

The Office of Cyber Infrastructure and Computational Biology,
National Institute of Allergy and Infectious Diseases

TB PORTALS PROGRAM DATA USE AGREEMENT

INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID) Office of Cyber Infrastructure and Computational Biology (OCICB), established the TB Portals Program as a multi-national collaboration for tuberculosis (TB) data sharing and analysis to advance TB research. A consortium of clinicians and scientists from countries with a heavy burden of TB, especially drug-resistant TB, work together with data scientists and IT professionals to collect multi-domain TB data and make it available to the clinical and research communities. These data are consolidated within the TB Portals, a web-based, open-access repository of socioeconomic, geographic, clinical, laboratory, radiological, and genomic data from TB patient cases with linked physical samples. In addition to this large metadatabase, the TB Portals also contain advanced analytical tools built by the Program to perform both domain-specific and meta-domain analyses of TB Portals data.

The TB Portals dataset is very unique and valuable. Clinical, imaging, genomic and other metadata are integrated in patient case records, which originate from countries around the world. Information from many of these patients are only available through the TB Portals Program. Additionally, the majority of cases in the TB Portals is from drug-resistant TB. Drug-resistant TB cases are a small, but dangerous, fraction of overall global TB burden, making them important to study, but often difficult to obtain to do so.

In line with overall Program aims, the TB Portals Program encourages collaborations that utilize its rich dataset for the purpose of secondary research use. To this end, the Program has established policies and processes designed to make its data available to the largest possible number of qualified investigators in a timely manner.

Data deposited in the TB Portals by the Submitters (defined below) have been stripped of all individually identifying information and have been assigned random, unique codes. However, the potential for deducing the identity of an individual from data stripped of identifiers is constantly evolving, due to the large number of individual data points and the advancement of computational tools. Therefore, to protect and promote the confidentiality and privacy of the individuals whose data have been deposited into the TB Portals, the Program requires all requesters of such data to sign and agree to the terms of this Data Use Agreement (DUA) as a



condition of access. A requester who is granted access to TB Portals data is expected to adhere to the specifications of this DUA, as executed in its final form. Failure to do so could result in denial of further access to TB Portals data.

Submitters have made an important contribution to advancing TB research for public health impact by submitting data to the TB Portals. The Program encourages investigators who request and receive access to the data in the TB Portals to adhere to appropriate and reasonable conditions for data use, collaborative relationships with the Program, and to ensure proper acknowledgement of the Submitters' and Program's contribution.

*The following DUA was developed using language and conditions as described in the **NICHD Data and Specimen Hub (DASH) Data Use Agreement, Version 10/30/2015:***
<https://dash.nichd.nih.gov/Resource/DataUseAgreement>.

TB PORTALS PROGRAM DATA USE AGREEMENT

This Data Use Agreement (the "DUA") is by and between
 the TB Portals Program, Office of Cyber Infrastructure and Computational Biology ("OCICB"),
 National Institute of Allergy and Infectious Diseases ("NIAID"),

DocuSigned by:

Alex Rosenthal

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(Alex Rosenthal, Chief Technology Officer, OCICB),

and

Zain Ali

, UET Lahore

(The "Recipient" and "Recipient Institution"),

and is effective as of the date of the last signature affixed hereto (the 10/8/2024).

I. DEFINITIONS

The following definitions apply for the purposes of this DUA:

“Authorizing Representative” is an individual that has the authority to sign this DUA on behalf of a company, organization, institution, or government. The Authorizing Representative may be the same person as the Recipient.

“Collaborators” are individuals collaborating with the Recipient, requiring access to the Data, and who are employed by a different institution than the Recipient.

“Data” refers to data and information collected and recorded from participants in research studies that are available through the TB Portals Program. For the purposes of this DUA, any associated study documentation provided along with the Data are included in this definition of Data. This Data is subject to release to the Recipient upon execution of a TB Portals Program DUA, approval by the TB Portals Program Lead, and, if applicable, by study-specific entities.

“Data Request Form” is the online form completed by the requester during the Data request process in the TB Portals.

“TB Portals Administrator” is the individual who interfaces with TB Portals users and manages Data submissions and requests.

“Recipient” is a lead individual who receives access to the Data on behalf of the Recipient Institution.

“Recipient Institution” is an institution, e.g., a non-profit or for-profit organization or corporation, which is the employer of a Recipient.

“Research Plan” is a description of the proposed research that serves as the basis for the Data access request. The Research Plan must include the title of the Research Project, description of the research need (study aims/goals, hypothesis that will be tested, methodology to be used, and the expected outcomes), and, if required by the Program, a design and analysis plan.

“Study” is the research study that collected the Data described in this DUA.

“Submitter” is an investigator who has submitted Data to the TB Portals.

Below is a list of general responsibilities based on the listed roles. Specific responsibilities pertaining to the terms and conditions of the DUA are incorporated directly into the DUA.

Roles	Responsibilities
Collaborators	<ul style="list-style-type: none"> • Execute separate DUA(s) with the TB Portals Program before receiving access to the Data that is the subject of the DUA based on which Data has been granted to the Recipient
TB Portals Program Administrator	<ul style="list-style-type: none"> • Communicates with the Recipient regarding any applicable terms and conditions pertinent to the DUA
Recipient	<ul style="list-style-type: none"> • Acknowledge and agree to abide by the terms of the executed DUA • Maintain compliance with the human subjects protection requirements, if applicable • Contribute to the analytic effort and public disclosure of study results
Recipient Institution	<ul style="list-style-type: none"> • Execute the TB Portals Program DUA • Acknowledge and agree to abide by the terms of the executed DUA

II. TERMS AND CONDITIONS

The Recipient requests approval to access Data listed in Appendix A from the TB Portals for purposes of the Research Plan, which is specified in the TB Portals online Data Request Form and incorporated herein by reference. The Recipient agrees to the following terms:

1. Non-Transferability of Agreement

This DUA is not transferable. There are no third party beneficiaries to this DUA. Any other individual, including any Collaborator that wishes to receive Data from the TB Portals is required to execute a separate DUA.

The following situations are examples of when the execution and approval of a new DUA is required:

- a. Any substantive change to the scope of the Research Plan
- b. The appointment of another Recipient to complete the Research Plan
- c. Change to the Recipient Institution. *Note, if the Recipient wishes to retain access to the Data, but has changed the institution under which this DUA was executed, a new DUA in which the new institution acknowledges and agrees to the provisions of the DUA is necessary. The Recipient agrees to notify the TB Portals Administrator about a change of institution within 30 days of starting at the new institution.

2. Approved Parties for Access to Data

The TB Portals Program authorizes the Recipient to access the Data. The Recipient agrees to the terms of this DUA.

3. Non-Distribution of Data

The Recipient agrees to retain control over the Data, and further agrees not to sell the Data, in any form, to any entity or individual or to otherwise distribute the Data to anyone. The Recipient shall not transfer any Data obtained or accessed under this DUA to individuals or organizations not specified in this DUA, except as required by law.

4. Research Use of the Data

Data obtained from the TB Portals Program listed in Appendix A will be used by the Recipient for studies and analysis specifically indicated and described in the Research Plan. The Recipient agrees that Data will not be used in any research that is not approved by the TB Portals Program as part of the Research Plan.

The Recipient will submit a separate and completed DUA for each Research Plan for which Data are requested.

5. Data Access for Research

Data are eligible for access by qualified investigators pursuant to the terms set forth in this DUA. The Recipient acknowledges that other investigators also have access to the same Data in the TB Portals, and that downloading and utilization of the same Data that the Recipient received from the TB Portals as well as the duplication of research from such Data are distinct possibilities.

6. Data Disclaimers

The Recipient agrees that although all reasonable efforts have been taken to ensure the accuracy and reliability of the Data, the TB Portals Program does not and cannot warrant the results that may be obtained by using any Data included therein. The TB Portals Program disclaims all warranties as to the accuracy of the Data in the TB Portals, or the performance or fitness of the Data for any particular purpose.

It is the specific intent of the TB Portals Program and the Recipient that nothing contained in this DUA gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose Data are used or disclosed pursuant to this DUA.

The Recipient understands and acknowledges that any request for access to the Data is undertaken at their sole risk and with no expense applied to any study or to the TB Portals Program.

7. Prohibition on Identification of Subjects

The Recipient shall not use Data to establish (or attempt to establish) the individual identities of any of the individuals from whom Data were obtained.

In the event the Recipient discovers, or is able to deduce, the identity of a specific individual, the Recipient shall immediately notify the TB Portals Administrator and suspend the use of the Data until further approval can be obtained. The Recipient shall not reveal the individual's identifying information, or any associated information (such as clinically significant information in the Data), to any person or attempt to contact the individual.

If, upon the use of the Data, the Recipient discovers any identifying information or any associated information (such as clinically significant information), the Recipient shall immediately notify the TB Portals Administrator.

8. Non-Endorsement and Liability

The Recipient agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Health and Human Services (HHS), the National Institute of Health (NIH), the NIAID, the OCICB, or the TB Portals Program, of the Research Plan, the entity or personnel conducting the Research Plan, or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

9. Compliance with the Recipient's Institutional Requirements

The Recipient acknowledges that access to the Data, if provided, is for research that is approved by the Recipient's Institution, which must be operating under an Office of Human Research Protections(OHRP)-approved Assurance, which may require Institutional Review Board (IRB) or equivalent institutional approval, if applicable. Furthermore, the Recipient agrees to comply with all applicable rules for the protection of human subjects, which may include Department of Health and Human Services (HHS) regulations at 45 C.F.R. Part 46, and other Federal and State laws for the use of this Data as well as local policy. The Recipient agrees to report any proposed change in the Research Plan promptly to the TB Portals Program. This DUA is made in addition to, and does not supersede, any of the Recipient Institution's policies or any applicable local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

10. Data Disclosure/Breach

The Recipient shall notify the TB Portals Administrator immediately upon the receipt of any legal, investigatory, or other demand for disclosure of Data. The Recipient shall notify the TB Portals Administrator promptly upon discovering any breach, or suspected breach, of any unauthorized disclosure of Data. Such prompt notification of a breach or suspected breach is not necessarily, but may be, grounds for DUA termination. The TB Portals Program may also seek injunctive relief against the Recipient to prevent any

disclosure of Data by the Recipient to anyone other than the TB Portals Program.

11. Intellectual Property

Data in the TB Portals are made available to the research community for their use to further the research and development of ideas that will benefit and improve public health. The TB Portals Program encourages the development of new diagnostics, therapeutics, or other interventions building on basic discoveries enabled through Data obtained from the TB Portals. Recipients are free to pursue patent protection on any inventions or discoveries developed through their analysis and use of TB Portals Data.

12. Security Requirements

The Recipient shall follow the security requirements listed below:

a. Maintenance of, and access to, Data

- i. The Recipient shall retain the original version of the Data and may make no copy or extraction of the Data available to anyone.
- ii. The Recipient shall keep the Data secure and confidential at all times and adhere to the Recipient Institution's information security best practices in all aspects of data management.

b. Retention of Data: Upon research termination or the termination of this DUA, the Recipient shall destroy all copies of the Data, except as required by publication practices or law to retain them.

13. Format of Data

Data under this DUA may take many formats, depending upon the available technology.

14. Return of New Datasets

The Recipient agrees to submit to the TB Portals Program any new datasets generated from the Data by either the date of acceptance of publication of the main/primary findings or one year after the analysis of the Data for a particular Research Plan is completed, whichever is the first to occur.

15. Acknowledgments and Optional Review

The Recipient agrees to acknowledge the TB Portals Consortium and the TB Portals Program itself in all resulting oral or written presentations, disclosures, or publications of the analyses, whether or not the Recipient is directly collaborating with the Submitter(s) or TB Portals Program. The TB Portals Consortium (<https://tbportals.niaid.nih.gov/Partners>) represents the larger network of Submitters and associated individuals involved in TB Portals data collection. Any manuscript resulting from the Data should include an acknowledgement, as specified by the TB Portals Program, which

can be obtained from the TB Portals website
(<https://tbportals.niaid.nih.gov/DataSharing>).

It is recommended that the Recipient share any abstracts, manuscripts, or presentations resulting from the Data with the TB Portals Program prior to submission or public presentation. The TB Portals Program highly encourages this, so that they may review and provide feedback on study design and interpretation of the results based on the Data used.

If the Research Plan involves collaboration with a Submitter or TB Portals Program staff, then the Recipient will acknowledge the Submitter or TB Portals Program staff as co-authors, as appropriate, on any publication. In addition, the Recipient agrees to include a reference to the Data analyzed and to cite the TB Portals in abstracts as space allows.

16. Permission to Post Information Publicly

The Recipient agrees to permit the TB Portals Program to post the Recipient's research use of the TB Portals along with the Recipient's name and the name of the Research Institution on the TB Portals website
(<https://tbportals.niaid.nih.gov>).

17. Annual Report

As a means to determine the effectiveness of the TB Portals, the Recipient will submit to the TB Portals Program an Annual Report with the following:

- a. Summary of research accomplishments and key discoveries, including a list of oral or written presentations, disclosures, abstracts, or publications resulting from the use of the Data
- b. Publication number (or a copy) of any published patent application for newly discovered or developed technologies

18. Data Use Reporting

When requested by the TB Portals, the Recipient agrees to respond to requests for information on the effectiveness of the TB Portals Data, workflows, and procedures (e.g., ease of access and use, utility of Data, policy compliance, and suggestions for improving data access, or the program).

19. Privacy Act Notification

The Recipient agrees that information collected from the Recipient, such as name, contact, funding, and data use information may be used in part, or in whole, for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. The authority for the collection of the information requested from the Recipient comes from the authorities regarding the establishment of the

National Institutes of Health (NIH), its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44U.S.C. 3101), and Sections 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 (<http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm>) covering “Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service (PHS),HHS/PHS/NIH/OD.”

The primary uses of this information are to document, track, monitor, and evaluate the use of TB Portals Data, as well as to notify interested parties of updates, corrections, or other changes to the Data.

20. Penalties for Violation of the DUA

The Recipient agrees that in the event that the TB Portals Program determines, or has a reasonable belief, that the Recipient has violated any terms of this DUA, the TB Portals Program will provide the Recipient with a 30 day notice to remedy the violation. If the Recipient does not rectify the violation, the TB Portals Program, at its sole discretion, will terminate the DUA and close the Recipient’s TB Portals account. Accounts that have been closed due to a violation of this DUA may be reactivated upon the submission of evidence of remediation that is acceptable to the TB Portals Program, a revised online data request, and a new DUA.

If the Recipient commits a material breach of this DUA, the TB Portals Program may, in its sole discretion, terminate this DUA with 10 days written notice and require that the Recipient destroy the Data as instructed by TB Portals Program. The following situations are examples of material breaches:

- a. Unauthorized distribution of Data (see Clause 3)
- b. Identification of subjects in the Data obtained from the TB Portals (see Clause 7)
- c. Unauthorized Data disclosure (see Clause 10)
- d. Retention of Data after the DUA expiration date (see Clause 12.b.)

The Recipient understands that as a result of this determination, or reasonable belief that a material breach of this DUA has occurred, the TB Portals Program may also refuse to release new data to the Recipient.

21. Termination of the DUA

Either the TB Portals Program or the Recipient may terminate this DUA without cause by providing 30 days written notice to the other party. This

DUA may also be terminated by mutual written agreement between the TB Portals Program and the Recipient.

In addition to the specific circumstances whereby the TB Portals Program may terminate this DUA (as indicated under various terms and conditions of this DUA), the TB Portals Program reserves the right to terminate the DUA if a Submitter withdraws the Data from the TB Portals – either permanently or to submit a redacted or revised dataset. In both cases, the TB Portals Program will terminate the DUA and instruct the Recipient to destroy the Data. If and when a redacted or revised dataset is deposited by a Submitter in the TB Portals, the Recipient may choose to execute a new DUA to obtain this new dataset.

22. Term of the DUA

This DUA will remain in effect for a period of three years from the DUA Effective Date and will automatically expire at the end of this period unless terminated earlier or renewed. The Recipient may request that the DUA be renewed three months prior to the expiration date by submitting an application to the TB Portals Administrator for renewal of the DUA.

23. Amendments

Amendments to this DUA must be made in writing and signed by the Recipient Institution and the TB Portals Program. Any amendment must be submitted and approved; the DUA becomes effective only following the date of approval.

III.PROCESSING OF THIS DATA USE AGREEMENT

The Recipient certifies, by his or her signature, to abide by all terms included in this DUA.

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

See the next page for Signatures.



IV. FOR THE OCICB:

<p>DocuSigned by:</p> <p><i>Alex Rosenthal</i></p> <p>5AB5283A3F9B410...</p>	<p>10/8/2024</p>
<p>Signature of the Division Director or Designee</p>	<p>Date</p>
<p>Alex Rosenthal</p> <p>Chief Technology Officer, OCICB/NIAID</p>	

V. FOR THE RECIPIENT INSTITUTION:

<p>Signed by:</p> <p><i>Umar Qasim</i></p> <p>D05114ED2D5343F...</p>	<p>10/8/2024</p>
<p>Signature of the Authorizing Representative</p>	<p>Date</p>
<p>Name of the Authorizing Representative: <u>Umar Qasim</u></p>	
<p>Job Title/Position of the Authorizing Representative: <u>Associate Professor</u></p>	

The Recipient acknowledges the terms of this DUA and agrees to abide by its terms.

<p>Signed by:</p> <p><i>Zain Ali</i></p> <p>A00BF49FA1C145C...</p>	<p>10/7/2024</p>
<p>Signature of the Recipient</p>	<p>Date</p>
<p>Name of the Recipient: <u>Zain Ali</u></p>	
<p>Job Title/Position of the Recipient: <u>Student</u></p>	



APPENDIX A – LIST OF DATA FILES TO BE OBTAINED FROM THE TB PORTALS PROGRAM

Imaging