

AIDS CLINICAL TRIALS GROUP (ACTG) / INTERNATIONAL MATERNAL PEDIATRIC ADOLESCENT AIDS CLINICAL TRIALS GROUP (IMPAACT) Network Standard Operating Procedures		
Title	ACTG / IMPAACT Clinical Research Site Tuberculosis Infection Control Policy	
SOP Number	ACTG-160	Effective: 03/17/2017
Version	1.0	Last reviewed: 03/14/2017
Originator	ACTG Network Coordinating Center	Page 1 of 8

1.0 PURPOSE

The purpose of this SOP is to provide Clinical Research Site (CRS) staff with prioritized information on effective tuberculosis (TB) infection control requirements to limit the spread of TB in the research facilities (including households, vehicles).

2.0 SCOPE

These procedures apply to all CRS staff involved in ACTG and IMPAACT research. This document does not cover recommendations for laboratory bio-safety. These procedures were developed from the Centers for Disease Control (CDC) and World Health Organization (WHO) guidelines, selected publications, and the Aurum Institute’s infection control guidelines, which were developed with PEPFAR funding.

3.0 PROCEDURES AND RESPONSIBILITIES

An infection control program aims to bring together practices which, when used appropriately, restricts the spread of infections. A breach in infection control can result in the spread of infection from patients to health care workers, other patients, patient attendants and relatives. Therefore, it is the responsibility of both health care workers (HCWs) and patients at sites to adhere to the infection control guidelines.

Elements that can be combined to achieve TB infection control include:

3.1 Facility Level Measures

Facility level measures constitute the framework for setting up and implementing the other controls (administrative, environmental, and personal protective equipment) at the level of the facility. These may be beyond the control of individual clinics or research sites, but whenever possible should be reviewed and addressed with facility management, or implemented together with other measures and controls, as they complement one another.

The facility level measures are to:

- 3.1.1 Identify and strengthen local coordinating bodies for TB infection control, and develop a facility plan (including human resources, and policies and

procedures to ensure proper implementation of the controls) for implementation of TB infection control.

- 3.1.2 Rethink the use of available spaces to address airflow, circulation and replacement to optimize implementation of TB infection control. Current airflow can be assessed using simple measures or through a professional assessment by an engineer.
- 3.1.3 Conduct on-site surveillance for TB infection and active disease among HCWs at least annually. Surveillance of HCWs should include a symptom screen, TB skin test or approved interferon-gamma release assay and/or chest x-ray. HCWs should also be encouraged to know their HIV status. Annual chest x-rays are not recommended for asymptomatic persons.
- 3.1.4 Offer a package of prevention and care interventions for health workers, including HIV prevention, antiretroviral therapy and isoniazid preventive therapy.
- 3.1.5 Address advocacy, communication and social mobilization for health workers, patients and visitors.
- 3.1.6 Monitor and evaluate TB infection control measures.

3.2 Administrative Control Measures

Administrative control measures are the first priority in any setting, and have the greatest impact in preventing the spread of TB. These measures reduce the production of droplet nuclei containing *M. tuberculosis* within a facility thereby preventing potential exposure of staff and other patients in the facility. They also prevent the spread of disease by identifying, separating, investigating and treating patients and staff suspected or known to have TB. The production of droplet nuclei is difficult to completely eliminate therefore further measures are required for TB infection control.

Concerted efforts in optimizing the following administrative controls are vital:

- 3.2.1 Promptly identify people with TB symptoms, separate potentially infectious patients, control the spread of pathogens (cough etiquette and respiratory hygiene) and minimize time spent in health care facilities.
- 3.2.2 Sputum samples should not be collected in enclosed rooms or in the vicinity of other patients or staff members, but rather in an adequately ventilated room or booth, or outside in the open air.
- 3.2.3 Maintain an open window policy and ensure cross ventilation whenever possible.

3.3 Environmental Control Measures

Environmental control measures include methods to reduce the concentration of potential droplet nuclei in the air and control of the direction of potentially infectious air flow. In many developed countries, this involves the use of

sophisticated mechanical ventilation systems which require resources not normally available in resource-constrained countries. However, it is possible to plan and implement simple measures optimizing natural ventilation at much lower costs with good results. Correct hand hygiene is also important.

Environmental control measures include ventilation systems (natural or mechanical) and air cleaning methods (e.g., upper room ultraviolet germicidal irradiation) when adequate ventilation cannot be achieved. Such systems should be checked at least annually.

Types of ventilation and other cleaning methods include:

- Natural ventilation
- Exhaust systems (e.g., extractor fan at window)
- Mechanical ventilation
- Upper room UV lights
- Other (e.g., in room air cleaning devices such as HEPA filter units)

Personal Protective Equipment

Personal protective equipment such as respirators should be used in addition to administrative and environmental controls in situations where there is an increased risk of TB transmission. Examples of high risk situations are HCWs caring for patients with, or suspected of having, infectious TB during aerosolgenerating procedures (e.g., bronchoscopy, intubation, sputum collection/induction, aspiration of respiratory secretions and autopsy or lung surgery with high-speed devices) and/or when providing care to infectious multi-drug-resistant (MDR-TB) or extensively drug-resistant TB (XDR-TB) patients or those suspected of having infectious MDR-TB or XDR-TB.

Respirators should be equivalent or greater than U.S.-certified N95 or EU-certified FFP2. These disposable respirators contain special particulate filters that protect the wearer from inhaling droplet nuclei containing tubercle bacilli. Respirators should be properly fit tested and should be used in high risk settings for TB transmission as previously described.

4.0 RECOMMENDATIONS

- 4.1 Document an infection control plan for each CRS, including: blood and body fluid precautions, hand washing and respiratory borne illnesses.
- 4.2 Appointment of a facility-based infection control officer to conduct regular assessments, including regular review of infection control practices in the management meetings of the CRS.
- 4.3 Review facility infrastructure to develop where possible separated areas for sputum collection, and waiting areas for TB cases.

- 4.3.1.1 Designate a well-ventilated area, separate from the general waiting area, for patients with known or suspected TB, or drug-resistant TB.
- 4.3.1.2 Designate a well-ventilated sputum collection area.
- 4.4 Review the existing airflow management in patient waiting areas and clinic rooms to ensure extraction and airflow is enhanced to reduce respiratory droplet spread.
- 4.5 Training and policy development for site, staff and participants to support rapid identification, treatment, and isolation of individuals with TB, to the extent possible.
- 4.6 Implementation and adherence of infection control practices at all clinical and research areas.
- 4.7 Ongoing staff training and education on infection control measures and practices using the Office of HIV/AIDS Network Coordination (HANC) training module.
- 4.8 Procurement of necessary equipment for infection control.
- 4.9 Respirators equivalent or greater than US-certified N95 or EU-certified FFP2 available to all HCWs providing care to patients/research participants who may have TB.
- 4.10 TB specific infection control education material (e.g., posters and/or pamphlets) in the waiting room and at strategically selected points to disseminate information within the facility.
- 4.11 Periodic testing of health care worker wellness and health screening is to be conducted. Health care workers with the potential for exposure to patients and/or to infectious materials will be baseline tested at hire, and at least annually thereafter, following the setting's IC policies or TB risk classification, which can include the testing of confidential HIV, TB, Hepatitis B, and where applicable, Hepatitis C screening. TB screening can include symptom screening, X-Ray (recommended for staff members with symptoms of TB), skin testing and/or interferon gamma assay.
- 4.12 Each site will be required to meet these recommendations as reviewed by the network periodically. Prior to study Activation, each site will be required to review their TB Infection Control compliance and complete a "Tuberculosis Infection Control Checklist Letter", see Appendix for Sample Checklist Letter. This letter will be completed by indicating "Yes", "No" or "In Progress" along with any comments pertaining to each item and will be dated and signed by the CRS

Leader. This completed letter will be submitted to the ACTG and/or IMPAACT to verify compliance with this SOP. Site compliance with this SOP will be monitored by the ACTG and/or IMPAACT at least annually and updates will be requested, especially, if any items were indicated as “No” or “In Progress”.

5.0 REFERENCES AND ADDITIONAL RESOURCES

- 5.1 The Aurum Institute TB Infection Control Manual
- 5.2 The epidemiology of tuberculosis in health care workers in South Africa: a systematic review. BMC Health Serv Res. 2016 Aug 20; 16(1):416. doi: 10.1186/s12913-016-1601-5. Grobler L, Mehtar S, Dheda K, Adams S, Babatunde S, van der Walt M, Osman M.
- 5.3 Infection Prevention and Control, a guide for health professionals in low-resource settings. Angela Dramowski, David Woods and Shaheen Mehtar. Available on the bettercare website (<http://bettercare.co.za>) Learning Programmes, Infectious Diseases. Print version ISBN 978-1-920218-82-9
- 5.4 WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households. Available on the World Health Organization website (www.who.int) Publications.
- 5.5 Implementing the WHO Policy. Available on the Stop TB Partnership website (www.stoptb.org).
- 5.6 Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. Available on the CDC website (www.cdc.gov), Morbidity and Mortality Weekly Report.
- 5.7 CDC and Prevention Division of Tuberculosis Elimination Appendix B; TB risk assessment worksheet. Available on the CDC website (www.cdc.gov), Diseases and Conditions, Tuberculosis, Publications & Products, Guidelines, Control and Elimination.
- 5.8 Guideline for Hand Hygiene in Health-Care Settings; Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Available on the CDC website (www.cdc.gov), Morbidity and Mortality Weekly Report.

6.0 INQUIRIES

Any questions concerning these guidelines can be addressed to the ACTG TB TSG at actg.strtbtsq@fstf.org.

Appendix: Sample Tuberculosis Infection Control Checklist Letter for Sites

[SITE LETTERHEAD]

[DATE]

Dan Kuritzkes, M.D.
Chair, ACTG Executive Committee c/o
ACTG Network Coordinating Center
Social & Scientific Systems, Inc.
8757 Georgia Avenue, 12th Floor
Silver Spring, MD 20910 U.S.A.

Re: ACTG / IMPAACT Clinical Research Site TB Infection Control Checklist to Conduct
[PROTOCOL NUMBER]

Responsible Institution: [NAME, CITY, COUNTRY, SITE NUMBER]

Dear Dr. Kuritzkes:

The purpose of this letter is to inform you that the above-mentioned Clinical Research Site (CRS) has the following TB Infection Control requirements in place to commence implementation of protocol XXXXX.

1. Document an infection control plan, including: blood and body fluid precautions, hand washing and respiratory borne illnesses.
Yes No In-Progress
Comment: [Click here to enter text.](#)
2. Appointment of a facility-based infection control officer to conduct regular assessments, including regular review of infection control practices in the management meetings of the CRS.
Yes No In-Progress
Comment: [Click here to enter text.](#)
3. Designate a well-ventilated area, separate from the general waiting area, for patients with known or suspected TB, or drug-resistant TB.
Yes No In-Progress
Comment: [Click here to enter text.](#)
4. Designate a well-ventilated sputum collection area.
Yes No In-Progress
Comment: [Click here to enter text.](#)
5. Review the existing airflow management in patient waiting areas and clinic rooms to ensure extraction and airflow is enhanced to reduce respiratory droplet spread.

Yes No In-Progress

Comment: [Click here to enter text.](#)

6. Training and policy development for site, staff and participants to support rapid identification, treatment, and isolation of individuals with TB, to the extent possible.

Yes No In-Progress

Comment: [Click here to enter text.](#)

7. Implementation and adherence of infection control practices at all clinical and research areas.

Yes No In-Progress

Comment: [Click here to enter text.](#)

8. Ongoing staff training and education on infection control measures and practices using the Office of HIV/AIDS Network Coordination (HANC) training module.

Yes No In-Progress

Comment: [Click here to enter text.](#)

9. Procurement of necessary equipment for infection control.

Yes No In-Progress

Comment: [Click here to enter text.](#)

10. Respirators equivalent or greater than US-certified N95 or EU-certified FFP2 available to all HCWs providing care to patients/research participants who may have TB.

Yes No In-Progress

Comment: [Click here to enter text.](#)

11. TB specific infection control education material (e.g., posters and/or pamphlets) in the waiting room and at strategically selected points to disseminate information within the facility.

Yes No In-Progress

Comment: [Click here to enter text.](#)

12. Periodic testing of health care worker wellness and health screening is to be conducted. Health care workers with the potential for exposure to patients and/or to infectious materials will be baseline tested at hire, and at least annually thereafter, following the setting's IC policies or TB risk classification, which can include the testing of confidential HIV, TB, Hepatitis B, and where applicable, Hepatitis C screening. TB screening can include symptom screening, X-Ray (recommended for staff members with symptoms of TB), skin testing and/or interferon gamma assay.

Yes No In-Progress

Comment: [Click here to enter text.](#)

13. Prior to study Activation, each site will be required to review their TB Infection Control compliance and complete a "Tuberculosis Infection Control Checklist Letter". This completed letter will be submitted to the ACTG and/or IMPAACT to verify compliance with this SOP. In order for sites to be considered successful at implementing this SOP, all responses are expected to be "Yes". Site compliance with this SOP will be monitored by the ACTG and/or IMPAACT at least annually and updates will be requested, especially, if any items were indicated as "No" or "In Progress".

Yes No In-Progress Comment: [Click here to enter text.](#)

Sincerely,

[NAME OF CRS LEADER]

CRS Leader

[NAME OF INSTITUTION]