

icddr,b Data Access Policy

icddr,b recognizes the public health, social and intellectual value of providing access to its knowledge data to increase the amount of their innovative analyses, and will share such data according to this policy.

1. Data from the icddr,b Data Repository (icddr,b Datasets) will be provided to interested researchers (Recipients) for purposes of secondary data analyses upon approval of a Data Licensing Application & Agreement (Application) ([to be] attached hereto as Annex A) by the icddr,b Data Repository Committee (DRC).
2. icddr,b Datasets are subject to any and all interests and limitations imposed by statutory requirement, icddr,b institutional policy, or written agreement with any third-party institution or individual (Interested Third Party). Requests for icddr,b Datasets that would negate or infringe any such interest will not be approved.
3. Biological, chemical and other material samples are not considered data for purposes of this policy and will not be made available under this policy.
4. Only those data that icddr,b's Internal Data Policy, donor and publisher requirements, and ethical considerations permit will be made publicly available in the icddr,b Data Repository.
5. Requests from interested researchers to conduct secondary data analysis of icddr,b Datasets will be considered by the DRC upon receipt of a completed Application and in discussion with the PI or her/his designated co-investigator, which must include a thorough description of the research project for which the data are requested. Recipients must also include a copy of their own institution's Institutional Review Board (IRB) approval of their study. In the event the Recipient is not affiliated with an institution that has an IRB satisfactory to the DRC, a full protocol must be approved by the icddr,b internal IRB process before the Application will be Approved.
6. icddr,b Datasets will only be provided with all personally identifiable information removed, and every reasonable effort will be made to keep the identification of study subjects in the strictest confidence. However, due to the wealth of individual level data available on study participants, the possibility of direct identification of a study subject cannot be completely eliminated. Therefore, only IRB approvals from an expedited or full review can be accepted. Waiver for exemption of IRB approval will only be accepted from icddr,b IRB.
7. As more fully set forth in the Application, use of icddr,b Datasets shall be strictly limited to use in and for the purpose of the described research project; may not be shared, sold, transferred, or otherwise released to another party without the written consent of the DRC; and must strictly comply with

subjects' informed consent and all applicable IRB requirements. Under no circumstances may a Recipient attempt to identify or contact study subjects.

8. The rights and interests of the respective icddr,b PI and Interested Third Parties shall take priority over the requests of Recipients and no grant of access to icddr,b Datasets shall be construed or allowed to infringe such priority rights and interests.
9. Considerations of the DRC will include but not be limited to:
 - a. Whether the request is appropriate and consistent with the mission of icddr,b;
 - b. Whether the proposed research is consistent with the subjects' informed consent;
 - c. Whether icddr,b researchers have been or will be involved in the development and execution of the proposed secondary analysis;
 - d. Whether the requested access would result in duplicative research and, if so, whether granting such access would be inappropriate under the circumstances; and
 - e. The capacity of the requesting party to correctly understand and/or interpret the requested data.
10. The DRC will set access fees on a periodic basis, which must be paid by the Recipient in a timely manner. Such fees will be waived for icddr,b Post-Doctoral Fellows and may be reduced or waived for students on a case-by-case basis.
11. In any abstract, manuscript, publication, dissemination, presentation or other public disclosure based on icddr,b Datasets, icddr,b, its PI, and the original donor must be properly acknowledged. Recipients publishing secondary analyses based on icddr,b Datasets must give each icddr,b Researcher who made an intellectually significant contribution to the dataset an option to be listed as an author, provided it would meet international standards for authorship in peer-reviewed journals and the policies of the publishers.
12. If the Recipient identifies an apparent error or inconsistency in any icddr,b Dataset received, Recipient must convey it to the DRC as soon as is reasonably possible.
13. Any proposed abstract, manuscript, publication or other formal public dissemination based on an icddr,b Dataset must be submitted to icddr,b for its review and comments at least 30 days prior to submission or presentation.

Recommended by the Senior Leadership Team (SLT) and Adopted by the Executive Director

30 April 2018

icddr,b Data Access Policy

Annex A: icddr,b Data Licensing Application and Agreement (DLAA)

Annex B: icddr,b Repository Standards & Procedures (attached)

icddr,b Data Repository Standards and Procedures

General

This document entails the responsibilities of icddr,b, its employees and those scientists visiting in an official capacity (such as a secondment or other long-term official relationship), collectively designated as icddr,b Researcher(s), regarding submission of data collected in icddr,b's research protocols, surveillance systems, surveys, clinical or laboratory records or statistics, training activities and any other data that (i) have intellectual value, and (ii) are generated through icddr,b activities, which together constitute **icddr,b Dataset**.

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Data Submission and Storage

1. Research Administration has undertaken an initiative to implement an online system to manage protocols and activities. The current planned project includes the following work flows: protocol, activity, proposal approvals; protocol addendum, continuation and extension approvals; protocol completion and abstract & manuscript approval. The development of this work is nearing completion. Once an effective online system is established, workflows for Protocol / Activity from submission to final archival will be completed through that electronic system, and the relevant PI or her/his designated staff shall directly upload data in the electronic system. Until such time, data should be submitted to the Repository Administrator located at Research Administration (RA) on an appropriate transfer

media.

2. The following steps will be followed to ensure 100% and timely compliance with the data archival policy by PIs as well as Heads of Units responsible for Routine (clinical, lab, DSS) data collection, and quality control:
 - a. For Research Protocols, PIs will be required to submit all data generated from the protocol along with adequate documentation (questionnaires, tools, data dictionary/code books, manuals, enumeration data and data monitoring or progress sheets if available/applicable, but not including constructed/calculated variables) at the time of submitting Protocol Completion reports. For qualitative data, this would include interview and discussion guides, observational notes (e.g., field notes, notes on interview/discussion situation), along with softcopies of transcribed data. The Protocol Completion report will be incomplete otherwise. Submitted materials must be certified by the Division Directors to be complete and correct. Protocol Completion reports are required to be submitted within 3 months of IRB approved Protocol completion. Failure to do so should trigger weekly reminders – for up to 12 weeks. After the 13th week of having missed the submission deadline for Protocol Completion reports and data, appropriate action will be taken based on policies determined by the SLT. Failure to submit Protocol Completion/data should also be reported at the SLT meetings. RA will analyse response rates of data received by time/division etc, and submit reports quarterly to the SLT. The report would also summarize pattern of use of the archived data (requests made, data provided, publication/thesis/reports completed).

For routine data, Heads of responsible units will be required to submit all routinely generated data along with adequate documentation/meta data (questionnaires, tools, data dictionary/code books). For such routine data collection platforms existing currently, "Activity" forms must be completed and approved, and data and documentation should be submitted within 6 months of revised icddr,b data policies coming into effect. For new platforms, pre-approval as an "Activity" is required and data and documentation should be submitted within 6 months of the platform being initiated. Updated data must be submitted every 6 months. Submitted materials must be certified by the Division Directors/Department Heads to be complete and correct. Failure to submit data and documentation should be reported at the SLT meetings for appropriate corrective action as per policies determined by the SLT.

All submitted data must be stripped of personal identifiers before submission.

- b. RA will verify 10% of all data files randomly selected for completeness and quality. A data set (and

documentation), once selected will be stripped of all Division/Department identifiers and independently sent to one PI and one data professional (from a previously established pool of such experts) will be asked to verify the data unbeknownst to each other. RA will reach a final determination on the quality and completeness of the submitted data and meta data, based on the feedback of the two experts. In order to ensure that this random checking has the desired impact on overall quality and completeness of submissions, icddr,b management will, from time to time, establish appropriate actions for PIs and Divisions / Departments submitting incomplete and/or poor quality data

- c. With the final authorization by RA, data shall be stored in the repository. Research / Routine Data and all allied Metadata will be stored in a searchable database and made available for secondary use following icddr,b Data Access Policy. Only RA will have full access of the data stored in the database.

Recommended by the Senior Leadership Team (SLT) and Adopted by the Executive Director

30 April 2018

Annex A: icddr,b Data Licensing Application and Agreement (DLAA)

Annex B: icddr,b Data Access Policy

Annex C: icddr,b Internal Data and Data Archival Policy