

**Infectious Diseases Institute  
DATA SHARING POLICY  
May 2008**

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**This policy addresses two aspects of Data Sharing**

- 1. Provision of IDI data to other researchers, institutions, and students.**
  - 2. Making additional data collected on IDI patients as participants in research studies and trials available to IDI**
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**1. PROVISION OF IDI DATA TO OTHER RESEARCHERS, INSTITUTIONS, AND STUDENTS.**

**Principles**

- IDI data are shared to allow new and extended use in high-quality, ethical research.
- IDI data may be shared when:
  - (i) The request is considered to have scientific merit and relevance.
  - (ii) The integrity of on-going research at IDI is maintained and the interests of data subjects and IDI researchers are balanced.
  - (iii) Use of data complies with other regulatory requirements and good research practice.
  - (iv) There is no disclosure of personally identifiable data.
  - (v) Recipients of data agree not to pass the data on to unauthorised parties
  - (vi) Recipients of data may not use the data in any way that could infringe the rights of the data subjects or otherwise affect them adversely.
  - (vii) The researcher agrees to comply with data sharing policy.

A condition of access to IDI data is that any additional data items collected as through a questionnaire, or extra measurements and laboratory tests will be made available to the IDI research and IT staff through the data management system. In addition, any errors or degradation of data must be notified to the IDI data managers. This will primarily be for purposes of maintaining proper clinical management of the IDI patients, as well as improving IDI data quality.

**Procedures:**

1. The recipient of the data will be required to complete a data request form, and specify a minimum dataset containing only the variables relevant to their specific purpose. The specific data required will be determined at the start of each study by completion of the data sharing agreement (See Appendix 1)
2. All requests for data sharing will be discussed in the monthly Clinic-Cohort meeting, and where appropriate, in the monthly Scientific Review Committee.
3. The source of the request and the nature of the data requested will be taken into consideration. The following matrix serves as a guide, and will be used in assessing each data request.

Requestor	Cohort Data	Clinic Data	Medical chart review	Collection of additional data	Sample Access
1. Staff or PhD and Masters students within IDI					
2. Research students within Makerere					
3. Other Ugandan Students					
4. Ugandan students currently resident outside Uganda					
5. Approved existing collaborators					
6. Outside Collaborators					

The Clinic-Cohort Committee may consider the following actions

- Approve the project for implementation
- Provisionally approve the project, returning it to the researcher for clarifications
- Re-submit the project, if the concept is desirable but a major revision of some part of the project is necessary for approval
- Reject the project application for a number of reasons, including but not limited to the following: 1) when it is assessed that the project is not sound or feasible in terms of research design; 2) when the project will require resources that are unavailable or incongruent to the significance of the project; 3) when implementation of the study will require data that are unavailable and unlikely to ever be collected

The group will also consider the level of resources that performance of the study will absorb, in particular, data management and statistics resource utilization at the time of the review and will prioritize the performance of projects accordingly.

Once the project has been approved, the group will instruct the preparation of suitable analysis datasets in the format requested by the investigator (e.g., STATA data format). The RDC will then check that all permissions are on file regarding data sharing and proceed to produce the data analysis files. These will be disseminated to the researchers or given to the IDI statistician to perform the required statistical analyses.

### **Access to Samples**

- Access to samples will be assessed using the same procedures, but because of limited availability, these requests will be subject to prioritisation by the Clinic-Cohort Committee and the IDI Scientific Review Committee.
- In addition, a Materials Access Agreement will be required for shipping outside IDI which is available from the MU-JHU lab.

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## **2. ENSURING DATA COLLECTED IN CLINICAL TRIALS OR OTHER RESEARCH STUDIES IS AVAILABLE TO IDI**

### **Rationale**

Patients participating in clinical trials often receive their routine monitoring and lab tests as part of the clinical trial. In addition, they may have other tests, such as viral load, drug resistance or tropism tests that are not routinely available.

Alternatively, additional information on adherence or other medical conditions may be collected as part of research studies.

In order to ensure continuity of care, it is essential that clinical, laboratory and treatment related data is made available and integrated with the patient's regular clinic record and in an electronic form during the trial or at completion.

## Procedures

- 1) The specific electronic data required by IDI will be determined at the start of each study. The SRC form will require sign off that Data sharing has been discussed and the data that will be provided to IDI during or at the end of the study.
- 2) Studies having blood samples tested in MUJHU will be required to use the lab requisition forms study codes and numbering according to the <IDI standard study coding and numbering system>

< STUDY CODE-STUDY NUMBER/IDI NUMBER >

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## REFERENCES

In compiling this document we considered:

- Lowrance W. Access to Collections of Data and Materials for Health Research: Medical Research Council / Wellcome Trust Commissioned Report. London: Wellcome Trust; March 2006.
- The MRC / UVRI Uganda Research Unit on AIDS, Medical Research Council (UK) Data Transfer Form; and,
- ALPHA Network Data Sharing and Authorship Form. Mwanza: developed October 2005.