

Details of the sample and data sharing process

1. Sample and Data – Definitions

Samples to be shared include any biological specimen obtained directly, or generated from material obtained directly, from participants of the PredictTB study. These specimens include sputum, blood, urine, saliva as well as nucleic acids, proteins, biochemicals, other biological materials human or bacterial, or bacterial isolates obtained from any of these body fluids.

Data to be shared include de-identified information collected from participants of the PredictTB study in the clinical research forms, metadata, imaging data (DICOM format) and data from end-assays. Sharing of end assay data may be delayed until publications have been submitted.

All shared data and samples will be de-identified and presented using the assigned participant identifier (PID).

2. Eligibility criteria for requesting parties and purpose of shared samples and data

A sample request can only be submitted by the principal investigator of the project for which the samples are being requested. A data request can only be submitted by an experienced data manager and analyst or if the requesting team have an experienced data manager and analyst.

Samples and data may only be shared in the context of non-commercial studies which are relevant to the advancement of TB or related research and for which any forthcoming products will adhere to the [Bill & Melinda Gates Global and Open Access Policy](#). Seeking direct financial benefits for the samples and/or data that have been shared is not permitted.

The shared samples and the shared data may only be used towards completion of primary and secondary project aims as described in the sample and/or data sharing request. Any additional/new involvements needing the use of these samples and/or this data will require a new sample and/or data sharing request to allow for expansion of the Material and Data Transfer Agreement (MDTA) extending the use of the samples and/or the data to other projects.

3. Submission of a request for sample or data sharing

Requests for sample or data sharing can be submitted by filling out the “PredictTB sample or data sharing request form” (available on the public project website www.predict-tb.com) and submitting it via email to the Secretary of the Sample Management Committee (predictsamples@ling-management.com).



Please note: The requesting party must state that they have the funds available for conducting the proposed work when submitting a sample and/or data sharing request.

We encourage the requesting research team to communicate with the PredictTB study team prior to submitting a formal request to better understand the nature of the provided samples/data. Any communication should be directed to the Secretary of the Sample Management Committee (predictsamples@ling-management.com), who will then put the requestor in direct contact with the appropriate study team member.

4. Decision on the request for sample or data sharing

The Sample Management Committee will require up to 6 months to return a decision to all requests, unless some reasonable urgency is implied.

5. Material and Data Transfer Agreement

In the case of sample sharing, an MDTA will be signed between each site that sends samples and the requesting party. After the MDTA is completed and signed, samples will be shipped within 90 calendar days providing all regulatory approvals are in place for shipping of the samples. In the case of data sharing, an MDTA will be signed between each site that sends data and the requesting party. After the MDTA is completed and signed, the data will be provided through locked or public databases.

6. Use of samples and/or data for development of any innovative technology or intellectual property

If samples and/or data are used for development of any innovative technology or intellectual property, whether patentable or not, the requesting PI shall promptly disclose this development to the Secretary of the Sample Management Committee.

7. Unused samples

The Secretary of the Sample Management Committee should be informed of any unused samples that are left over or never used and the recipient must agree to take the Secretary's advice to either return or destroy the samples.



GENERAL SAMPLE SHARING AGREEMENT FAQs

1. How will samples be transferred?

Both raw and processed samples may be transferred. As described in the MDTA, samples will be transported per the regulatory and shipping guidelines of the countries of origin and destination. Any infectious material packed in a containment laboratory (such as a biological safety level 3 laboratory) will be shipped in a designated containment carrier specially designed to prevent exposure to the infectious agent. The requestor must agree to receive infectious samples packed as above, per country-specific requirements and by a service that permits tracking. Further, the requestor must also assume responsibility for unpacking the samples in an appropriate containment facility. Anything packed in a containment laboratory must only be opened in a containment laboratory of similar nature. The requestor will pay for shipping costs.

2. What details will be provided about the samples and how they were generated?

All shared samples will be deidentified. No personally identifiable information will be shared at any time. All details pertaining to collection of the samples and any techniques or methodologies used for processing of the shared sample will be provided upon request. Standard clinical and scientific terms will be used to define the samples and associated data. Information will also be provided on the infectious nature of the sample.

3. Who will the samples be shared with?

Samples will be shared with the accountable individual who, for this sample sharing agreement, will be the principal investigator of the project for which the samples are being requested.

Samples may only be used for the project for which requested. Use of the samples for any additional project(s) will require a new request for sample sharing to be initiated.

The requesting investigator may not share the samples with a third investigator. Any additional investigator requiring access to the same samples (such as the requesting investigator's collaborator) must also submit an independent sample sharing request.

4. For what period will the MDTA be valid?

The agreement shall enter into force on the date of the last signature to it and will be effective for the period defined in the terms of the specific MDTA.

5. How is the PredictTB Trial consortium to be acknowledged?

Any scientific publications resulting from the use of shared samples must allow authorship for select PredictTB principal investigators and cite the primary protocol manuscript (<https://gatesopenresearch.org/articles/1-9/v1>).

6. What are criteria for delaying or denying a submitted request?

The Secretary or the Sample Management Committee reserves the right to request more information if any of the following are found to be true:

- i. Lack of a clearly defined project or project aims for which samples are being requested,
- ii. Lack of clarity on how the requested samples will be used towards accomplishment of the project goals,
- iii. Requesting samples for multiple diverse projects in one sample request.

The requesting party will be asked to clarify the ambiguity. If a subsequent submission still does not adequately elucidate the project purpose and/or aims the request will be rejected.

7. In which cases can an executed sample sharing agreement be voided?

The Sample Management Committee reserves the right to annul any sample sharing agreement if the requesting party is found engaging in any of the following activities:

- a. Obtaining or dissipating personally identifiable information of the participants on this protocol.
- b. Disseminating samples to third parties not included on the sample sharing agreement.
- c. Non-compliance with ethical and regulatory practices for non-clinical or clinical research.
- d. Seeking financial benefits for the samples that have been shared.
- e. Manipulation of the provided samples outside of the MDTA agreement.

Any sharing of samples and data will occur with a commitment to protect the rights and confidentiality of the human subjects involved in this research.

The policy that directs the sample and data sharing protocol is described in the PredictTB grant and the [BMGF sharing policy](#).