

**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 [Participant Site: _____]**

MPEP#: [#_____]

Purpose Dear Participant:

The purpose of this letter of agreement is to ensure Participant Site (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 [Date_____].

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**