research data and other relevant research outputs.

The researcher may request that metadata describing research data is embargoed or withheld from external view, explaining the reason it is needed (for instance, to allow time to obtain a patent, publish research findings, or comply with contractual obligations). Decisions to approve requests will be made by the Research Data Manager in the first instance and escalated to the Research Governance Committee where needed.

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 must ensure that research data and other resources (such as collection tools, software code and processing scripts) created and/or used in the research process are cited in research publications, including journal articles, conference papers, and other outputs.

Data citation standards should be followed, where accepted by the publisher. For instance, if a Data Access Statement is permitted, this should describe how research data may be accessed, cite a relevant persistent identifier (such as a DOI), and outline any conditions associated with access and use.

4. CONTACTS

Questions related to the Research Data Management Policy and its implementation should be directed to the Research Data Manager based within the LSHTM Library & Archives Service (researchdatamanagement@lshtm.ac.uk).

5. DEFINITIONS

- *Research Data Repository:* A system for storing, managing and sharing data. LSHTM Data Compass is an example of an institutional data repository.

- *Research Funder:* An agency responsible for the financial support of research activities.

- *Non-Exclusive Licence:* A licence that grants the same rights to an intellectual property to several licensees. This differs from an exclusive licence, which assigns rights to a specific licensee, to the exclusion of others.

- *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.

- *Resource Output:* A resource produced as part of the research process. This includes research data, code, scripts, collection tools (interview guides, questionnaires), standard operating procedures, participant consent forms, and other resources.

- *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 time period is influenced by institutional, legislative, regulatory, contractual and other requirements. 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
http://www.rcuk.ac.uk/documents/documents/concordatonopenresearchdata-pdf/