MRC/UVRI and LSHTM Uganda Research Unit

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Data and Biospecimen 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 users 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.

The Unit Biobank also stores biospecimens for the different research projects or collaborative projects, which have been approved by the UVRI Research Ethics Committee (or as appropriate per local regulations) and the Uganda National Council for Science and Technology. The purpose of collecting biospecimen and their associated data in accordance with high-quality standards is to produce and distribute good quality samples and related data for research.

Uganda Medical Informatics Centre (UMIC) is an infrastructural data centre project in Entebbe Uganda and part of the MRC/UVRI and LSHTM. The UMIC data centre facility enables the integration, curation and analyses of large scale population health resources, including those encompassing genomics, complex phenotypes and clinical data sets. The UMIC recognises, and is committed to, the benefits of making its Data readily available to the Research Community through early deposition in public databases.

For this reason, the Unit has formulated this policy and processes to allow appropriate and responsible sharing of the Unit's research data/biospecimens and access to genetic data for scientific research.

2 SCOPE

This Data and Biospecimen Sharing Policy (**Policy**) covers all studies conducted by the Unit globally regardless of the source of funding. This policy applies to data/biospecimen sharing requests/collaborations and genomics data access 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 (and elaborated below) and the applicable Uganda National Council for Science and Technology guidelines.

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 through 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

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 Unit Director. The PI can have delegated responsibility per this policy with the Unit Director providing oversight and ultimate responsibility. In the absence of the PI, the Unit Director will be the ultimate Custodian
Data and Biospecimen Sharing Committee	The Committee that oversees and monitors data/specimen access and sharing requests in respect of data/biospecimen 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/specimens from a Collection.

Collaborator	An individual or organization who shall work jointly on a project to collect/manage the data.
Access	Refers to offering access to biospecimens and associated data of collections, to approved applications from bona fide researchers that undertake research that is in the public good.

4 RESPONSIBILITIES

The Unit's Investigators will:

- Design research studies and manage research data/stored biospecimens with the expectation that data/ biospecimens will be shared;
- Have in place a data/biospecimens 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.

Data/Bio Specimen Requestor:

- Is responsible for submitting sample or data access requests and complying with the access procedures.
- Complete the Data/Biospecimen Access Request Form.
    - If they need biospecimen samples they also need to complete in the Biospecimen Access request form
    - If they need access to the genetics data they need to read the UMIC read_me document and also complete in the UMIC data access application and agreement form
- Confirm they have ethical approval for their project where applicable.

- Sign the DSA/MTA and must continue to comply with the DSA/MTA for the duration of their research project and be willing to undergo audits by the Unit's Research Governance Department/Designee.
- Cater for costs of data/biospecimen retrieval, dispatch, and or shipping.
- Submit research meta-data and make any data/results available to any subsequent researchers using the same collection.
- Acknowledge the relevant individuals and the MRC/UVRI and LSHTM Uganda Research Unit in all publications and provide copies of all publications to the Unit within 4 weeks of publication.

5 Key Principles for biospecimens

- Biospecimens can be readily available to bonafide researchers, interstate, and international researchers with experience in biomedical research.
- All exchanges and transfers (including importation and exportation) of materials for research purposes shall require MTA clearance by the local Research Ethics Committee of Record where applicable and the Uganda National Council for Science and Technology, except for exchange of human materials between organizations within the country where the MTA does not have to be cleared by these entities.
- The Unit shall negotiate an appropriate contract in the form of an MTA with the recipient/provider organization.
- Researchers are obliged to return results of their studies, data and the remaining samples after testing the biospecimens so that future researchers can benefit from their work.

5.1 Data sharing:

5.1.1 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 must 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.

5.1.2 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 or third parties without the prior written agreement of the Unit.
- Supplied data must only be used for the purpose described in the approved Proposal and 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.

5.1.3 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 (usually 1 year) following publication of the primary results.

5.1.4 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.

5.1.5 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 using the Data Sharing form (Appendix A).
- If requested data is from a completed study, the Data sharing coordinator will share the data sharing form for completed studies to be filled by the requestor (Appendix B) this shall also be accessible online via the Unit website and MRC data visibility platform (https://apps.mrcuganda.org/mrcdatavisibility). The data requestor will specify the variables needed from the data. The 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 PI/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.

5.1.6 Biospecimen sharing Procedures:

- A flowchart of the access procedure can be found in Appendix C.

  • Requests for biospecimen will be made using the Biospecimen Access Request Form (can also be found on the website) detailing the purpose, scope, and intended use of the requested samples (Appendix D).

  • This shall be shared with the Data Sharing Coordinator on datasharing@mrcuganda.org to be shared with the independent data sharing committee for approval before being shared with the Unit Director

5.1.7 Genetics data access

- There are two levels of approval
  - Data Sharing Committee (DSC) Approval
  - MRC/UVRI and LSHTM Approval
- To gain full approval for data usage, you should do the following
  - Fill the UMIC Data Access Application Form
  - Sign the UMIC Data Access Agreement
  - Sign the MRC/UVRI and LSHTM Data Sharing Agreement Form

5.1.8 Ownership

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

5.1.9 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.

5.2 REFERENCES

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