



LSHTM RDM POLICY SUPPORT DOCUMENT: DATA ACCESS PROCEDURES

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Amendments	v2 – updated URLs to policy document. No other changes.
Related Policies & Procedures	See References section

1. SCOPE (i.e. who does this affect)

This procedure document applies to LSHTM Researchers required to make research data available in compliance with the FAIR guiding principles for scientific management and stewardship. This include researchers receiving public funding through Research Councils UK (MRC, ESRC, and others) and European Commission, among others.

2. OVERVIEW

The London School of Hygiene & Tropical Medicine seeks to maintain a research culture built upon transparency and openness that ensures knowledge can be widely disseminated, adopted, and used to address ongoing public health challenges. Fundamental to this is a need to share data and other resources that underpin research findings for the purpose of independent verification and use in further health research. At the same time, it is important that research participants are protected from harm by ensuring the information they provide is kept private where there is a reasonable expectation of confidentiality.

The FAIR guiding principles for scientific management and stewardship establish a set of practices that data producers and publishers should perform to enhance access to scientific research by ensuring it is made available in a form that is Findable, Accessible, Interoperable, and Reusable (FAIR).

This document sets out processes by which researchers may apply the FAIR guiding principles for scientific management and stewardship to balance the potentially conflicting obligations that apply to their research outputs, enabling them to be made “as open as possible and as closed as necessary”¹. It supplements the Research Data Management Policy and is supported by deposit guidelines held on intranet that outline how research data may be submitted to LSHTM Data Compass.

3. FAIR SHARING OF RESEARCH DATA

The FAIR guiding principles for scientific management and stewardship establish a set of practices that data producers and publishers should perform to enhance access to scientific research by ensuring it is made available in a form that is Findable, Accessible, Interoperable, and Reusable (FAIR).

To make data findable:

- Publish a description of the research outputs in an appropriate digital repository, such as LSHTM Data Compass, so that researchers outside your research team can learn of its existence (see 4.4)
- Cite the Digital Object Identifier (or other permanent ID) associated with the description in appropriate locations – your journal publications, project reports, the project website, etc. (see 4.7).

To make data accessible:

¹ As recommended by the European Commission

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

- Provide a clear method to obtain the research data, either by making it available openly or through a control mechanism (see 4.5).
- For restricted data, consider access conditions that will need to be met and how this will be handled (see a-d in 4.5)

To make data interoperable:

- Apply well-documented standards applicable to your research field when creating, organising and labelling data, rather than develop your own practices, where appropriate standards exist (see 4.2).
- Use open formats that can be accessed and processed using several software tools, in addition to those used by researchers in your subject field (see 4.2).

To make data reusable:

- Produce and provide supporting information that helps a researcher outside your project team to understand and use your research data (see 4.3)
- Apply a licence that clearly describes how it may be accessed and used (see section 4.6)

The remainder of this document will outline how these objectives may be achieved by LSHTM researchers.

4. ACTIVITIES

4.1. Identify research outputs suitable for sharing

Review the outputs to be produced or captured during the research process – research instruments, data, software code, scripts, and other resources - and identify those that should be made available for the purpose of independent verification and/or to fulfil external requirements.

Research outputs must only be made available in compliance with ethical and legal permissions set out in participant informed consent forms, consortium agreement, and other legal agreements. Further information on data ethics can be found in the LSHTM Standard Operating Procedure on Informed Consent (LSHTM-SOP-005). Advice may be obtained from the Research Governance and Integrity Office (RGIO) or the Research Data Manager, based within the Library & Archives Service.

4.2. Adopt standards and formats that support reuse

Research data should be made available in a form that allows them to be accessed, analysed, and/or combined with other datasets with minimal barriers. To enable this, the use of well-documented, domain standards and open file formats are encouraged. The FAIR Sharing portal (see section 9 for URL) provides examples of data and metadata standards relevant to scientific research. Queries on this topic should be directed to the Research Data Manager, based within the Library & Archives Service.

4.3. Provide support material sufficient to understand and re-apply the analysis

Research data that are shared must be accompanied by support material that can be used to understand the context in which it was created/captured and how the analysis may be re-applied. This may take the form of survey questionnaires, codebooks, Standard Operating Procedures, informed consent forms, processing scripts, software code, workflows and other resources. Queries on the type of material that should accompany research data should be directed to the Research Data Manager, based within the Library & Archives Service.

4.4. Publish a data description to make researchers aware of their existence

To enable researchers outside your team to learn of the research data's existence, a data description should be published in the School's research data repository, LSHTM Data Compass (<http://datacompass.lshtm.ac.uk/>) and other research catalogues that will be consulted by researchers within your field. The data description should outline the data content, context in which it was obtained, how it may be accessed, permitted usage, and other relevant details.

The permanent identifier for the data description, typically a Digital Object Identifier (DOI), may be cited in journal publications, project reports, staff and researcher profiles and other locations.

4.5. Choose an appropriate access method

Researchers are encouraged to make research outputs open for free, unrestricted download, where possible. However, it is recognised that there are often good reasons to restrict how outputs can be obtained and used.

An impact assessment should be performed to determine the implications of making research outputs available (e.g. participant re-identification, patent application being rejected) and appropriate measures adopted to minimise risks. Any restrictions should be documented, to clearly explain the reason that they are necessary and how access may be obtained. Further information on this topic can be found in the LSHTM Standard Operating Procedure on Confidentiality and Anonymisation of Research Data (LSHTM-SOP-036-01) and the LSHTM Data Classification and Handling Policy.

In cases where research outputs must be shared in controlled conditions, four questions should be addressed:

a. How will access requests be submitted?

Automated methods should be used to contact Data Custodians, such as the request button provided by LSHTM Data Compass. This ensures the request is received by the Data Custodian via their preferred communication method.

If an email address must be used, it should be a shared account for a research group or department, rather than the author's email, which may become inactive when they leave their role.

b. Who will evaluate access requests?

Research funders and journal publishers increasingly state that a formal Data Access Committee must be setup to handle access requests, with requirements imposed on membership and reporting. Researchers must ensure they comply with any external requirements for the handling and evaluation of access requests.

Requests to access research data made available through LSHTM Data Compass must be reviewed by at least two people with appropriate knowledge of the research and data, to ensure evaluation is consistent and fair. This is likely to be performed by the Principal Investigator and study team in the short-term. However, responsibility may be delegated to a custodian, who will act on their behalf on a temporary or permanent basis. In the absence of a designated custodian, responsibility will devolve to the Head of Department (see 5).

An Applicant who has had their data access request denied may submit an appeal to the Research Data Manager. The appeal and the reason for the original decision will be passed to the Research Governance Committee for consideration.

c. What eligibility criteria will be applied?

Define the criteria that an Applicant must fulfil to obtain the requested research data. For example, to comply with conditions established in the informed consent form, an Applicant may be asked to state the purpose for which they wish to use the research data, demonstrate they have the necessary analysis expertise and/or ethics approval for their research, and sign a licence agreement. Advice on this topic may be obtained from the Research Governance and Integrity Office (RGIO).

d. How will outputs be transferred?

Data should be transferred to Applicants specified in the Data Transfer Agreement only. If other researchers wish to analyse the data, they must be added to an amended version of the agreement.

Appropriate security measures should be adopted to protect data from unauthorised access during transfer and storage. E.g. data encryption. Queries on data security can be directed to the Head of IT Security, IT Audit and Compliance or Research Data Manager.

4.6. Assign a licence

The ability to share research data and enable it to be used by others is dependent upon intellectual property rights being understood and documented from the outset of the research process.

For open data, researchers are encouraged to apply a licence that enables it to be accessed and used for any purpose. For example, Creative Commons Attribution (CC-BY) or Open Data Commons Attribution Licence (ODC-By).

For restricted data, a Data Transfer Agreement should be developed that clearly describes permitted and non-permitted uses. This should be sent to the Applicant to sign prior to being provided with the research data.

Advice may be obtained from the LSHTM Legal Office and Research Data Manager, based within the Library & Archives Service.

4.7. Cite the research data in publications and other outputs

Good research practice is built upon the recognition of all source material used in the research process, including research instruments, data, software code, scripts, and other resources.

Good citation practice should be followed, where appropriate standards exist. For instance, by citing the Digital Object Identifier (DOI) of research outputs in a Data Access Statement or reference list.

Citation styles vary for different publishers and funders – some provide specific guidelines for digital outputs, some state that they should be cited in the same way as physical resources, while others state that digital outputs should not be included in a reference list. Consult submission guidelines and contact the publisher for advice.

Guidance on data citation may be obtained from the Research Data Manager based within the Library & Archives Service.

5. NON-AVAILABILITY OF THE DATA CUSTODIAN

The following section applies to Data Custodians making data available through LSHTM Data Compass:

- **The Data Custodian is temporarily unable to evaluate access requests, e.g. due to workload, illness, conflict of interest, etc.**
Contact the Research Data Manager to discuss handover of responsibility. A temporary Data Custodian may be allocated responsibility for making decisions during an interim period, after which duties will revert back to the current Data Custodian. If during this time, the temporary Data Custodian is also unavailable, responsibility will devolve upwards to the current Data Custodian's Head of Department.
- **The Data Custodian is no longer able to evaluate access requests on a permanent basis, e.g. due to retirement, resignation from LSHTM, etc.**
Contact the Research Data Manager to discuss handover of responsibility. The Data Custodian may designate an individual with appropriate expertise to replace them, ideally one employed by LSHTM. If a suitable replacement is not available, responsibility will devolve upward to the Data Custodian's Head of Department.
- **The Data Custodian is no longer able to evaluate access requests and has not designated a replacement**
A new Data Custodian will be selected by the School. The process will be overseen by the Research Data Manager, in consultation with the Head of Department, Research Governance Committee and other relevant individuals.

6. APPEALS

An applicant who has had their data access request denied may submit an appeal to the Research Data Manager. The appeal and the reason for the original decision will be passed to the Research Governance Committee for consideration.

7. DEFINITIONS

- *Applicant*: An end user who submits a request to gain access to non-public data
- *Data Creator*: one or more people responsible for creation, capture, or development of the data being requested.
- *Data Custodian*: A researcher who is responsible for receiving and evaluating data access requests. Equivalent to a corresponding author for publications.
- *Data Access Committee*: A group, consisting of two or more people, who accept formal responsibility for evaluating access requests submitted by an Applicant and setting conditions under which it will be transferred.

8. CONTACTS

Questions related to the Data Access Procedures should be directed to the Research Data Manager based within the Library & Archives Service (researchdatamanagement@lshtm.ac.uk).

9. REFERENCES

- Concordat on Open Research Data (28th July 2016):
<https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/>
- FAIRsharing.org: <https://fairsharing.org/>
- FORCE11. The FAIR Data Principles. <https://www.force11.org/group/fairgroup/fairprinciples>
- Guidelines on FAIR Data Management in Horizon 2020. Version 3.0. 26 July 2016.
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
- LSHTM Data Classification and Handling Policy
<https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security>
- LSHTM Research Ethics:
<https://lshtm.sharepoint.com/Teaching-and-Support/Pages/research-ethics.aspx>
- LSHTM Good Research Practice Policy:
<https://www.lshtm.ac.uk/research/research-governance-integrity/research-governance>
- LSHTM Information Management and Security Policy:
<https://www.lshtm.ac.uk/aboutus/organisation/information-management-and-security>
- LSHTM Research Data Management Policy:
https://www.lshtm.ac.uk/sites/default/files/research_data_management_policy.pdf
- LSHTM Standard Operating Procedure on Confidentiality and Anonymisation of Research Data (LSHTM-SOP-036-01). [https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-\(sops\).aspx](https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx)
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[https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-\(sops\).aspx](https://lshtm.sharepoint.com/Research/Research-Governance/Pages/standard-operating-procedures-(sops).aspx)
- Wilkinson, M.D. et al. (2016). The FAIR Guiding Principles for scientific data management and stewardship. Scientific Data. <https://doi.org/10.1038/sdata.2016.18>