WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

TDR/TB/Specimenbank/2010

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

For administrative use

MATERIAL REQUEST FORM & MATERIAL TRANSFER AGREEMENT

WHO TUBERCULOSIS SPECIMEN BANK

A. Requesting Party	
B. Shipping Address **e-mail address**	

C. Clinical Specimens Requested

Specimen are only offered in allotments of 20, 50 or 200. Please indicate the appropriate number of specimen requested for each specimen type:

Specimen type	**Number of Specimen** (check one box per row where applicable)
Sputum (0.5ml)	20 ☐ 50 ☐ 200 ☐
Saliva (0.5ml)	20 ☐ 50 ☐ 200 ☐
Urine (1.5ml)	20 ☐ 50 ☐ 200 ☐
Serum (0.5ml)	20 ☐ 50 ☐ 200 ☐

D. Clinical Specimens from the WHO Tuberculosis Specimen Bank are intended only for use in research, development, testing and/or evaluation of new tuberculosis diagnostics, which are appropriate for use and affordable in developing countries, hereinafter referred to as "the Research, Development, Testing and/or Evaluation".

Describe the Research, Development, Testing and/or Evaluation for which you are requesting Clinical Specimens (give details and continue on a separate sheet, if necessary). Please reference any previously published or abstracted information concerning this assay: Minimal information will specify the type of assay to be developed, the technical platform to be used, a summary of the data generated from in house specimen, the cut-off values. Any data disclosed will be treated as confidential information. For commercial products please attach a product/package insert.

E. GENERAL TERMS AND CONDITIONS

The general terms and conditions contained in this Section E govern the release of any Material (as defined below) to the Recipient.

The Material Request Form, which shall be duly completed by the Recipient, incorporating these general terms and conditions, and any correspondence (award letter) from WHO/TDR to the Recipient informing the Recipient of WHO/TDR's agreement to release quantities of Material to the Recipient, together comprise the Material Transfer Agreement between WHO/TDR and the Recipient.

The clinical specimens described in Section C above (hereinafter referred to as "the Material") and any information relating thereto (hereinafter referred to as "the Information") are provided on the following conditions:

Scope of Use

1. The entity requesting and receiving the Material and Information (the "Recipient") will use the Material and Information exclusively for the purpose of the Research, Development, Testing and/or Evaluation activities, described under Section D of the WHO/TDR TB Specimen Bank Material Request Form. On completion of the aforesaid Research, Development, Testing and/or Evaluation activities, the Recipient will cease to use and destroy any remaining quantities of the Material and any and all copies of the Information unless WHO advises the Recipient otherwise in writing.

2. The Material 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 and/or Information without the prior written authorization of WHO/TDR.

3. Unless stated in the Material Request Form and agreed to by WHO/TDR, the Recipient will not permit the Material 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, Development, Testing and/or Evaluation 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 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 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 and Information are, 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 and/or Information.

   The Recipient will treat the Material and Information, as confidential and proprietary to WHO and/or persons or entities collaborating with WHO, and will only disclose such Material 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**. Recipient is free to file patent application(s) claiming inventions made by Recipient through the use of Material, provided that Recipient shall not disclose any confidential Information 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 8 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 Specimen Bank and any contributors thereto (as indicated by WHO/TDR) in all patent applications that reference the Material.

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. "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 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. Prior to publication or presentation of any results using the Material, 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 will contain an acknowledgement of WHO, the WHO/TDR TB Specimen Bank and any contributors thereto as indicated by WHO and include a reference to the WHO/TDR specimen 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, Development, Testing and/or Evaluation 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. The Material is not appropriate, nor intended, for use in humans.

12. The Recipient will ensure that the Material 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. The Recipient furthermore undertakes to comply with all applicable guidelines, including but not limited to the **UN guidelines for shipping infectious material, Category B "Diagnostic specimens" UN3373** and the **WHO Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens, WHO/EMC 97.3.**. WHO will provide the Recipient with a copy of these Guidelines upon request. The 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 the Repository's choice. Recipient agrees to inform WHO/TDR by electronic mail 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 is 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.

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 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 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 and the Repositories 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 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 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 and/or Information does not infringe on the intellectual property or other proprietary rights of others).

18. WHO/TDR and the Repositories disclaim any and all responsibility and liability for any damages of any kind in connection with or arising out of the Material (whether in contract, tort, negligence, strict liability, statute or otherwise).

Termination

19. On completion of the Research, Development, Testing and/or Evaluation activities using the Material and Information, or on expiration or earlier termination of this Agreement, the Recipient will cease to use any remaining quantities of the Material 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 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. The Material Transfer Agreement, comprising the Material Request Form (incorporating these general terms and conditions) and any correspondence (award letter) from WHO/TDR to the Recipient informing the Recipient of WHO/TDR's agreement to release quantities of Material to the Recipient, 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.

Agreed and accepted on behalf of the Recipient

Principal Investigator	**Responsible Administrative Authority**
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

Please return this form (**two** copies with original signatures) to:

Martine Guillerm

Special Programme for Research and Training in Tropical Diseases (TDR)
World Health Organization
1211 Geneva 27, Switzerland
Fax no.: +41 22 791 4854

Approved by WHO:

Signature:
Name:
Title:
Date: