

Attachment 4: Participant Biosafety Compliance Letter of Agreement

Form Approved
OMB No. 0920-0600
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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

XXXXX (MPEP XXXX) Year: XXXX

Purpose In the setting of quality management system practices, this letter of agreement is to ensure that the requestor understands and complies with the biosafety guidelines for working with viable strains of *Mycobacterium tuberculosis* Complex 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 send by fax or email it to CDC's Division of TB Elimination Laboratory Branch (DTBE/LB) before *Mycobacterium tuberculosis* isolates will be sent. DTBE/LB will only ship isolates to sites meeting applicable biosafety containment. The requestor will be notified if isolates cannot be shipped. Please call 404-639-2862 if you have any questions.

Deadline for submission of this form is XX/XX/XXXX.

Recommended Laboratory Facilities, Equipment and Practices

Manipulations of viable strains of *M. tuberculosis* 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 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 *M. tuberculosis* in the laboratory has been completed
 - Biosafety is addressed in laboratory protocols using the requested organism
 - Laboratory personnel are knowledgeable about hazards of working with *M. tuberculosis* 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 strains of *M. tuberculosis* 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 strains of *M. tuberculosis* 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

(MPEP «MPEP_ID»)

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. The 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. Use of the isolates and derived material will be confined to quality management systems practices, to include verification, validation, panel and proficiency testing, and not research and development

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