

International Centre for Diarrhoeal Disease Research, Bangladesh Data Licensing Application & Agreement (DLAA)

1. Purpose

The International Centre for Diarrhoeal Disease Research, Bangladesh (“icddr,b”) has supported collection of research, health and demographic surveillance and survey data since 1960. It is an objective of icddr,b to promote optimal use on an international scale of such a resource to add value to its initiatives and activities. icddr,b and its researchers have a responsibility to research and surveillance subjects, to the public in general, and to the scientific community in particular, to encourage as rapid scientific and public health progress as possible using these resources. In order to take full advantage of them and maximize their research value, it is important that data be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

icddr,b seeks to promote the development of valuable discoveries, innovations, inventions and policies beneficial to public health based upon use of icddr,b Data. Therefore, research performed pursuant to this Agreement shall be designed to achieve, in so far as circumstances and applicable rights permit, the following objectives:

- (i) continued research for public health purposes;
- (ii) application of new knowledge for improvements in public health; and
- (iii) making technologies and products available for distribution on reasonable terms in the public health sector and on preferential terms in low and middle income countries.

Towards this end, icddr,b and the Applicant/Recipient identified below (“the Parties”) hereby enter into this Data Licensing Application & Agreement (“Agreement”) as of the date specified on the final page hereof. Until approved and signed below by icddr,b’s Authorized Representative, this document constitutes only an application for access to icddr,b data. icddr,b reserves the right at its discretion to deny this application.

2. Applicant/Recipient

The following party requests access to icddr,b Data at its sole risk, and at no expense to icddr,b and agrees to pay fees to support costs related to generate specific data requested from the database :

Applicant Institution (“Recipient”): _____

Authorized Representative: _____

Title: _____

Surface Mail Address: _____

Email Address: _____

Telephone _____

Fax number _____

**Recipient's
Principal Investigator ("PI"):**

Title:

Surface Mail Address:

Email Address:

Telephone

Fax number

3. Data Requested

icddr,b agrees to transfer to Recipient, for limited, non-exclusive use by PI to conduct the Research Project described in Paragraph 4, the following icddr,b Data:

4. Research Project

The icddr,b Data identified in Paragraph 3 will be used by the Applicant PI solely for purpose of the following proposed research ("Research Project") (provide project title):

Pursuant to the icddr,b Data Access Policy, incorporated herein by reference and attached as **Annex A**, Recipient must attach as **Annex B** a copy of its own Institutional Review Board (IRB)-approved protocol for the proposed Research Project. In the event Recipient contends that IRB review of the proposed Research Project is not warranted, the applicant must apply to the Chair of icddr,b's IRB with written justification of IRB non-applicability and a full description of the proposed Research Project. Only icddr,b's IRB has the right to waive requirement of IRB approval of the proposed project.

If the icddr,b Data Repository Committee (DRC) decides an IRB review and approval is necessary, or Recipient's IRB is not satisfactory to the DRC, a full protocol must be submitted to and approved through icddr,b's IRB process before this Application will be approved identifying a PI who is a staff member of icddr,b.

Recipient agrees that the icddr,b Data will not be used in any analysis that is not disclosed and approved as part of the Research Project. Recipient will submit a new Data Licensing Application and Agreement for each research project for which icddr,b Data are requested, including when the already accessed Data is used alone or in combination with newly requested icddr,b Data for analysis to address an objective that is different from the data acquired for the original purpose(s). If any non-compliance is identified, icddr,b will inform the journal and will request to stop publication.

5. icddr,b Researchers

icddr,b investigators have made a substantial contribution in collecting and recording these data. Additionally, they have the best understanding and interpretation of data, which is essential for their prudent use. Although icddr,b DRC and the PI or her/his designated co-

investigator originating the primary data are responsible to review and recommend data sharing and the Executive Director is the approval authority, involvement of the PI of the primary data collection or her/his designated co-investigator would be necessary to provide needed clarification to the requesting researcher. icddr,b encourages appropriate collaborative relationships between outside investigators and its investigators.

Does the Research Project involve icddr,b investigator(s) as co-investigator(s) (check one)?

YES _____

NO _____

If YES, their names are:

The work they will perform is described briefly below (if more space is needed, please attach as **Annex C**):

If no, provide justification:

6. icddr,b Data

For purposes of this Agreement, "icddr,b Data" refers to research, surveillance, survey, routine clinical and/or laboratory data, with certain deletions and recoding at icddr,b's discretion, and associated records collected and recorded from icddr,b research, surveillance, survey and clinical subjects that are released to requesting institutions and investigators for specific purposes and with certain restrictions and conditions as contained herein.

Notwithstanding this definition of "icddr,b Data" or the terms and conditions of this Agreement, Recipient's obligations under this Agreement shall not extend to any information:

- (i) that can be demonstrated to have been publicly known at the time of disclosure; or
- (ii) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
- (iii) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
- (iv) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon the data provided under this Agreement; or
- (v) that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure and promptly inform icddr,b.

7. Non-transferability & Confidentiality

This Agreement is not transferable and the icddr,b Data is confidential. Recipient agrees that substantive changes made to the Research Project and/or appointment by Recipient of another principal investigator to complete it requires written approval by icddr,b or execution of a new Agreement in which the changes and/or new principal investigator are designated. Recipient agrees to retain strict control over icddr,b Data, to treat it as confidential with at least as much care as it would treat its own confidential information, but in no case less than a reasonable amount of care, and agrees not to transfer, share, sell or make icddr,b Data otherwise available to any other entity or individual without written consent from icddr,b. Upon expiry of the agreement, the recipient must destroy or erase the data set taken from icddr,b.

8. Non-Identification

Data provided by icddr,b under this Agreement will be stripped of all personal identifiers to the maximum extent possible, but the confined nature of some geographic areas from which the subjects were drawn, and the wealth of data available on them in publicly available records, could in certain instances make the individual identification of some subjects possible. To protect the confidentiality and privacy of these participants and their families, Recipient agrees that icddr,b Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom icddr,b Data were obtained. Any attempt to do so will be considered a material breach of this Agreement, which may subject Recipient to legal action from icddr,b or surveillance and research participants, their families, or relevant government entities.

9. Recipient's Compliance with IRB Requirements

Recipient agrees to comply fully with all conditions imposed by Recipient's and/or icddr,b's IRB and with the subjects' informed consent, as applicable. It is intended that the Recipient's agreements herein shall inure to the benefit of the research subjects, as well as to the Parties. Recipient agrees to report promptly to icddr,b any proposed change in the research project and any unanticipated problems involving risks to subjects or others.

10. Publication

Prompt publication of the results of the Research Project is encouraged. Recipient agrees to provide icddr,b a copy of any abstract ten (10) days in advance of submission for publication and any manuscript or other formal public dissemination thirty (30) days in advance of submission for publication, in order to permit review and comment and to ensure compliance with the confidentiality requirements of this Agreement and the limitations it imposes on the use of the icddr,b Data provided.

11. Authorship

Whether or not the applicant's Research Project involves a collaboration with icddr,b co-investigators, the Recipient is encouraged to include icddr,b PI/co-investigators as co-authors, as appropriate, on any publication, as described in Data Access Policy.

12. Acknowledgments

Recipient agrees to acknowledge the contribution of icddr,b and the original donor in any and all oral and written presentations, disclosures, and publications resulting from Recipient's analyses of icddr,b Data as follows:

“This manuscript is based on data collected and shared by the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) from an original study it conducted with support from [donor name provided].”

In addition, the manuscript or other documents produced will be reviewed by the icddr,b co-investigators (if any) or other icddr,b personnel, pursuant to Paragraph 10, for scientific content and consistency of data interpretation with previous icddr,b publications and the Recipient will use the applicable acknowledgment below.

If Recipient agrees to incorporate significant comments from the review, Recipient will use the following acknowledgment:

"This manuscript has been reviewed by icddr,b for scientific content and consistency of data interpretation with previous icddr,b publications and significant comments have been incorporated prior to submission for publication."

If Recipient does not agree to incorporate significant comments from the review, Recipient will use the following acknowledgment:

"This manuscript was not prepared in collaboration with investigators of icddr,b and does not necessarily reflect the opinions or views of icddr,b."

13. Non-Endorsement, Indemnification

Recipient agrees not to claim, infer, or imply icddr,b endorsement of the Research Project, the entity or personnel conducting the Research Project or any resulting commercial product(s), except as described in Paragraph 12. To the extent permitted by law, Recipient agrees to hold icddr,b, and all other investigator(s) who generated icddr,b Data harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of icddr,b Data.

14. Accuracy of Data & Obligation to Notify

If the Recipient identifies an apparent error or inconsistency in any icddr,b Data received, Recipient shall convey it to icddr,b as soon as reasonably possible.

15. Amendments

Amendments to this Agreement must be made in writing and be signed by authorized representatives of the Parties.

16. Termination

icddr,b may terminate this Agreement and any other such agreement with Recipient if Recipient is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice by icddr,b's authorized representative of such default. icddr,b reserves the right to terminate this Agreement with immediate effect if any problems arise that in its opinion present an unacceptable risk to subjects or others, or icddr,b or the sponsor of the primary study. Upon termination of this Agreement, Recipient agrees to destroy all copies of icddr,b Data in Recipient's possession as soon as reasonably possible.

17. Disqualification, Enforcement

Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional icddr,b Data. icddr,b shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening

to violate the confidentiality requirements or use limitations of this Agreement, or both. Proceedings may be initiated against the violating party, or legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this Agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this Agreement may subject Recipient to legal action on the part of surveillance and research participants, their families, or relevant government entities.

18. Accurate Representations

Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

19. Prior Agreements

Execution and continued validity of this Agreement is contingent upon Recipient's compliance with all terms and conditions of any and all other of Recipient's agreements with icddr,b.

This Agreement is entered into as of the last date indicated below by and between:

**RECIPIENT's
Authorized Representative:**

**RECIPIENT's
Principal Investigator:**

Name:
Title:

Date: _____

Name:
Title:

Date: _____

<p style="text-align: center;"><u>APPLICATION HAS BEEN:</u></p> <p>_____ APPROVED _____ DENIED ON: _____ (DATE)</p> <p>CERTIFIED BY AUTHORIZED REPRESENTATIVE OF icddr,b DATA REPOSITORY COMMITTEE:</p> <p>_____ Chair, Data Repository Committee</p>

**icddr,b's
Authorized Representative:**

Prof. John David Clemens
Executive Director

Date: _____

Annexes

- Annex A: icddr,b Data Access Policy
- Annex B: IRB-Approved Protocol or approval of IRB non-applicability (as mentioned under Clause 4) and Full Project Description
- Annex C: Description of icddr,b Researcher Involvement (if applicable)