

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

**UNDP / World Bank / WHO
Special Programme for Research and Training
in Tropical Diseases (TDR)**

For administrative use

MATERIAL REQUEST FORM
WHO/TDR TUBERCULOSIS STRAIN BANK

Instructions: Please provide all requested information. Missing information will delay the approval process or may result in request denial.

Return the completed original form to:

**Martine Guillerm
WHO/TDR
20 Appia Avenue
Geneve-27, Switzerland 1211**

To expedite review, send a scanned copy (pdf) of the original completed forms to guillerm@who.int

A. Applicant Information

Legal Entity _____

Principle Investigator:

First Name _____ M. I. _____ Last Name _____

Title/Position _____

Telephone _____ Fax _____ E-mail _____
ext.

Department _____ Building _____ Room Number _____

Street Address (P.O. Boxes are not acceptable) _____

City _____ State/Province (required for US/Canada) _____
Other _____

Zip/Postal Code _____ Country _____

Responsible Administrative Authority¹:

First Name _____ M. I. _____ Last Name _____

Title/Position _____

Telephone _____ Fax _____ E-mail _____
ext.

Address if different from Principle Investigator:

Department _____ Building _____ Room Number _____

Street Address (P.O. Boxes are not acceptable) _____

City _____ State/Province _____
Other _____

Zip/Postal Code _____ Country _____

Web Site Address _____

Check type of entity:

Diagnostics industry

Government

Research Foundation

Diagnostic Lab

Hospital/Clinic

Contract Lab

Other Industry

Other (explain) _____

¹ Principle Investigator and Responsible Administrative Authority must be employees of Applicant

B. Shipping Address

If other than Applicant's address above.

Organization Name _____

Department _____

Street Address (P.O. Boxes are not acceptable) _____

City _____ State/Province _____
Other _____

Zip/Postal Code _____ Country _____

Telephone ext. _____ Fax _____ E-mail _____

C. Biosafety Officer

First Name _____ M. I. _____ Last Name _____

Telephone ext. _____ Fax _____ E-mail _____

D. Collaborator(s)² - if multiple, attach separately

Legal Entity: _____

Principal Investigator or other Focal Point:

First Name _____ M. I. _____ Last Name _____

Telephone ext. _____ Fax _____ E-mail _____

² Any third party, collaborating (financially, technically or otherwise) with the Applicant on the proposed project. By completing this Form, the Applicant confirms that any agreements which Applicant may have concluded with any such third party are consistent with, and will not in any way prejudice, Applicant's obligations under this Form and/or (if WHO/TDR approves the release of the requested materials to the Applicant) the Material Release Form and Material Transfer Agreement.

Department _____ Building _____
 Street Address (P.O. Boxes are not acceptable) _____
 City _____ State/Province _____
 Other _____
 Zip/Postal Code _____ Country _____

E. Material Request

Viabile strains Heat-inactivated bacterial suspensions

Description of the request	Indicate number requested
1. <i>M. tuberculosis</i> complex and other mycobacterial strains (panel of 5 strains)	
2. <i>M. tuberculosis</i> susceptible to all drugs	
3. <i>M. tuberculosis</i> mono-resistant to first-line drugs. Specify: <input type="checkbox"/> Isoniazid <input type="checkbox"/> Rifampicin <input type="checkbox"/> Ethambutol <input type="checkbox"/> Streptomycine <input type="checkbox"/> Low resistance <input type="checkbox"/> High resistance	
4. <i>M. tuberculosis</i> polyresistant, specify the association requested <input type="checkbox"/> Isoniazid resistant and other (specify)..... <input type="checkbox"/> Rifampicin resistant and other (specify)	

<p>5. <i>M. tuberculosis</i> multi-drug resistant (resistant to isoniazid and rifampicin) plus other resistance (no extensively drug resistant available)</p> <p>First-line drug, specify</p> <p><input type="checkbox"/> Ethambutol</p> <p><input type="checkbox"/> Streptomycin</p> <p>Second-line drug, specify</p> <p><input type="checkbox"/> Ofloxacin</p> <p><input type="checkbox"/> Kanamycin</p> <p><input type="checkbox"/> Capreomycin</p> <p><input type="checkbox"/> Ethionamide</p> <p><input type="checkbox"/> p-aminosalicylate</p>	
<p>6. Other phenotype, specify</p>	
<p>7. Other request, specify</p>	
<p>8. Specify if the material is requested for External Quality Assurance or blinded testing and need to be coded</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p>	

F. Scope of Use

In the space below (and on an additional sheet, if necessary), describe the Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory Quality Management of Drug Susceptibility Testing Methods activities for which isolates of *M. tuberculosis* are being requested. What are the expected outcomes and impact of this work. If applicable, please reference any previously published articles or abstracts with information concerning the diagnostic assay being developed and/or evaluated.

G. Applicant Profile

Provide a brief description of the Applicant (i.e. type of entity, mission, activities, etc.).

H. Biographical Sketch of Applicant

In the space provided (and on an additional sheet, if necessary), the sketch must include educational background, past and present employers and job titles. Include a list of up to 5 representative publications and institutional, departmental or laboratory Web site addresses, if applicable.

I. Laboratory and Biosafety Practices

M. tuberculosis is categorized as a Risk Group 3 organism, and biosafety level (BSL) 3 standards must be followed to ensure superior containment of aerosols in the laboratory workplace. WHO/TDR requires that recipient laboratory facilities are adequate for safe handling, manipulation, use and storage of MTB.

The Applicant requesting viable strains must submit evidence to WHO/TDR of recent (past 12 months) BSL-3 certification from an accredited Certifying Agent.

If Certifying Agents are not available in the Applicant's country, WHO/TDR will provide the Applicant with contact information of BSL-3 certified laboratories in the region, and the National TB Reference Laboratory with whom the Applicant could build a collaboration.

For information regarding requirements for BSL-3 facilities see: WHO Laboratory Biosafety Manual - Third Edition

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

J. Applicant Acceptance of Responsibility

PLEASE PRINT:

Name of Legal Entity: _____

Department: _____

Street Address: _____

City: _____

State/province: _____

Postal code: _____

Country: _____

Telephone: _____

Fax: _____

On behalf of the Applicant (institution, company or other legal entity), we hereby certify that we shall:

- 1) Ensure that only qualified personnel work with the Material in proper facilities
- 2) Provide sufficient internal security to assure access to the Material only by those individuals authorized to work with them
- 3) Not transfer, export, resell, or otherwise dispose of the Material to any third party under any circumstances without express written authorization from WHO/TDR and if applicable, appropriate government agencies
- 4) Obtain and maintain adequate workers compensation insurance for its staff, or equivalent insurance, to cover claims for accident, illness, injury or death in connection with the possession, handling, use, storage and/or disposal of the requested Material and obtain and maintain liability insurance in an adequate amount to cover third party claims (including WHO) for death or bodily injury, or loss or damage to property, arising from or in connection with the possession, handling, use, storage and/or disposal of requested Material, reasonably acceptable to WHO, naming WHO as an additional assured party, before the commencement of the activities for which the Material are being requested.
- 5) Comply with all applicable regional, national and local laws and regulations pertaining to these Material and their handling, storage, use, transportation and/or possible disposal;
- 6) Destroy all Material according to accepted practices for destruction of microbiological cultures upon completion of the work; and
- 7) Comply with all terms of the Material Release Form and Material Transfer Agreement, if approval for release of Material is granted by WHO/TDR.

We understand that by providing this signed form to WHO/TDR, we are accepting responsibility for the Material and all risks associated with their possession, handling, use, storage and/or disposal in our facility, as well as any adverse events resulting from our violation of the safety requirements or unauthorized dissemination of the Material.

If WHO/TDR approves the release of the requested Material, we (as the Recipient) will enter into and abide by the obligations contained in the WHO/TDR Tuberculosis Strain Bank Material Release Form and Material Transfer Agreement.

Applicant:

Name: _____

Title: _____

Signature: _____ Date: _____

Responsible Administrative Authority (if different from Applicant):

Name: _____

Title: _____

Signature: _____ Date: _____

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

**UNDP / World Bank / WHO
Special Programme for Research and Training
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For administrative use

**MATERIAL RELEASE FORM &
MATERIAL TRANSFER AGREEMENT**

WHO/TDR TUBERCULOSIS STRAIN BANK

Instructions: Please provide all requested information. Missing information will delay the approval process or may result in request denial.

A. Recipient Information

Legal Entity Name

Principal Investigator

First Name M. I. Last Name

Telephone ext. Fax E-mail

Responsible Administrative Authority:

First Name M. I. Last Name

Telephone ext. Fax E-mail

B. Material Approved for Release & Fees

Based on an assessment of the completed 'Material Request Form', WHO/TDR has approved the release of the Material items indicated in the table below.

In advance of shipment, the Recipient undertakes to pay the Prince Leopold Institute of Tropical Medicine, Antwerp ("ITM") a Fee for the Material of US\$ 120 per strain or per heat-inactivated bacterial suspension for a profit organization and US\$ 60 for a non-profit organization. The Recipient will pay a handling fee of US\$ 132 for 1 to 30 strains, US\$ 250 for 31 to 100 strains and US\$500 for more than 100 strains. In addition the Recipient will pay the shipping costs.

Strains or heat-inactivated bacterial suspensions will be accompanied by genotypic and phenotypic profiles, except when the strains will be used for external quality assessment purposes, in which case the strains will be coded and no information identifying the strain type will accompany the Material.

Description of material for release:

Fee

USD

Fee for the material:

Strains

Profit organization 120 USD per item 120x strains

Non-profit organization 60 USD per item 60x strains

Heat-inactivated bacterial suspensions

- Profit organization 120 USD per item 120x suspensions
- Non-profit organization 60 USD per item 60x suspensions

Handling fee

- US\$ 132 for 1 to 30 strains or heat-inactivated bacterial suspensions
- US\$ 250 for 31 to 100 strains or heat-inactivated bacterial suspensions
- US\$ 500 for more than 100 strains or heat-inactivated bacterial suspensions

Total fees:

C. Shipping & Billing Information

Shipping

N.B: **All shipment costs must be paid by the Recipient.** The distribution of strains to Recipients will be undertaken in accordance with the UN guidelines for shipping infectious material, Category A "Infectious Substances" UN2814, the "Recommendations on the TRANSPORT OF DANGEROUS GOODS Model Regulations Volume I Thirteenth revised edition", ST/SG/AC.10/1/Rev.13 Vol. I and the provisions of "Transport of Infectious Substances", WHO/CDS/CSR/LYO/2004.9 (section 19). According to the above document, heat-inactivated bacterial suspensions are exempted from dangerous goods requirements and regulations.

Organization Name _____

Department

Street Address (P.O. Boxes are not acceptable) _____

City _____ State/Province (required for US/Canada) _____
Other _____

Zip/Postal Code _____ Country _____

Telephone _____ Fax _____ E-mail _____
ext. _____

Billing

N.B. Payment is required in advance of shipment.

Billing Department _____

Contact person (Complete first and last name) _____

Street Address (P.O. Boxes are not acceptable) _____

City _____ State/Province (required for US/Canada) _____
Other _____

Zip/Postal Code _____ Country _____

Telephone (Including Country Code) _____
ext. _____

Fax (Including Country Code) _____

D. GENERAL TERMS AND CONDITIONS

The Mtb strains or heat-inactivated bacterial suspensions described in Section E of the WHO/TDR TB Strain Bank Material Request Form (hereinafter referred to as "the Material") and any information relating thereto (hereinafter referred to as "the Information") are provided on the following conditions:

As used in this agreement, "Replicate" means any biological or chemical material that represents a substantially unmodified copy of the Material such as, but not limited to, material produced by growth of cells or microorganisms or amplification of Material. "Derivative" means material created from the Material that is substantially modified to have new properties.

Scope of Use

1. The entity requesting and receiving the Material and Information (the "Recipient") will use the Material, Replicates and Derivatives and Information exclusively for the purpose of the Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory

Quality Management of Drug Susceptibility Testing, described under Section F of the WHO/TDR TB Strain Bank Material Request Form. On completion of the aforesaid Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory Quality Management of Drug Susceptibility Testing, the Recipient will cease to use and destroy any remaining quantities of the Material, Replicates and Derivatives, and any and all copies of the Information unless WHO advises the Recipient otherwise in writing.

2. The Material, Replicates and Derivatives and Information are supplied by WHO/TDR to the Recipient solely for the use and subject to the restrictions on use as set out in this document. The Recipient shall not distribute, sell, offer for sale or otherwise transfer the Material, Replicates, Derivatives and/or Information without the prior written authorization of WHO/TDR.
3. Unless agreed to in the Material Request Form, the Recipient will not permit the Material, Replicates, Derivatives and/or Information, or any part or modifications thereof, to come into the possession or control of any other entity or person, except those who are engaged in the above-mentioned Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory Quality Management of Drug Susceptibility Testing at the facility and under the supervision, of the Recipient and who have accepted the same obligations of confidentiality and restrictions on use in respect of the Material, Replicates, Derivatives and Information as set forth in this document.
4. Recipient agrees that WHO has no control over the use that is made of the Material, Replicates, Derivatives and Information by the Recipient, or parties collaborating with Recipient. Consequently, Recipient agrees that WHO shall not be liable for such use.

Ownership of the Material and Intellectual Property

5. All rights and title in the Material, Replicates, Derivatives and Information is, and will remain, solely and exclusively vested in WHO/TDR. Other than explicitly provided herein, this Material Release Form will not be construed as conveying to the Recipient any rights or title to the Material, Replicates, Derivatives and/or Information.

The Recipient will treat the Material, Replicates, Derivatives and Information, including the phenotypic and genotypic profile of the Material, as confidential and proprietary to WHO and/or persons or entities collaborating with WHO, and will only disclose such Material, Replicates, Derivatives and Information under like obligations of confidentiality and restrictions on use as those contained herein. Such obligations of confidentiality will not apply to Information which the Recipient can show was in the public domain at the time of its acquisition hereunder, or becomes part of the public domain otherwise than by breach of the undertakings set forth in this Material Release Form.

6. **Inventions and Patents made by Recipient through the use of Material, Replicates or Derivatives.** Recipient is free to file patent application(s) claiming inventions made by Recipient through the use of Material, Replicates or Derivatives, provided that Recipient shall not disclose any confidential Information (including but not limited to the phenotypic and genotypic profile of the Material) in or in connection with such patent applications. In order to avoid the disclosure of confidential Information as aforesaid and/or prejudice to proprietary rights of WHO or parties collaborating with WHO, the Recipient shall provide WHO/TDR with a copy of intended patent applications and other related disclosures for review in accordance with paragraph 9 below, prior to their submission or presentation to any patent office or other third party. Recipient will retain ownership of any such inventions and corresponding patents or patent applications. Recipient agrees to acknowledge WHO, the WHO/TDR TB Strain Bank and any contributors thereto (as indicated by WHO/TDR) in all patent applications that reference the Material, Replicates or Derivatives.

7. **Commercial Purposes.** Without the prior written authorization by WHO (which WHO shall be free to grant or refuse, in its sole discretion), Recipient shall not make or allow others to make any commercial use of the Material, Replicates and/or Derivatives. "Commercial use" as aforesaid means any large scale manufacture and for-profit or not-for-profit distribution other than for research purposes. In addition, Recipient agrees to ensure that any commercial use of the results obtained through use of the Material, Replicates and/or Derivatives shall be designed to achieve that any resulting product shall be made widely available to the public, including to the public sector of developing countries on reasonable terms.
8. **Publications** Recipient may publish or otherwise publicly disclose the results of the work with the Material, Replicates and/or Derivatives. Prior to publication or presentation of any results using the Material, Replicates and/or Derivatives, the Recipient will provide WHO with a copy of such intended publication or presentation for the purposes of ensuring that it contains no disclosure of confidential and/or proprietary Information. Any objection to publication or presentation for the aforesaid reason will be notified by WHO to the Recipient within a period of sixty days of receipt of the draft copy. In the absence of such an objection within that sixty-day period, the publication or presentation may proceed. Recipient agrees to provide WHO with 5 free copies of any such publications or presentations.
9. All such intended publications and presentations of the results using the Material, Replicates and/or Derivatives will contain an acknowledgement of WHO, the WHO/TDR TB Strain Bank and any contributors thereto as indicated by WHO and include a reference to the WHO/TDR strain catalogue numbers. The Recipient agrees to consult WHO with regard to giving appropriate acknowledgement as aforesaid, before such publication is published or presentation is made.

Confidentiality Obligations of WHO

10. Any information provided by the Recipient to WHO under, or in connection with, the Material Request Form, will - if marked 'confidential' - be treated by WHO as confidential and proprietary to the Recipient, for a period of five years after the disclosure of such information to WHO. In this connection, WHO will only use and disclose such information for the purpose of evaluating such information and determining (in WHO's sole discretion) the merit of releasing Material for Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory Quality Management of Drug Susceptibility Testing - activities by the Recipient.

However, there will be no obligations of confidentiality and restrictions on use, to the extent that WHO is clearly able to demonstrate that the aforementioned information or any part thereof:

- I. was known to WHO prior to their disclosure by the Recipient hereunder; or
- II. has been independently devised, or arrived at, by or for WHO without access to the disclosure made by the Recipient hereunder; or
- III. was in the public domain at the time of disclosure hereunder, or becomes part of the public domain through no fault of WHO; or
- IV. becomes available to WHO from a third party, who is not in breach of any obligations of confidentiality owed to the Recipient.

Safety; compliance with laws

11. Recipient acknowledges that the Mtb strains and their Replicates are categorized as a Risk Group 3 organism and constitute known pathogens. As a result, Recipient undertakes to comply with biosafety level 3 standards to ensure superior containment of aerosols in the laboratory workplace. The same applies to Derivatives, unless Recipient can convincingly demonstrate that the Derivatives should not be classified as Risk Group 3 organisms. Evidence of laboratory compliance with biosafety level 3 standards must be provided with the Material Request Form, but in any event before the Material will be shipped. Furthermore, to receive the Material, the Recipient must obtain necessary permits and written proof of approval to hold the Material (including Replicates and Derivatives) from national authorities, copies of which must be attached as an Appendix to the Material Request Form or this Material Release Form, before Material will be shipped. The Material, Replicates and Derivatives are not appropriate, nor intended, for use in humans.
12. The Recipient will ensure that the Material, Replicates and Derivatives will at all times be stored, used and handled (including any possible disposal and transportation) in compliance with all relevant laws, rules and regulations (foreign and domestic) applicable to the use of infectious substances and other biological materials. Recipient will take all appropriate safety and handling precautions to minimize health or environmental risk.

Shipping

13. The Material will be packaged and shipped in accordance with applicable laws and regulations. The Material will be shipped Free On Board (FOB) point of shipment, via carrier of ITM's choice. Recipient agrees to inform WHO/TDR electronically of the date of receipt and any loss or damage to the Material within three (3) working days of receiving the Material.
14. The Recipient is responsible for ensuring that all permits required for the Recipient to receive the Material, are obtained and that sufficient proof of such permits is provided to WHO/TDR. WHO/TDR will notify the Recipient when the Material Request Form or this Material Release Form and Material Transfer Agreement are submitted without the necessary permits, and the Recipient will have a two (2) month period after such notification to supply proof of the necessary permit(s) before an order will be cancelled. An additional charge will be levied if special processing or packaging is necessary.

Insurance

15. The Recipient agrees to obtain and maintain liability insurance in an adequate amount to cover third party claims (including by WHO) for death or bodily injury, or loss or damage to property, arising from or in connection with: (i) the possession, use, storage and/or disposal of the Material, Replicates, Derivatives and/or Information, and/or (ii) Recipient's activities under this Agreement.
The Recipient furthermore agrees to obtain and maintain adequate workers' compensation or equivalent insurance for its staff to cover claims arising from or in connection with: (i) the possession, use, storage and/or disposal of the Material, Replicates, Derivatives and/or Information, and/or (ii) Recipient's activities under this Agreement.

Indemnification

16. The Recipient agrees to assume full responsibility for, and to hold harmless WHO/TDR, the Prince Leopold Institute of Tropical Medicine, Antwerp and other contributors to the Repository from any and all claims, costs, expenses and liabilities resulting from, or otherwise related to: (i) the possession, use, storage and/or disposal of the Material, Replicates, Derivatives and/or Information; and/or (ii) Recipient's activities under this agreement.

Limitation of liability

17. WHO and persons and entities collaborating with WHO make no warranty of merchantability or fitness of the Material, Replicates, Derivatives or Information for any particular purpose, or any other warranty, either express or implied (including but not limited to any warranty that the use of the Material, Replicates, Derivatives and/or Information does not infringe on the intellectual property or other proprietary rights of others).
18. WHO/TDR, the Prince Leopold Institute Tropical Medicine, Antwerp and other contributors to the Repository disclaim any and all responsibility and liability for any damages of any kind in connection with or arising out of the Material, Replicates, or Derivatives (whether in contract, tort, negligence, strict liability, statute or otherwise)

Termination

19. On completion of the Research and/or Diagnostic Development and/or Diagnostic Evaluation and/or Laboratory Quality Management of Drug Susceptibility Testing using the Material, Replicates, Derivatives and Information, or on expiration or earlier termination of this Agreement, the Recipient will cease to use any remaining quantities of the Material, Replicates, Derivatives and Information for any purpose. Unless WHO advises the Recipient otherwise in writing the Recipient will destroy all such remaining quantities of the Material and Replicates and Derivatives and any and all copies of the Information and provide written proof thereof to WHO/TDR no later than thirty (30) days from the date of expiration or termination. Recipient understands that WHO/TDR may terminate this Agreement at any time with written notice to Recipient.

Miscellaneous

20. Any dispute relating to the interpretation of application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties will accept the arbitral award as final. The arbitration shall take place in Geneva, Switzerland, unless the Parties agree otherwise.
21. Nothing in or relating to this Agreement shall be construed as an obligation on the part of WHO to submit to any national legislation or jurisdiction, and/or as a waiver of any of the privileges and immunities enjoyed by WHO under any national or international law, convention or agreement.
22. This Material Release Form and Material Transfer Agreement sets forth the entire understanding between the parties and supersedes any prior agreements, written or verbal. It shall only be capable of change by written amendment executed by duly authorized officers of the parties.

Signed for and on behalf of WHO/TDR

Signed for and on behalf of Recipient

Principal Investigator

Name:

Name:

Title:

World Bank/UNDP/WHO Special
Programme for Research and
Training in Tropical Diseases
(TDR)

Date:

Title:

Date:

Responsible Administrative Authority

Name:

Title:

Date: