MRC/UVRI and LSHTM Uganda Research Unit

# Data Sharing Policy

## 1 INTRODUCTION

The MRC/UVRI & LSHTM Uganda Research Unit (the **unit**) strongly supports the view that:

- publicly funded research data are a public good which should be made available to all bonafide with as few restrictions as possible (in line with UKRI-MRC policy);
    - Greater data sharing could enhance public well-being by maximising utilisation of gained knowledge, reducing redundant research and facilitating scientific innovation; and
    - The approach to scientific data sharing must be responsible and must recognise legal, regulatory, ethical and commercial constraints.

For this reason, the Unit formulated a policy and processes to allow appropriate and responsible sharing of the unit's research data for scientific research.

## 2 SCOPE

This Data Sharing Policy covers all studies conducted by the Unit globally and regardless of the source of funding. This policy applies to data sharing requests/collaborations concerning prospective and completed unit studies. In developing this Policy, the Unit was guided by the FAIR principles for Data sharing- the 2016 international research community as published.

### 2.1 Findable

Data will be discoverable via search engines and catalogues, have machine-readable metadata and a unique persistent identifier such as a Digital Object Identifier (DOI) for the published data.

### 2.2 Accessible

Once the user finds the required data, s(he)/they need to know how they can be accessed, possibly including authentication and authorisation and this shall be done though data sharing agreements.

**2.3** Interoperable

The data to be shared will usually need to be merged with other data hence shall be shared in formats such as CSV that can easily be merged and imported into other analysis applications.

**2.4** Re-usable

The ultimate goal of FAIR is to optimise the reuse of data. To achieve this, metadata and data should be well-described so that they can be replicated and/or combined in different settings.

## 3 KEY DEFINITIONS

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| Data Sharing Agreement | An agreement between the Unit and a data requester/collaborator which sets out the terms upon which the Unit agrees to provide the requester/collaborator with access to certain data in a collection for the purposes set out in the relevant approved proposal. |
| Collection | A research dataset, including summary datasets, or set of human samples with associated data, in respect of a study conducted by the Unit. |
| Custodian | The individual, organisation, body or committee with responsibility for the relevant Collection. Typically, this is the principal investigator (**PI**) or chair of the study Steering Committee. For on-going studies with an active PI, the PI will be considered the Custodian. In absence of the PI, the Unit director will be the Custodian. |
| Data Sharing Committee | The Committee that monitors and oversees data access and sharing requests in respect of data in a Collection and decides on requests in consultation with the Custodian. The committee is impartial in its decision making. |
| Proposal | Means a proposal submitted by a Requester in accordance with this Policy. |
| Requester | An individual or a group of researchers seeking access to data from a Collection. |
| Collaborator | An individual/organization working with the Unit to collect data. |

## 4 RESPONSIBILITIES OF THE UNIT'S INVESTIGATORS

The Unit's Investigators will:

- Design research studies and manage research data with the expectation that data will be shared;
- Have in place a data management and sharing plan where a research proposal involves the generation of datasets that have clear scope for wider research use and hold significant long term value;
- Share data from research activities in accordance with this Policy and the terms and conditions of applicable grants and contracts; and abide by the International Committee of Medical Journal Editors' (ICMJE) requirements that:
    - as of 1 July 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement
    - NIH states that clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.
    - In addition, the Unit's Investigators must take into consideration local / regional requirements and regulations regarding data sharing.

**4.1** Data sharing:

**4.1.1** Eligibility

- The data sharing will be only for the purposes of health and medical research and within the constraints of the consent under which the data were originally gathered.
- The Custodian of the Collection will not consider any proposals for data sharing that unblind, or potentially unblind, randomised comparisons in active / ongoing trials.
- It is expected that data requesters should be employees of a recognised academic institution, health service organisation, commercial research organisation or from the pharmaceutical industry. Also requesters have experience in medical research.
- Requesters must be able to demonstrate through their peer review publications in the area of interest, their ability to carry out the proposed use of the requested dataset from a Collection.
- The Requesters must not have a conflict of interest that may potentially influence their interpretation of any analyses. Requesters must declare all actual or potential conflicts of interest in relation to the requested dataset

or to previous research conducted by the Requesters. Requesters must also declare funding sources for the requested work for which the requested dataset will be used, and update the Unit about subsequent funding sources that are secured with support of the acquired data after the data are shared with them. All such conflicts of interest and funding sources must also be declared in all publications and presentations resulting from the shared dataset. The Unit reserves the right to refuse sharing its data in the face of potential adversarial conflicts of interest.

**4.1.2** Terms of Sharing

- Requester will be required to enter into a Data Sharing Agreement with the Unit, which meets the Unit's data sharing requirements.
- Data supplied from a Collection may be transferred only to Requester(s) named in the original application and as specified in the relevant Data Sharing Agreement. Data from the Collection may not be transferred to individuals outside the Requester's research group.
- Supplied data must only be used for the purpose described in the approved Proposal as further stipulated in the Data Sharing Agreement.
- All data provided to a Requester will be de-identified and identifying data will not be made available to Requesters.
- The Requester and individuals within his/her research group must not attempt to identify any individual from the data provided. Should the Requester or individuals within his/her research group believe that they inadvertently identified any individual, they must not record such identifiable data, or share the identification with any other person or attempt to contact the individual. Such identification must be promptly reported to the Unit.
- Data Recipients must agree not to link the de-identified data provided with any other dataset without the permission from the Custodian or Data Sharing Committee.

**4.1.3** Period of Data Unavailability

It is the Unit's policy that the full data package (comprising the full analysable data set, the full protocol, the full statistical analysis plan, and the analytic code) may be shared with eligible Requesters after a reasonable period (1 year) following publication of the primary results.

**4.1.4** Limits on Data Sharing

For some research, delays or limits on data sharing may be necessary and appropriate to:

- Safeguard research participants. In particular, for research involving samples or information pertaining to human subjects, data must be managed and shared in a way that is fully consistent with the terms of the consent under which samples and data were provided by the research participants;
- Allow appropriate opportunity to exploit the dataset for additional pre-specified hypotheses, gain intellectual property protection or to the further development of a technology for public benefit;
- Protect against clear conflicts of interest, where analyses may be requested to support commercial aims rather than those related to the broader public good; or meet other legal (including contractual), regulatory, or ethical obligations.

NB. For prospective studies, consent procedures should include provision for data sharing in a way that maximises 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 clearly set out. Current and potential future risks associated with this should be explained to research participants.

**4.1.5** Data Sharing: Processes

- In the first instance, potential Requesters are strongly encouraged to approach the relevant study investigators informally to discuss feasibility of data sharing. Study investigators can refer such requests to the Data Sharing Coordinator on datasharing@mrcuganda.org to be shared with the independent data sharing committee.
- If requested data is from a completed study, the Data sharing coordinator will share the data sharing agreement for completed studies to be filled by the requestor (Appendix A) this shall also be accessible online via the MRC data visibility platform (https://apps.mrcuganda.org/mrcdatavisibility). The data requestor will specify the variables needed from the data. The independent data sharing committee will receive, review and advise the Unit director to approval/reject a data sharing request. If rejected, the committee will

provide a reason for rejection. The requestor can reapply after resolving areas of concern.

- If the requested data is for an ongoing study or collaboration on a project about to begin the Data sharing committee will share a data sharing agreement template for collaborations to be filled by the requestor (appendix B). The study steering committee will advise the independent data sharing committee if the requested data can be shared or the request deferred to a future date. The requestor shall be informed accordingly.

#### **4.1.6** Data Sharing costs

A minimal data sharing costs shall be incurred as a cost-recovery for data sharing

Data-sharing costs that may require consideration:

- Staff time for data processing (anonymisation, cleaning, preparing data for sharing, etc.)
- Software-related training
- Software licence costs for the data sharing platform
- Technical services such as cloud storage, server maintenance, domain hosting charges, etc. that shall be used for the long term data storage

The UK Data Service data management costing tool and OpenAIRE identifying and assessing Research Data Management (RDM) costs guide may be helpful in recognizing the data sharing costs.

### 4.2 REFERENCES


- https://www.ukri.org/publications/mrc-data-sharing-policy/data-sharing-policy/
- NHMRC Statement on Data Sharing
- https://www.georgeinstitute.org/data-sharing-policy
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5615020/
- Wellcome Trust: Policy on Data Management and Sharing
- Groves, Abraham Haileamlak, Astrid James, Christine Laine, Larry Peiperl, Anja Pinborg, Peush Sahni, Sinan Wu. Sharing Clinical Trial Data: A Proposal from the International Committee of Medical Journal Editors.
- *The Lancet*. Volume 387, No. 10016, e9–e11, 23 January 2016. https://ardc.edu.au/resource/fair-data/


## 5 REVISION HISTORY

| Version number | Replaces | Reason/description of change |
|---|---|---|
| V2.0<br>(Sept 2021) | V1.0 | Edits to Data Sharing committee, FAIR data principles and new templates for data sharing agreements |

## 6 APPROVAL

| | Name | Signature | Date |
|---|---|---|---|
| **Title of Owner / Author** | | | |
| **Reviewers** | | | |
| **Approved by: Unit Director** | | | |

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