

Attachment D: Participant Biosafety Compliance Letter of Agreement

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-0600)

**Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* (MTB)
Drug Susceptibility Testing—Participant Biosafety Compliance Letter of Agreement between the Centers for
Disease Control and Prevention and [INSERT LABORATORY NAME]**

Purpose Dear Participant:

The purpose of this letter of agreement is to ensure that [INSERT LABORATORY NAME] (herein "Laboratory") understands and complies with the biosafety guidelines for working with viable strains of *Mycobacterium tuberculosis* as outlined in the *Guidelines for Safe Work Practices in Human and Animal Clinical Diagnostic Laboratories* ([MMWR: January 6, 2012](#)).

An authorized representative of Laboratory must sign and date this letter agreement and fax or email it to CDC's Division of TB Elimination Laboratory Branch (DTBE/LB) before Model Performance Evaluation Program (MPEP) isolates will be shipped to the participating site. DTBE/LB will only ship isolates to sites meeting applicable biosafety containment. A site will be notified if isolates cannot be shipped. Please call 404-639-4013 if you have any questions concerning this document.

Deadline for submission of this form is _____

Recommended Laboratory Facilities, Equipment and Practices

Viable TB strain manipulations must be performed in a Biosafety Level 3 (BSL-3) laboratory* that meets the following criteria:

- Facility
 - Restricted access to the laboratory with a series of two self-closing doors
 - Seams, walls, and ceiling are sealed and easy to clean and decontaminate
 - Laboratory exhaust air is not re-circulated to any other area of the building
 - A hands-free sink is available for hand washing
 - An eyewash station is available
 - The laboratory is equipped with a Class II-A1 or II-A2 Biological Safety Cabinet (BSC) that is re-certified annually
- Standard Microbiological Practices
 - A risk assessment for working with TB in the laboratory has been completed
 - A TST or IGRA program is available and testing is done at least annually
 - A biosafety manual specific for the laboratory is available
 - Testing personnel are knowledgeable about hazards of working with TB and demonstrate proficiency in laboratory procedures
 - BSL-3 personal protective equipment (PPE) is used based on risk assessment of laboratory procedures and practices
 - All procedures involving manipulation of viable TB strains are conducted in a BSC or other physical containment devices
 - Decontamination of laboratory waste must be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, or other validated decontamination method).

*If a BSL-3 laboratory is not available, a BSL-2 laboratory may be used if the following requirements are met:

- A risk assessment determines that viable TB strains can safely be worked with in the separate, closed BSL-2 laboratory using BSL-3 practices as outlined in the above mentioned MMWR supplement

- Laboratory exhaust air is exhausted to the outside of the building
- The laboratory director approves the practice

Participant Compliance

Please initial the statement that applies to your laboratory:

- ___ Meets all of the above recommendations for a BSL-3 laboratory
- ___ No BSL-3 laboratory is available but meets all of the laboratory requirements as described above for a BSL-2 laboratory with BSL-3 practices
- ___ No BSL-3 laboratory is available and does **not** meet all of the laboratory requirements as described above for a BSL-2 laboratory

Laboratory warrants and represents that the information provided above is current, complete and accurate. In requesting participation in MPEP, Laboratory acknowledges and understands the potential risks associated with manipulation of live cultures of *M. tuberculosis* and will work with these isolates under the appropriate biosafety containment as determined by our institutional policies and procedures.

_____	_____
Person Completing Form (Print)	Position/Title
_____	_____
Person Completing Form (Signature)	Name of Organization
_____	_____
Date	City/State

Please email a PDF attachment of the signed document or fax the signed document to:
 Laboratory Branch (TB) MPEP Program
 CDC MPEP email: TBMPEP@cdc.gov
 Fax: 404-639-5491