

University of Toledo Medical Center Tuberculosis Exposure Control Plan and Policy

2024 - 2025

SCOPE: This plan applies to the University of Toledo Health Science Campus, including the Medical Center, Clinics and all associated patient care areas. In this document these entities will be collectively referred to as UTMC.

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I. INTRODUCTION

This plan incorporates the concerns and responsibilities of numerous disciplines and departments involved with the control and management of tuberculosis (TB) among patients, students, employees, and visitors at UTMC.

The very nature and essentials of patient care involve risk for the transmission of infectious diseases such as TB both to other patients and to health care workers. It is the goal of this plan to lower this risk as much as is reasonably possible using well established principles of epidemiology, biological safety, infection prevention, and patient care.

II. OVERVIEW OF INFECTION PREVENTION MEASURES

This plan is based on a hierarchy of tuberculosis control measures based upon recommendations and guidelines published by the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), and applicable Ohio State Administrative Codes. At the top of the hierarchical list of control measures are early detection, isolation and treatment of persons with active tuberculosis as well as engineering controls such as room ventilation designed to reduce the risk of exposure to persons with infectious tuberculosis by reducing the concentration of aerosols of infectious bacilli. The lowest stratum level on the hierarchy of TB control is equipment such as a respirator mask. Such equipment is useful in situations of known or suspected high risk as an adjunct measure to engineering controls and physical separation of infected patients or non-human primates.

III. RISK ASSESSMENT

- A. Occupational Health and Infection Prevention will maintain records summarizing the results of all investigation(s) of health care workers and patients with known or suspected exposure to *Mycobacterium tuberculosis (M. tuberculosis)*.
- B. Occupational Health will provide reports to the hospital Infection Control Committee quarterly that include, along with appropriate demographic information, the number of hospital employees with known or suspected occupational exposure to TB, the number of employees who had either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) and their baseline status; the number of employees who converted their TST or IGRA after a known or suspected exposure to a patient with active tuberculosis; and the number of employees with suspected exposure who were lost to follow-up.
- C. Occupational Health will maintain records on all TST/IGRA testing done on new employees and TST/IGRA testing of current employees (including post-exposure testing). In an annual report to the Infection Control Committee, Occupational Health will summarize, including appropriate demographic information, the following data:
 - i. Current employees who had annual TST/IGRA screening.
 - ii. Employees who have had a TST/IGRA conversion.
- D. Infection Prevention maintains a database that includes all patients with documented newly acquired infectious tuberculosis. A report is made by the Infection Preventionist to the appropriate public health department upon recognition of diagnosis of tuberculosis. Annually, the Infection Control Committee assesses cases of newly diagnosed TB in the hospital community for risk trends.
- E. Occupational Health will annually summarize the following in written reports provided to Infection Prevention and Environmental Health and Radiation Safety (EHRS); and will present this information to the Infection Control Committee.
 - 1. The TST/IGRA conversion incidence by job location and/or job description (whichever is more appropriate). This information is provided for use in the annual TB risk assessment.
 - 2. An analysis of nosocomial TB exposures and any evidence of trends or unusual circumstances. Individual cases will be investigated and reported describing the factors leading to such exposures with recommendations for preventing future exposures whenever possible.

F. Occupational Health, Infection Prevention and Control and EHRS will assess the potential of occupational exposure to TB for all employees of UTMC through the annual risk assessment process. Since this encompasses multiple sites and types of services, specific areas or functional groups within the setting have separate risk classifications. Each employee will be assigned at least one of the following exposure determinations:

Airborne Pathogens

- o) No likely or anticipated exposure to *M. tuberculosis*.
- 1) Work assignment for all or part of the employee's scheduled work time in areas where there is a risk of exposure to TB aerosols (e.g., patient care areas/buildings). New hires to these areas are evaluated by Occupational Health for infection with *M. tuberculosis*.
- 2) Work assignment is in a high-risk area and employee is an N95 respirator user (See Section VIII F).
- 3) Work assignment is in a high-risk area and employee is a Controlled Air Purifying Respiratory (CAPR) respirator user (See Section VIII F).
- 4) Work assignment is in a high-risk area and employee is evaluated annually by Occupational Health for infection with *M. tuberculosis*.
- 5) No Occupational Health requirement.
- 6) Works with non-TB mycobacteria.
- 7) Non-clinical work assignment for all or part of the employee's scheduled work time in areas where there is a risk of exposure to TB aerosols (e.g., patient care areas/buildings). New hires to these areas are evaluated by Occupational Health for infection with *M. tuberculosis*.
- 8) "Special Occupational Health Review"- annual TB Questionnaire with Occupational Health review for those employees with latent TB infection, not in a high-risk area/group for TB exposure.

Animal Contact

- o) No Exposure
- 1) Animal Contact
- 2) Works with non-human primates

IV. RESPONSIBILITIES

A. Employees

- a. New employees that will have face-to-face contact with potential patients suspected of having TB will be medically cleared to wear a respirator prior to use and either be:
 - i. fit-tested and trained for N95 respirator mask use or
 - ii. training on CAPR use
- b. Employees with exposure determinations for Airborne Pathogens 4 or animal exposure contact 2 (non-human primates) will be trained and have **annual fit testing** for use of N95 masks **and/or** CAPRs.
- c. Only employees that have been fit tested and cleared for N95 respirator masks may use them.
- d. Employees will conduct a "user seal-check" prior to each use of the N95 respirator mask. User "seal check" is taught during initial and annual training, if you are unfamiliar with this process you should NOT be using an N95.
- e. Only employees that have annual fit testing can continue to wear an N95 mask. Refer to **S08-034 Respiratory Protection Program** for a list of positions requiring N95 use/annual fit testing.
- f. Employees will report any incidents of possible exposure to tuberculosis to Infection Prevention, Occupational Health or EHRS as soon as that exposure is recognized.

B. Department Managers

- a. Document each of their employees' compliance with the UTMC tuberculosis policy and compliance with educational programs as part of their yearly performance evaluation.
- b. Enforce the requirements of this plan.

- c. Assist Occupational Health and/or EHRS in the scheduling of any training, fit-testing, medical evaluations, or in any other activity relating to compliance of this program.
- d. Assist Occupational Health and/or EHRS in identifying areas and job tasks at risk.
- e. Assure that appropriate respiratory protection is available in facilities that house non-human primates.

C. Infection Control Committee (ICC)

- a. The ICC receives reports quarterly from both local public health and Occupational Health that include any TB activity. ICC reports these findings via their minutes to the Executive Committee of the Medical Staff.
- b. The Chairperson of the ICC will review and then arbitrate any controversies or disagreements over proper isolation of individual patients with known or suspected tuberculosis. The authority for this activity is outlined in the bylaws of the UTMC Medical Staff. These bylaws specifically state that the ICC has the responsibility and authority to mandate ICC activities.
- c. The Chairperson of the ICC will be notified of any investigations of tuberculosis exposure of employees and students undertaken by Occupational Health, EHRS and/or Infection Prevention.
- d. The ICC and the UTMC Safety Committee will review the TB Exposure Control Plan at least annually.

D. Infection Prevention and Control Department

- a. Assure compliance with UTMC policies related to the initiation and discontinuation of Airborne Infection Isolation (AII) of all patients with known or suspected infectious tuberculosis. See Section VIII of this document, "Management of Patients with Known or Suspected Tuberculosis" for details on the specific safety precautions to be used with AII. On-call advice is available 24 hours a day, 7 days a week by calling Infection Prevention via pager (419-218-3744); or by paging the Infectious Disease Service on-call provider via the hospital operator.
- b. Participate (in conjunction with Occupational Health and EHRS) in the orientation and continuing education of all new and current employees concerning tuberculosis control policies.
- c. Review the tuberculosis control plan in conjunction with Occupational Health and EHRS annually.
- d. Report or assist in reporting all cases of known or suspected tuberculosis to the patient's county of residence health department. In turn, the health department will notify the Ohio Department of Health (Appendix A).
- e. Notify the Infection Prevention Medical Director of all patients placed in isolation for confirmed infectious tuberculosis, all positive AFB smears in inpatients with suspected infectious tuberculosis, and all *M. tuberculosis* positive cultures.
- f. Notify Occupational Health and/or EHRS of all patients placed in isolation for confirmed infectious tuberculosis that require an employee contact investigation for potential exposure.
- g. Identify (in conjunction with EHRS) potentially exposed employees and students and provide this list to Occupational or Student Health, respectively, for further evaluation.

E. Environmental Health and Radiation Safety (EHRS)

- a. Infection Control, EHRS and Occupational Health will assess the potential for each UTMC employee for occupational exposure to TB during the annual risk assessment. This assessment will include a review of each employee's work responsibilities with particular reference to their likelihood for occupational exposure to TB. (See Section III, F)
- b. Works with Facilities to assure that appropriate ventilation or other engineering controls required by this plan are provided as needed (e.g., assuring monitoring of AII room air pressure).
- c. Works with Central Supply to assure that appropriate respiratory protection is available on all units caring for a patient in an AII room for TB.

- d. Identify (in conjunction with Infection Prevention) potentially exposed employees and students and provide this list to Occupational Health or Student Health, respectively, for further evaluation.
- e. Manage and conduct reviews of the University of Toledo Respiratory Protection Program (Procedure No: S-08-034) and the Respiratory Protection Program Policy for TB (Section VIII F).

F. Occupational Health

- a. New Employee Screening New employees will be evaluated for:
 - i. Prior TB history and any previous therapy for tuberculosis.
 - ii. Prior TST placement or IGRA testing (to include dates of the most recent negative or positive TST or IGRA test and any known prior TST or IGRA conversions).
 - iii. Prior therapy for active or latent tuberculosis including dates, types of treatment and results of prior chest radiographs.
- b. Follow-up treatment of all employees with suspected tuberculosis (infection or disease):
 - i. CDC guidelines for the management of tuberculosis will be the basis for all therapeutic decisions after evaluation by an Occupational Health Licensed Independent Provider (LIP).
 - ii. Evaluation of all employees with suspected or known active tuberculosis is the responsibility of Occupational Health. Such employees will be relieved from work until active disease is ruled out by appropriate medical and microbiological studies. Grounds for removing any employee from work may include but are not limited to the development of signs or symptoms suggestive of active tuberculosis and/or radiographic changes consistent with active pulmonary tuberculosis. All employees with confirmed active tuberculosis will be reported to the health department in the employee's county of residence to facilitate evaluation of the employee's contacts outside of UTMC (per Ohio Revised Code).
 - iii. Follow-up of all employees with potential exposures (See Section VI).
 - iv. Periodic screening of employees (see Section V).
 - v. Implement the Respiratory Protection Program Policy for TB (Section VIII, F).
- c. Coordinate medical clearance for respiratory protection for all new employees and students requiring respiratory protection; conduct initial and annual respirator fit testing and training as described in the institution's Respiratory Protection Plan.
- d. Collate, organize and provide data on exposure determinations and provide department managers and supervisors with access to reports regarding employee compliance to the requirements associated with their assigned exposure determination. Reports are also provided to Occupational Health, ICC, and the Safety Committee as needed.
- e. All UTMC medical students and other allied health students will have tuberculosis testing, TST or IGRA, depending on risk factors, within 12 months prior to matriculation.
- f. All UTMC medical students and other allied health students are required to have annual TB testing.
- g. All students who have a documented or suspected exposure to a patient with infectious TB will be evaluated at the Student Health Center using the same criteria as for UTMC employees (see Section VI).
- h. Students have two weeks following notification of the need for post-exposure TB testing in which to record a current TB test result with UTMC Student Health. A second test will be required approximately 8-10 weeks after exposure. Noncompliant students will be restricted from clinical rotations.
- i. Students who perform patient care activities and travel to countries for any reason that is designated by CDC/WHO as high hazard/high burden for TB and Mexico must have a recorded tuberculin skin test t or IGRA result with UTMC Student Health within a time frame of greater than 8 10 weeks and not more than six (6) months after returning to UTMC.

j. Any student with active TB will be restricted from the classroom/patient care/campus study and living areas until treated and evaluated by the same criteria used to manage UTMC employees.

G. Microbiology Laboratory

- a. Specimens will be accepted for Mycobacteriology isolation, identification, and susceptibility testing in the UTMC Microbiology Laboratory. Routine Acid-Fast Bacilli (AFB) smears and cultures will be done 7 days a week. The Laboratory will report all positive Acid-Fast Bacilli findings immediately to Infection Prevention.
- b. All positive AFB findings will be forwarded to the Ohio Department of Health following Ohio State protocol.
- c. Provide an annual report to the ICC and EHRS summarizing all isolates of *M. tuberculosis* and their susceptibilities.
- d. Positive Culture and Smear Results

Microbiology Lab personnel will call the patient's physician <u>and</u> Infection Prevention via pager (419-218-3744) with:

- i. The first positive AFB smear result of each admission or encounter;
- ii. The first positive identification of *Mycobacterium tuberculosis* complex (e.g., *Mycobacterium tuberculosis, Mycobacterium avium, Mycobacterium bovis*) per patient;
- iii. Susceptibility results on drug resistant isolates; or
- iv. A noted change in the susceptibility pattern of the patient's most recent isolate.

H. Anatomic Pathology

- a. The Department of Pathology (including Cytopathology and Surgical Pathology) will notify Infection Prevention when specimens, tissues or organs are found on pathological examination to exhibit findings consistent with an infectious form of mycobacteria. These reports will be made by phone and in writing to Infection Prevention. Whenever possible, samples of these suspicious specimens will be sent to the Microbiology Lab for AFB culture to confirm disease and for epidemiological investigation by Infection Prevention and the Ohio Department of Health.
- b. The Pathology Department will notify Infection Prevention when microscopic examination of any specimen discloses any form of mycobacteria.
- c. The Surgical Pathology Department will notify Infection Prevention when they encounter any necrotizing caseous granulomatous lesion with or without a cavitary component, which has findings consistent with an infectious form of tuberculosis. All procedures that have the potential to produce aerosols on specimens from patients known to have active multi-drug resistant tuberculosis are to be performed within a certified biological safety cabinet using appropriate biosafety precautions for the specific process/procedure in accordance with CDC/National Institute of Health (NIH) guidelines.
- d. Cytopathology will notify Infection Prevention of any AFB smear-positive results.

V. TUBERCULIN TESTING

A. Selective Screening: See Appendix C

- a. All incoming new employees and/or unpaid workers (e.g., volunteers, students, providers, and observers), working in patient care areas or Health Science Campus buildings will be screened for risk factors for TB through a screening questionnaire.
- b. Tuberculin testing is used to screen all new employees that will be working with in a clinical setting that involves patient care and/or ancillary services that involve direct face-to-face contact with patients, including, student healthcare workers, trainees and volunteers.
- c. Any employee, working in a non-clinical setting, from a country defined as high risk for Tuberculosis by the World Health Organization (WHO), will be screened upon hire; if there is no history of a positive TB test reaction or treatment for TB, IGRA testing will be completed.

- d. New employee's working in **non-clinical settings who are not from a high-risk country and with no direct face-to-face contact with patients** will complete a TB screening questionnaire only. Testing will only be completed with a known employment-related exposure.
- e. All personnel that process specimens for the recovery of Acid-Fast Bacilli (AFB) will receive annual screening and tuberculin testing or ICRA.

B. TEST SELECTION

- a. See Appendix C Employees will be questioned at the time of testing whether they have known or suspected immunosuppressive conditions; such individuals will be evaluated and counseled by an Occupational Health provider regarding their risk of TB.
 - **i.** Persons with any of the following clinical conditions or other immunocompromising conditions are included:
 - 1. Silicosis,
 - 2. Diabetes mellitus.
 - **3.** Chronic renal failure,
 - 4. Certain hematologic disorders (leukemia and lymphomas),
 - 5. Other specific malignancies (e.g., carcinoma of the head, neck, or lung),
 - **6.** Body weight ≥10% below ideal body weight,
 - 7. Prolonged corticosteroid use,
 - **8.** Other immunosuppressive treatments (including tumor necrosis factor-alpha $[TNF-\alpha]$ antagonists),
 - 9. Organ transplant,
 - 10. End-stage renal disease (ESRD), and
 - 11. Intestinal bypass or gastrectomy

C. Interpreting TB Test Results

a. See Appendix C.

D. Periodic Employee Surveillance

- a. Employees with initially negative TB test:
 - i. Non-laboratory personnel no annual requirement
 - ii. Personnel working with AFB specimens in the laboratory will complete annual TB testing and a screening questionnaire
 - 1. Lab personnel with Latent TB Infection (LTBI) are required to complete an annual questionnaire that includes specific questions concerning the absence or presence of symptoms suggestive of active TB or other risk conditions (see Section VIII A)
 - iii. Employees with a history of positive TST or IGRA who have completed a full course of preventative therapy that is acceptable by the CDC require an annual symptom screen through Occupational Health

iv. Employees who are new converters:

- 1. All employees with documented recent TST or IGRA conversion will be counseled by Occupational Health, referred for medical evaluation and have the following tests:
 - a. Chest X-ray
 - b. Clinical assessment that includes evaluation of the person's health history, including high risk associated disease(s) (see Section VIII A), possible source of conversion and whether the conversion was likely or possibly related to their occupation
 - c. HIV testing
- 2. For employees determined to have Latent Tuberculosis Infection (LTBI), prophylaxis will be recommended based on current recommendations of the CDC/US Public Health Service and the medical advisor.
- 3. If no drug prophylaxis is given for LTBI, an **annual symptom screen** is required.

- v. Treatment of employees with active tuberculosis:
 - 1. Anti-tuberculous therapy based on current CDC recommendations will be advised for all employees with active tuberculosis.
 - 2. Treatment is with the employee's personal physician or with the health department in the employee's county of residence.
 - 3. Employees will be relieved from work activities until local health department of the employee's county of residence and Occupational Health authorizes their return.
 - 4. All employees with active tuberculosis will be informed of the risk of disease among household contacts. In such instances, follow-up and treatment of household contacts will be the responsibility of the local health department of the employee's county of residence.
- vi. Pregnancy is not a contraindication for TST or IGRA. The same guidelines used for non-pregnant employees will be utilized to test and evaluate pregnant employees with two exceptions:
 - 1. Pregnant employees infected with *M. tuberculosis* will be informed of the possibility that infection can progress more rapidly during pregnancy.
 - 2. Pregnant employees who meet current guidelines for prophylactic therapy or treatment of active disease will be handled on an individual basis in conjunction with their primary physician. [Note: both INH and Rifampin are considered safe and appropriate for use in pregnancy in general, preventative therapy and treatment of active disease.]

VI. EXPOSURE INVESTIGATION

All exposures will be defined as contact with a patient or non-human primate with infectious pulmonary or laryngeal tuberculosis and adequate AIRBORNE precautions were not utilized or other exposures to TB aerosols has occurred. NOTE: Extra-pulmonary tuberculosis occurs outside of the pulmonary system and does not require isolation unless it is identified in open, draining wounds.

- A. Infection Prevention will notify Occupational Health when a patient with infectious tuberculosis has been admitted to the hospital or seen in the clinics where AII was inadequate. It will be the responsibility of Occupational Health to follow up on possible employee exposures.
- B. Records of patients will be reviewed, and department managers will assist Occupational Health with contacting collecting names of potentially exposed employees. Occupational Health, with assistance from Infection Prevention, will notify department managers of all such exposures; Infection Prevention will notify the physicians of any known exposed patients. It will be the joint responsibility of Occupational Health and department managers to prepare a list of exposed employees for subsequent follow-up and evaluation. It will be the responsibility of individual physicians to notify exposed patients and arrange for their follow-up and evaluation.
- C. Post-exposure testing will focus on a "first circle" of exposure (those staff with direct, close, face-to-face contact as defined by Infection Prevention and Occupational Health), such that the maximum number of staff tested in most cases will be less than 20. Any conversions within this first group will result in testing of all those exposed. In addition, community conversion data on all cases will be aggressively pursued to assist with the decision on the depth of testing. Exposed staff will be asked to define their estimated cumulative hours of exposure, if needed. All such evaluations will include the documentation of the circumstances of the exposure, the level and duration of the exposure, and the presence or absence of signs and/or symptoms of active TB in the source patient. Those chosen for "first circle" testing will be those with the most exposure time.
- D. Surgical Pathology employees who are directly involved with the handling and/or preparation of surgical specimens confirmed as positive for TB complex will be included in TB exposure investigations when AII precautions were not utilized.

- E. Employees to be evaluated will be notified and evaluated by Occupational Health. All such evaluations will include the presence or absence of signs and/or symptoms of active TB in the exposed employee, prior TST or IGRA status of the employee and the subsequent risk of TB infection and/or disease in the employee. Employees have three weeks post notification to respond, or their department director or chairperson will be notified. Any employee who has not had TB test results recorded in Occupational Health within six weeks of notification will be restricted from further work at UTMC.
- F. Occupational Health if any of their employees have been exposed to tuberculosis. It will be the responsibility of these outside contractors to contact such exposed individuals and arrange for their appropriate evaluation and follow-up.
- G. Exposed employees will have their TST or IGRA status established following a significant exposure. If the employee has not had a TST placed or IGRA performed within the last three months prior to exposure, a baseline TST or IGRA will take placed at that time. When the TST is negative, a follow-up TST will be repeated 8 10 weeks later. If IGRA is performed, instead of TST, and is negative following exposure, a second IGRA will be completed 8-10 weeks later.
- H. In all instances of nosocomial transmission of TB, an attempt will be made to identify the source. When a source patient is identified, drug susceptibility testing will be performed, and the results of these studies will be shared with all providers who evaluate and treat exposed or infected contacts.
- I. When an employee returns from providing patient care in an area that is high risk for TB, the employee will notify and undergo an evaluation by Occupational Health when returning to work.

VII. EDUCATION

- A. Responsibility for the education of staff concerning TB control policies, procedures and their implementation will be the responsibility of ICC, with assistance from Occupational Health, EHRS and Staff Development.
- B. All employees whose jobs involve a potential for exposure to TB will receive education that is specific for their work responsibilities. Training is conducted at the time of employment by EHRS and Infection Prevention and Control. Education is conducted annually thereafter. Although the level and detail of training may vary according to job description, the following elements are included in training for employees with potential work-related exposure.
 - i. Basic concepts of the transmission, pathogenesis and diagnosis of TB (including the difference between TB infection and active disease due to TB, potential signs and symptoms of TB and the possibility of late reactivation of asymptomatic TB infection).
 - ii. The risk of occupational exposure to TB, the rationale for isolation and situations that increase the risk of exposure to TB, and the steps to be taken if exposure occurs.
 - iii. The hierarchy of control measures designed to prevent transmission of TB outlined in this plan and a summary of policy/procedures related to this goal. Area-specific control measures will be provided to personnel who work in areas with special or unique risks.
 - iv. The rationale and necessity of annual TST or IGRAs in high-risk areas, the potential significance of a positive TST or IGRAs and the responsibility and obligation to participate in annual testing programs.
 - v. All records related to annual education and training of employees will be stored in a computer database. Compliance reports are sent to Senior Leadership Team on a regular basis by EHRS for Infection Control Training.

VIII. MANAGEMENT OF PATIENTS WITH KNOWN OR SUSPECTED TUBERCULOSIS

A. Recognition of Patients with Potential Tuberculosis Infection

i. Diagnosis of active TB should be considered in any patient with unexplained prolonged cough (lasting greater than 3 weeks) or complaints such as hemoptysis, night sweats, weight

loss, or fever in whom an alternate diagnosis has not been established or thought to be highly likely. All patients with suspected TB should be immediately placed in a designated Airborne Infection Isolation (AII) room (negative pressure) by their primary health caregiver until active infectious tuberculosis is excluded. It is the responsibility of the physicians and nurses caring for the individual patients to assess for signs and symptoms of TB and to initiate AII for suspected and/or known cases of TB. Questions concerning the medical or epidemiological rationale for continuing such isolation should be forwarded to Infection Prevention.

- a. If an AII room (negative pressure) is not available, movement of patients not requiring an AII room will immediately occur to open the AII room (negative pressure) for the suspect/active TB patient.
- b. If due to an unusually high census of patients requiring Airborne Isolation, place the patient in a private room, with a portable HEPA filtration unit, with the door closed and **immediately contact Infection Prevention** for determination of room changes.

NOTE: It is never acceptable to house a suspect/active TB patient in a regular patient room for an extended period of time. **See** <u>Policy 3364-109-ISO-404 Infection</u> **Control Precautions.**

ii. Groups at High Risk for TB

- a. Close contacts of active TB cases
- b. Individuals born in countries with high TB rates. See **Appendix I** for a list of areas with increased incidence of TB
- c. Alcoholics / IV drug abusers
- d. Residents and employees of high-risk congregate settings (e.g., long-term care facilities, homeless shelters, dormitories or prisons)
- e. Persons with certain medical conditions which increase the risk of developing clinical TB once tuberculosis infection has occurred:
 - > HIV infection (due to immunosuppression)
 - Silicosis
 - > Abnormal chest radiograph showing fibrotic lesions
 - Diabetes Mellitus
 - Prolonged corticosteroid therapy
 - > Immunosuppressive therapy
 - ► Hematologic and reticula endothelial diseases
 - > End-stage renal disease
 - > Intestinal bypass
 - Post-gastrectomy
 - Chronic malabsorption syndromes
 - ➤ Head, neck, and lung cancers
 - > Being 10% or more below the ideal body weight

iii. Signs and Symptoms of Active TB

- Persistent cough (>3 weeks)
- Hemoptysis (bloody sputum)
- > Fever
- Night Sweats
- Unexplained weight loss
- > Chest X-ray changes suggestive of TB
- Chest pain
- > Anorexia
- > Fatigue
- iv. Appropriate diagnostic studies should be conducted on all patients with suspected TB. These studies include sputum samples for AFB smears and AFB cultures (<u>initially three</u>

- consecutive sputum specimens collected at least eight hours apart, one of which should be an early morning specimen) and chest radiography. In selected instances, bronchoscopy, the induction of sputum for microbiologic studies, NG aspirations (pediatric patients), and/or bone marrow biopsy may be undertaken. All initial specimens from any source should have cultures performed. Drug susceptibility testing should be done on initial isolates.
- v. When patients with previously diagnosed TB are admitted to UTMC before there is microbiologic and/or clinical confirmation of cure, Airborne Infection Isolation (AII) room must be utilized pending further assessment and evaluation of their infectiousness. Questions concerning prior TB treatment at the patient's county health department should be directed to Infection Prevention at or pager 419-218-3744.

B. Inpatient Precautions for Patients

- i. All patients with known or suspected pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain *M. tuberculosis*) will be placed in Airborne Precautions in an appropriately ventilated (negative pressure) isolation room (see Section IX A 1) and Infection Prevention should be notified. For a list of approved / monitored negative pressure rooms see Appendix D: Airborne Infection Isolation (AII) Rooms for Known and Suspect TB Patients.
 - a. This Isolation will include admission to a designated isolation room and the wearing
 of proper protective respiratory devices by all persons entering the patient's room.
 Proper protective respiratory devices are described in detail in the EHRS Policy <u>Sosog4 Respiratory Protection Program</u>.
 - b. If a negative pressure room is not available, movement of patients not requiring AII will immediately occur to open the negative pressure room for the suspect/active TB patient.
 - c. If due to an unusually high census of patients <u>requiring Airborne Isolation</u>, place the patient in a private room, with a portable HEPA filtration unit, with the door closed and <u>immediately contact Infection Prevention</u> for determination of room changes. NOTE: It is never acceptable to house a suspect/active TB patient in a regular patient room for an extended period of time. **See Policy** 3364-109-ISO-404 Infection Control Precautions.
 - d. <u>Visitors</u> are to wear surgical masks while in the patient's room. The patient's primary nurse is responsible for providing the visitors with instructions on how to wear the mask before allowing the visitors to enter the patient's room.
 - e. For Pediatric Patients in the Emergency Room, Clinic or Surgical Setting placed on Airborne Precautions for known or suspect TB their primary caregivers must be suspected as the source of the patient's infection until they are proven to be free of TB disease.
 - ✓ Provide surgical masks for both the Pediatric Patient and any caregivers present during the visit
 - ✓ Place in AII room if available
- ii. If the patient is in an area that lacks AII rooms (e.g., Radiology) then a portable high-efficiency particulate air filter (HEPA) will be placed in the patient room (NOTE: this must be cleared first by paging Infection Prevention at 419-218-3744). The portable HEPA should be turned on and off following the instructions on the unit.
 - a. HEPAs can be ordered through Distribution Services. For immediate needs or emergent situations call the EHRS or Infection Prevention.
 - b. Contact Infection Prevention for further assistance.
 - c. Return all equipment by calling distribution. NOTE: If more than one person will be wearing a CAPR hood, it must be wiped out with an appropriate disinfectant wipe and allowed to dry prior to the next person wearing it.

- iii. Airborne Infection Isolation (AII) room is required for:
 - a. Patients presenting with signs and symptoms of TB (see Section VIII).
 - i. If a patient presents with only one or two of these signs and symptoms of TB and belongs to one of the groups that are at high-risk for TB, then suspicion for active TB should be raised.
 - b. Patients with **positive sputum smears for AFB** in whom an alternate diagnosis has **not** been established or strongly expected. If *M. tuberculosis* complex is identified, the drug susceptibility pattern of that isolate must be determined before AII is discontinued regardless of any subsequent smear results.
 - c. AII is required for any patient with active multi-drug resistant tuberculosis (MDR-TB). **Isolation for MDR-TB may not be discontinued without approval from an Infectious Disease physician.**
- iv. Infection Prevention and EHRS will ensure the use of proper precautions. Central Supply will assure that appropriate respiratory protection is available and Facilities will monitor ventilation status.
- v. Airborne Isolation (AII) room may be initiated by any caregiver or Infection Prevention personnel without retribution. Erroring on the side of caution is encouraged. **A provider order is NOT required to initiate isolation.**
- vi. Patients placed in an AII room will be instructed by the staff on the need to adhere to AII room policies and to cover their mouth and nose with tissues when coughing or sneezing. Patients are to stay in their AII rooms until tuberculosis has been ruled out. (See section "viii" below for the criteria required to discontinue isolation.)
 - a. The only time a patient may leave their room is if a diagnostic procedure must be performed outside of the AII room.
 - b. Patients who refuse to adhere to protocol will be reported immediately to Infection Prevention for legal/risk and Health Department consultation and review. Legal action may be taken to enforce appropriate AII precautions when requested by the attending physician, the Health Department or Infection Prevention. The UTMC Patient Safety Officer will assist local law enforcement as needed in enforcing courtordered isolation.
- vii. In the event that a patient with known or suspected TB must be transported to another area within the hospital for any reason, the patient must wear a surgical mask that covers the nose and mouth during the period of transport and while in an area that is not a designated AII.
 - a. Persons who transport such patients **do not** need to wear respiratory protection outside the AII room while the patient is wearing a mask.
 - b. In instances where diagnostic testing must be done outside of the AII room, efforts to schedule the procedure at the end of the day and at a time when it can be performed rapidly and without prolonged waiting are encouraged.

viii. Discontinuation of Airborne Isolation (AII)

- a. A physician order is required to discontinue AII, along with the appropriately documented rationale for the decision.
- b. Patient with **confirmed** active pulmonary or laryngeal TB who have **sputum smears positive for AFB are considered infectious and must be kept on AII until**:
 - > They have three consecutive sputum smears collected at least eight (8) hours apart which are negative. These specimens are not to be collected until at least fourteen (14) days of treatment and the last smear positive specimen should have been collected at least seven (7) days previously to the three negative sputum smears; **AND**

- They have been compliant on TB medications to which the organism is judged to be susceptible for at least 14 days of therapy; **AND**
- > There is evidence of clinical response to TB treatment
- c. In instances in which an alternate diagnosis has not been established, and TB is still considered in the differential diagnosis, <u>AII may be discontinued under the following</u> circumstances:
 - ➤ The patient has three consecutive sputum smears collected at least eight (8) hours apart which are negative; **AND**
 - > The patient has been compliant on TB medications to which the organism is judged to be susceptible for at least 14 days of therapy; **AND**
 - ➤ There is evidence of clinical response to TB treatment
- d. AII room is not required for patients admitted with a diagnosis of "rule out tuberculosis" if that diagnosis is considered unlikely by consultation with an Infectious Disease (ID) Physician; **AND** this is documented in the Medical Record by the ID Physician.
- e. When an alternate diagnosis to tuberculosis is either confirmed or deemed highly probable, the attending physician will document the findings and the supportive data in the patient's medical record.
- f. For patients in whom adequate sputum cannot be obtained, Airborne Isolation may be removed if:
 - ➤ An alternate diagnosis or explanation of symptoms exists;
 - An evaluation by an Infectious Disease Physician has deemed TB unlikely.
- g. Airborne Isolation may be discontinued for patients with soft tissue or open draining TB lesions when the wound is either no longer draining or the draining material no longer contains Acid-Fast material on at least two occasions and the patient is on effective anti-tuberculosis chemotherapy.
- h. Under special circumstances, AII may be discontinued at the discretion of the Chairperson of the Infection Control Committee.

ix. Discharge Planning Criteria

- a. Unless discharged to an institution with AII room facilities or home with restrictions as required by the Health Department in the patient's county of residence, discharge of institutionalized patients with active TB requires a minimum of two criteria:
 - i. Initial therapy with a minimum of four anti-tuberculosis drugs until susceptibility test results are known, and
 - ii. At least three negative AFB smears collected at least eight (8) hours apart with specimens collected after 14 days of anti-tuberculosis drugs.

The Health Department in the patient's county of residence must be notified no less than 48 business hours before a patient with active tuberculosis is discharged (see Appendix A). The Infection Prevention staff will provide assistance to discharge planners, as needed, in contacting the patient's local health department.

- b. Patients who may be infectious at the time of discharge should only be discharged to other facilities with AII room capabilities or to home unless the Health Department in the patient's county of residence has approved alternative arrangements. The local Health Department has final say on where a patient may be discharged to.
- c. It is the responsibility of the attending physician to write discharge orders that adhere to provisions described above. These criteria can only be altered at the discretion of the Chairperson of the Infection Control Committee in corroboration with the patient's personal physician and/or the local Health Department.

C. Outpatient Management of Patients (Refer to Appendix B)

i. For all clinics:

- a. Notify Infection Prevention when patients are seen (or scheduled to be seen) for known or suspected TB in clinics. Infection Prevention and Occupational Health will provide advice concerning the use of proper precautions and will ensure that confirmed employee exposures are evaluated.
- b. If a patient with known or suspected infectious pulmonary or laryngeal tuberculosis (or open draining wounds or abscesses that contain or are suspected of containing M. tuberculosis) must be seen in an outpatient clinic, and the visit cannot be rescheduled to a time when the patient is no longer considered infectious, the clinic should be notified prior to the patient's arrival.
- c. The *patient should be instructed to wear a surgical mask* when entering the building where the clinic is located and the clinic staff should place the patient directly into the exam or procedure room and close the door the patient should not spend any time in a waiting room with other patients or visitors. These precautions should also be taken with <u>coughing</u> children with known or suspected tuberculosis. If the patient can wear a surgical mask during the entire visit, employees do not need to take respiratory precautions.
 - i. If the patient can't tolerate wearing a surgical mask for the entire visit:
 - i. Reschedule the appointment until the patient is determined to be non-infectious by the local health department.
 - ii. If the patient must be seen, schedule for the last appointment of the day, ask patient to arrive at a time when they can immediately be escorted to a treatment room. All staff entering the treatment room or in close contact (3 to 6 feet of the patient) must wear CAPR or N95 masks during the entire visit.
 - iii. When the appointment is finished, escort patient directly out of the building.
 - iv. If additional testing is required (i.e., x-ray or lab work) call the appropriate department, inform them of the diagnosis and need to schedule patient at end of shift with appropriate PPE
- d. If the clinic is not equipped to handle TB patients (employees are not fit-tested and ventilation is not adequate) and the patient cannot wear a surgical mask during the entire visit, consider referring the patient to a clinic that is equipped to handle TB patients, an Emergency Department, or the health department in the patient's county of residence. Clearing ventilation time for exam rooms under these circumstances (after the patient has left) requires not using the room for one hour with the door closed. After the one hour has passed, staff can clean the room and use as normal.
- e. Patients are no longer considered infectious if they meet all three criteria that follow:
 - They have three consecutive sputum smears collected at least eight (8) hours apart which are negative. These specimens are not to be collected until at least fourteen (14) days of treatment and the last smear positive specimen should have been collected at least seven (7) days previously to the three negative sputum smears; **AND**
 - They have been compliant on TB medications to which the organism is judged to be susceptible for at least 14 days of therapy; AND
 - ➤ There is evidence of clinical response to TB treatment.
- f. Before discontinuing AII precautions for subsequent clinic visits by the patient, clinic personnel should obtain verification that the patient is receiving effective therapy and is no longer infectious (contact the Health Department in the county of the patient's residence).
- ii. <u>In all UTMC on-campus clinics, if the patient cannot wear a surgical mask for the entire visit:</u>

- a. If an AII room is not available, a portable HEPA filter unit should be placed in the exam room or procedure room where the patient will be seen contact EHRS and Distribution Services to access a HEPA filter unit. The HEPA filter should be turned on and off following the instructions on the unit. For immediate needs or emergent situations call the EHRS Safety office.
- b. All employees entering the room or enclosed area where there is a patient who is not wearing a surgical mask and has known or suspected TB must wear an appropriate respiratory protection device. Proper protective respiratory devices include N95 respirator masks for those employees who are fit-tested by Occupational Health or EHRS and a Controlled Air Purifying Respiratory (CAPR) for those who are not fit tested. If CAPRs are needed in an area where they are not stocked or if additional CAPRs are needed they can be obtained through Distribution Services or EHRS.

iii. For off-site clinics:

- a. Before the patient arrives confirm that the patient is no longer infectious or reschedule the visit if medically possible.
- b. If the suspicion of infectious TB disease is discovered during a clinic visit, place a surgical mask on the patient as soon as possible and place the patient in an exam room with the door closed. Contact the health department in the patient's county of residence and make plans to refer the patient. Notify Infection Prevention by pager (419-218-3744).
- c. Keep the patient in the closed exam room until the patient referral is complete. Provide the patient with surgical mask(s) for use when traveling to home or the next referral location and educate the patient on the need to wear the mask at all times when out in public.
- d. Ventilation time for exam rooms if the patient was not able to wear a surgical mask, is one hour with the door closed after the patient has left the room. Once the hour has passed, the room can be cleaned and put back into service.

D. Engineering Controls

i. Airborne Infection Isolation (AII) Rooms – Inpatient

Patients with known or suspected tuberculosis will be placed inn AII rooms following the criteria described in Appendix D. The doors of these AII rooms must remain closed. Allow 30 minutes with the door closed after a known or rule out TB patient leaves an AII room before entering without respiratory protection. Such designated AII rooms remain under negative air pressure with respect to the corridor, have a minimum of 12 air exchanges per hour and have appropriate exhaust capabilities. Facilities monitors this negative airflow periodically using a smoke test. In addition, a list of AII rooms (See Appendix D) will be maintained by Facilities and EHRS and provided to any bed control personnel, departmental managers, nurse managers and Infection Prevention. It is the responsibility of Facilities to maintain records on the testing and utilization of these isolation rooms and to notify the Infection Control Committee of deficiencies and inadequacies of ventilation controls.

ii. Portable High-Efficiency Particulate Filter Units

Portable high-efficiency particulate air (HEPA) filter units will be used in the control of tuberculosis in known or suspected cases of infectious TB who are hospitalized in the Operating Room, the Ambulatory Care areas, the Outpatient Clinics, the Radiology departments and the Interventional Cardiac Catheterization Laboratory **or any area where such patients may be housed and recommended AII ventilation is not available with approval from Infection Prevention**. The portable HEPA should be turned on and off following the instructions on the unit. EHRS will be responsible for education concerning the proper utilization of such devices. Portable HEPAs are available through Distribution Services. For immediate needs or emergent situations call Central Supply to obtain a HEPA filter. EHRS and Infection Prevention and Control

are responsible for providing on-call advice concerning the use and advisability of such units and for preparing and maintaining the "Portable HEPA Operating Instructions". Clinical Engineering / Biomed is responsible for the electrical safety, maintenance and motor performance of the units.

E. High Hazard Procedures

i. Cough-inducing procedures (e.g., bronchoscopy, sputum collection, sputum induction, aerosolized pentamidine treatment, etc.) on patients with known or suspected TB should be performed in rooms that meet the ventilation requirements as outlined for AII rooms (Appendix D). If such rooms are not available, contact Infection Prevention via pager (419-218-3744) to review options and possible need for supplemental control devices such as a portable HEPA. The portable HEPA should be turned on and off following the instructions on the unit. EHRS will be responsible for education concerning the proper utilization of such devices. Portable HEPAs are available through Distribution Services.

After completion of cough-inducing procedures, patients with known or suspected TB must remain in the AII room/portable HEPA room with the door closed until coughing subsides and be instructed to use tissues to cover their mouth and nose when coughing. Cough-inducing procedures other than inductions to collect sputum samples for TB evaluation should not be performed on patients with active TB unless absolutely necessary. Employees must wear respiratory protection while cough-inducing procedures are performed on patients with known or suspected tuberculosis. Patients with known or suspected TB who are recovering from sedatives or anesthesia following procedures such as bronchoscopy must be monitored in a separate AII room. After the patient leaves the treatment or procedure room, the room door should remain closed for a period of 30 minutes to allow for proper air turn over. During this time, the door must remain closed, employees should wear appropriate respiratory protection when entering the room and, if used, the portable HEPA should be left running during this time. After 30 minutes with the door closed the room may be cleaned and used as normal.

ii. Aerosol-Generating Procedures:

a. Laboratory workers handling specimens potentially containing TB organisms must adhere to the CDC/NIH guidelines. Procedures causing aerosolization of TB must be performed within a Biological Safety cabinet (BSC).

F. Respiratory Protection

- i. All employees must wear an appropriate respiratory protection device to enter an enclosed area where a known or suspected tuberculosis patient or non-human primate is located.
- ii. Appropriate respiratory protection is worn by all personnel performing or assisting in cough inducing procedures such as bronchoscopy or the delivery of aerosolized pentamidine treatments on patients with known or suspected TB. Appropriate respiratory protection must also be worn by personnel mixing or administering BCG outside of a Biological Safety cabinet.
- iii. Appropriate respiratory protection is worn by all personnel performing or exposed to TB aerosol-generating procedures in the autopsy suite or in the laboratory and those Engineering and Operations HVAC employees who may be exposed to TB aerosols in the air handling system.
- iv. The Respiratory Protection Program is administered by EHRS.
- v. The N95 respirator mask (N95)

- a. A list of personnel requiring N95 respirator fit-testing can be found by viewing the **S08-034 Respiratory Protection Program**.
- b. The primary respiratory protection device is the CAPR.
- c. Training on the proper use of respiratory protection is required and is provided by either Occupational Health, EHRS Services, or the unit director prior to initial use and annually thereafter.
- d. The N95 will be available in areas housing patients with the possibility of requiring an AII room. The N95 mask is approved for individual use only and cannot be shared between medical personnel working in the same area at different times. The mask cannot be used between patients. It can be reused with the same patient, by the same employee for up to 8 hours, as long as: 1) it is properly stored, 2) it is not visibly contaminated or wet, and 3) it is intact (e.g., not crushed or torn). The N95 can NOT be written on or decorated.
 - It is important to note that these respirators are authorized for use in protecting employees from TB droplet nuclei.
- e. N95 respirator masks can be ordered from Distribution Services and are also stocked on the AII Carts.
- f. <u>Employees must wear the N95 respirator mask (type and size) that they</u> were fit-tested for to ensure a proper seal.
- g. <u>Employees will conduct a "user seal-check" prior to each use of the N95 respirator mask. See Appendix G.</u>
- h. Priority fit-testing for the N95 is possible for small numbers of personnel that are providing direct care to a patient on AII on the non-fit-tested nursing units when the patient cannot be moved to a fit-tested nursing unit for medical reasons. This decision will be made in collaboration with Infection Prevention and EHRS.

vi. CAPR

- a. A list of personnel designated as CAPR users can be found in Policy **So8-034 Respiratory Protection Program.**
- b. The CAPR will be used by all employees that are not fit-tested with the N95 mask including those employees with facial hair interfering with the sealing surface of the N95.
- c. Training on the proper use of the CAPR is required and is provided by Occupational Health, EHRS, and/or the unit director. On-line training for the CAPR is also required through the Safety Test Bank. The module is called CAPR Use at UTMC. Contact EHRS at 419-530-3600 or through the operator for assistance in utilizing the CAPRs.
- d. CAPRs are located in Central Supply and must be ordered (AII Cart will be delivered to the nursing unit). Disposable CAPR inserts and face coverings can be reordered through Distribution Services.
- vii. **Note:** Anytime a person wearing a respirator of any kind experiences difficulty breathing, chest pain, or other symptoms they should exit the room and remove the respirator. If these symptoms are not relieved, seek medical attention.

viii. Respirator Approval Process

- a. Employees may only wear the respirator for which they have been approved. Substitution by manufacturer, size, or model is not allowed.
- b. For full information on types and use of Respirators see **Policy So8-034 Respiratory Protection Program.**

ix. Monitoring

a. <u>Failure of designated personnel to comply with the Respiratory Protection Program constitutes a violation of UTMC work rules.</u>

IX. APPENDICES

Appendix A: County and State of Ohio Public Health Services

A. Local Health Departments

Tuberculosis is a reportable disease in Ohio. Chapter 3701 lays out the requirement for Hospitals and providers to report communicable diseases. Chapter 339.78 of the Ohio Revised Code requires: When a physician completes diagnostic studies confirming that an individual has tuberculosis, the physician shall report the confirmed case of tuberculosis to the county or district tuberculosis control unit. A physician shall make a report to the tuberculosis control unit prior to completion of diagnostic studies if the signs and symptoms demonstrated by an individual are sufficient for the physician to suspect that the individual has tuberculosis. At any time it is determined that an individual's tuberculosis is resistant to one or more drugs, the physician shall make a report to the unit

Physicians or the Infection Prevention Department at UTMC will forward case reports to the health department of the patient's county of residence who will then forward them to the Ohio Department of Health. Cases of known or suspected TB should be reported by the end of the next business day.

<u>Local Health Departments</u> provide the following TB control services regardless of the patient's ability to pay:

- i. Follow-up of all contacts of cases and collaboration with other counties as needed
- ii. Directly observed treatment for active cases
- iii. Assistance in locating clinic services
- iv. All tuberculosis medication for prophylaxis and treatment if the patient is unable to purchase these on their own
- v. Tuberculin skin testing or IGRA
- vi. Chest x-ray as indicated for persons with a positive TST or IGRA
- vii. *M. tuberculosis* evaluation of persons with a previous positive TST or IGRA and a negative chest x-ray
- viii. Maintenance of a registry of patients with tuberculosis who reside in the county

B. Ohio Department of Health

Tuberculosis is a reportable disease in Ohio and requires:

- i. Case Report: Licensed providers must report cases and suspected cases of reportable communicable diseases and conditions in persons who have consulted them professionally (see above).
- ii. Laboratory Report: Each smear positive for Acid-Fast bacilli and each culture positive for *M. tuberculosis* should be reported by the end of the next business day after receiving the report. The completed report is sent to the Health Department of the patient's county of residence.

C. Statutes of the State of Ohio provide the following for TB control:

- i. **Duty to pay:** outpatient treatment paid for by the patient's local health department.
- ii. **Public health powers to direct:** examination, outpatient care, in-home isolation, or hospitalization for persons with (or suspect) tuberculosis.
- iii. **Confidentiality**: Protection is provided to the individual, but release of information for statistical purposes, public health control measures, and to medical persons providing care for a patient is enabled.

Appendix B: Management of Known and Suspect Patients in Outpatient Clinics

- 1. When a known or suspected TB patient is scheduled to attend a clinic appointment, do the following:
 - a. Notify Infection Prevention and Control via pager (419-218-3744)
 - b. Request a HEPA Filter Unit and CAPR cart from Distribution Services call ahead to assure the cart has arrived prior to the patient.
 - c. Schedule the patient for the last appointment of the day.
 - d. Ask the patient to wear a surgical mask during the entire visit to the facility. If needed provide the patient with the surgical mask as soon as they enter the area.
 - e. Patients with suspected or confirmed TB disease should be placed in a separate room (e.g., treatment room) with the door closed, apart from other patients and not in an open waiting area.
 - f. If the patient is unable to tolerate a mask, they should be scheduled at the end of the day and educated on observing strict respiratory hygiene and cough etiquette.
 - g. If the patient is unable to tolerate wearing a mask throughout the entire visit, then staff entering the room must wear a CAPR.
 - h. All cough-inducing and aerosol-generating procedures should be performed in locations that have appropriate environmental control (e.g., in a booth or negative air pressure room) and should remain in that location until coughing subsides. When possible, schedule all cough-inducing and / or aerosol-generating procedures in the hospital setting where Airborne Infection Isolation (AII) rooms (negative pressure) are available.
 - i. After the patient leaves the outpatient treatment room, close the door and allow it to remain closed for 1 hour. After 1 hour has passed the room may be opened and cleaned for use with the next patient. Note: Allowing the room to sit with the door closed allows for proper turn-over of room air and for any suspended TB particles to fall. Once TB touches the surface it is no longer considered active.
 - i. Note: Rooms with an average air exchange of 6 per hour take approximately 69 minutes to clear a room 99.9%; rooms with an air exchange of 12 per hour takes approximately 35 minutes to clear a room 99.9%. For comparison, typical Surgical Suites have air exchanges of 15 to 20 per hour.

Appendix C: TB Surveillance Groups

A. New Employees – all new employees will complete a **health screening questionnaire** in addition to the following based upon their status at time of the pre-employment screening:

	1 .
Employee Type	Required New Employee Screening
Any new employee who will work in a clinical	Screening Questionnaire
setting involving patient care and/or ancillary	IGRA Testing
services that involve direct face-to-face contact with	*A two-step TST may be substituted for IGRA
patients (includes: students, healthcare workers,	testing for those persons not from a country
trainees and volunteers).	defined as high risk for TB and without history
	of exposure to TB.
Any employee, working in a non-clinical setting,	Screening Questionnaire
from a country defined as high risk for Tuberculosis	IGRA Testing
by the World Health Organization (WHO).	
New employees working in non-clinical settings who	Screening Questionnaire only
are NOT from a country defined as high risk for	
Tuberculosis by the WHO.	

NOTE: a person, by court order, may be held for a time frame determined by the court, to determine their clinical and infectious tuberculosis status as a public health precaution. Such a person should have a reasonable possibility of having an infectious form of tuberculosis.

B. Testing and Follow-Up Requirements – all employees receive a **health screening questionnaire** in addition to:

Current Status	Required Testing	Results	Follow Up Required
No Prior Testing	IGRA** or 2 Step TST*	Positive	Chest X-ray and referral to Family Medicine. Cannot begin work until cleared medically.
No Prior Testing	IGRA or 2 Step TST	Negative	Can begin work.
Undocumented positive responder	IGRA or 2 Step TST	Positive	Chest X-ray and referral to Family Medicine. Cannot begin work until cleared medically.
Undocumented positive responder	IGRA or 2 Step TST	Negative	Can begin work.
Previous negative responder	IGRA or 2 Step TST***	Positive	Chest X-ray and referral to Occupational Health or Primary Care Provider. Cannot begin work until cleared medically.
Previous negative responder	IGRA or 2 Step TST***	Negative	Can begin work.
Previous documented positive responder	One baseline Chest X-ray (if none in past 12 months)	Negative	Can begin work.
Previous documented positive responder	One baseline Chest X-ray (if none in past 12 months)	Evidence of active disease	Referral to Occupational Health or Primary Care Provider. Cannot begin work until cleared medically.
Foreign born from documented High-Risk Country; History of BCG; High Risk History of exposure	IGRA or 2 Step TST	Negative	Can begin work.
Foreign born from documented High-Risk Country; History of BCG; High Risk History of exposure	IGRA or 2 Step TST	Positive	Chest X-ray and referral to Family Medicine. Cannot begin work until cleared medically.

^{*}TST = Tuberculin Skin Test

1. Annual Requirements

- a. All personnel that process specimens for the recovery of Acid-Fast Bacilli (AFB) are required to have annual testing for *M. tuberculosis* utilizing a TST or an IGRA
 - i. Known previous positive responders will be required to complete a screening questionnaire for symptoms;
 - 1. Symptoms present: Chest x-ray and referral to Occupational Health or Primary Care Provider for work up
 - 2. Asymptomatic: no follow up required
 - ii. All personnel that do not process AFB specimens are tested upon hire and if an exposure occurs
- b. Any employee that converts from a negative responder to a positive responder will be referred immediately for a chest x-ray and to Occupational Health or Primary Care Provider for follow up
- 2. Known or Suspected Exposure to active *M. tuberculosis* in addition to a screening questionnaire, all exposed employees will be tested for *M. tuberculosis* through Occupational Health. *Goal is to complete initial testing within 18 days of exposure.*

		<i>y</i>	J <u>I</u>		_
Current Sta	tus Re	guired Testing	Results	Follow Up Required	

^{**}IGRA = Interferon Gamma Release Assav

^{***}A single TST may be used if a previous negative TST is documented within the past 12 months.

Previous negative responder	IGRA or 2 Step TST	Negative	Repeat testing 8-10 weeks; If second testing results are negative – no further follow up required
Previous negative responder	IGRA or 2 Step TST	Positive	Chest X-ray and referral for follow up with Occupational Health or Primary Care Provider
Previous known TST or IGRA positive responder	Symptom Screen	Negative	Repeat screening in 8-10 weeks X 1; If second testing results are negative – no further follow up required
Previous known TST or IGRA positive responder	Symptom Screen	Positive	Chest X-ray and referral for follow up with Occupational Health or Primary Care Provider

3. Interpretation of tuberculin skin test and IGRA test results according to the purpose of testing for *M. tuberculosis* infection in a health-care setting.

Purpose of testing	TST	IGRA
Baseline	≥10mm is considered a positive result (either first or second step): 0-9mm is considered a negative result	Positive
Serial testing without known exposure	Increase of ≥10mm is considered a positive result (TST Conversion)	Change from negative to positive (IGRA Conversion)
Known exposure (close contact)	≥5mm is considered a positive result in persons who have a baseline TST result of omm; an increase of ≥10 mm is considered a positive result in persons with a negative baseline TST result or previous follow-up screening TST result of >0 mm.	Change to positive

NOTE:

- A. In the instance of post exposure testing, a change from a negative TST to a positive should not be interpreted as a boosted result. This change indicates a TST conversion, recent exposure, transmission, and infection.
- B. All healthcare workers who are immunocompromised should be referred for a medical and diagnostic evaluation for any TST result of ≥5mm on baseline or follow-up screening.

Appendix D: Airborne Infection Isolation (AII) rooms for Known and Suspect TB Patients

Patients in AII should be placed in one of these rooms. If all of these rooms are occupied by patients requiring AII, or the unit is not appropriate for placement of the patient, contact Infection Prevention for assistance with placement (pager 419-218-3744).

Contact Distribution Services to have CAPR Cart delivered to the appropriate location.

Room #	Description	Current Status	Room Monitor
H1260	ED Isolation Room #20	Tested, Ready for Use	Yes – Local
H1261	ED Isolation Room #19	Tested, Ready for Use	Yes – Local
H1268	ED Isolation Room #16	Tested, Ready for Use	Yes – Local
H1300	ED Isolation Room #21	Tested, Ready for Use	Yes – Local
HOPACU1	Pre-Op Room #1	Tested, Ready for Use	Yes – Local
HIPACU1	Recovery Room #1	Tested, Ready for Use	Yes – Local
H3176	3D	Tested, Ready for Use	Yes – Local/Engineers
H3223	MICU	Tested, Ready for Use	Yes – Local/Engineers

H3225	MICU	Tested, Ready for Use	Yes – Local/Engineers
H3227	MICU	Tested, Ready for Use	Yes – Local/Engineers
H3229	MICU	Tested, Ready for Use	Yes – Local/Engineers
H4176	4D Fan	Tested, Ready for Use	Yes – Local
H5176	5D Fan	Tested, Ready for Use	Yes – Local/Engineers
H5179	5D Fan	Tested, Ready for Use	Yes – Local/Engineers
H3107	3A Fan	For Emergency Use Only	NO
H3108	3A Fan	For Emergency Use Only	NO
H3109	3A Fan	For Emergency Use Only	NO
H3110	3A Fan	For Emergency Use Only	NO
H3111	3A Fan	For Emergency Use Only	NO
H6180	6D	For Emergency Use Only	NO
H6186	6D	For Emergency Use Only	Yes – Local
H6190	6D	For Emergency Use Only	Yes – Local
H2218	SICU Isolation room	Tested, Ready for Use	Yes – Local
H2220	SICU Isolation room	Tested, Ready for Use	Yes – Local
DH1565	Endo Cleaning Room	Tested, Ready for Use	NO – use smoke test or
			tissue test
DH1570	Endo Bronchoscopy	Tested, Ready for Use	Yes – Local
	Room		

These rooms are to be used only for designated TB AII rooms unless there are no other available rooms on the unit for placement of non-TB or AII patients. Contact Infection Prevention (pager 419-218-3744) for assistance with room placement issues related to infectious diseases.

See Appendix E for AII room preparation and maintenance during patient care of known or suspected TB disease/infection.

Appendix E: Airborne Infection Isolation Room Instructions

- 1) **PERFORM THE TISSUE TEST** by holding a small piece of tissue in front of the door just above the handle outside of the room. Slightly crack the door. The tissue should be pulled towards the room.
 - If there is a key switch beside the patient door, it should be set to negative (-).
 - If the room is not operating correctly or you need assistance call Facilities.
- 2) CLOSE ALL DOORS AND KEEP THEM CLOSED This is necessary to maintain negative airflow.

3) PLACE AIRBORNE INFECTION ISOLATION SIGNS ON THE DOOR TO THE PATIENT ROOM.

- Additional signs can be ordered through Distribution Services.
 - Call Distribution Services for a CAPR Cart ask that it be delivered STAT.
- Assure at least 3 types of **Respiratory Protection** are in the CAPR Cart for use by all employees and visitors:
 - ✓ NIOSH-Approved N95 Respirator Masks Medium and Small
 - ✓ Disposable Isolation Masks for use by visitors

- Controlled Air Purifying Respiratory (CAPR) for those who are not fit-tested with the N95:
 ✓ CAPR are plugged into the charger when not in use.
- CAPR can be ordered from Distribution Services.

4) WEAR APPROVED RESPIRATORY PROTECTION TO ENTER PATIENT ROOM

- An annual fit-test by Occupational Health, EHRS or designee is required to use an N95 respirator mask, otherwise use a CAPR.
- Perform a user "seal-check" each time you wear an N95 respirator mask.

5) THE PATIENT SHOULD WEAR A DISPOSABLE ISOLATION MASK IF TRANSPORT OUTSIDE OF THE ROOM IS ESSENTIAL

• Patients on Airborne Infection Isolation are not to leave their room unless medically necessary or Infection Prevention has given approval.

6) VISITORS SHOULD WEAR SURGICAL MASKS AT ALL TIMES WHILE WITH THE PATIENT.

• Nursing should provide instruction to visitors on how wear the surgical mask to assure the nose and mouth are fully covered and how to properly discard after use.

7) **NOTIFY INFECTION PREVENTION**: pager 419-218-3744

- Infection Prevention can provide guidance on all types of isolation precautions and ensure that the patient location is the best place for the patient.
- Infection Prevention will assist with coordinating with the health department in the patient's county
 of residence as needed.
- 8) BEFORE DISCONTINUING ISOLATION FOR A TB PATIENT NOTIFY INFECTION PREVENTION VIA PAGER (419-218-3744)
- 9) KEEP DOORS CLOSED FOR AT LEAST 30 MINUTES AFTER AN AIRBORNE INFECTION ISOLATION PATIENT LEAVES THE AII ROOM

Helping You Wear it Right

3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+

Application

Always read and follow User Instructions.



Remove the respirator from its packaging and hold with straps facing upward. Place the bottom strap under the center flaps next to the "ATTENTION" statement.



Fully open the top and bottom panels, bending the nosepiece around your thumb at center of the foam. Straps should separate when panels are opened. Make certain the bottom panel is unfolded and completely opened.



Place the respirator on your face so that the foam rests on your nose and the bottom panel is securely under your chin.



Pull the top strap over your head and position it high on the back of the head. Then, pull the bottom strap over your head and position it around your neck and below your ears.



Adjust for a comfortable fit by pulling the top panel toward the bridge of your nose and the bottom panel under your chin.

Make certain hair, facial hair, jewelry and clothing are not between your face and the respirator as they will interfere with fit.



Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.

Note: Always use two hands when molding the nosepiece. Pinching the nosepiece with one hand may result in improper fit and less effective respirator



Perform a **User Seal Check**

Check the seal of your respirator each time you use the respirator.

Place one or both hands completely over the middle panel. Inhale and exhale sharply. Be careful not to disturb the position of the respirator. If air leaks around your nose, re-adjust the nosepiece as described in Step 6. If air leaks around respirator edges, adjust panels and position of straps and make certain respirator edges fit snugly against the face. If you cannot achieve a proper seal, do not enter the contaminated area. See your supervisor.

Removal

Can be performed using one or both hands

One hand



Without touching the respirator facepiece, slowly lift the bottom strap from around your neck up over your head.

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Lift off the top strap. Do not touch the respirator.



Store or discard according to your facility's infection control policy.

Do's Don'ts

For wearing N95 respirators in non-surgical healthcare settings



N95 respirator

Tight-fitting cover that when properly fitted to the face protects the wearer from very small particles that float in the air, such as TB, measles, and chickenpox. It should fit the face tightly with no gapping. An N95 respirator is intended to provide more protection than a procedure mask by blocking at least 95 percent of very small (0.3 microns) particles. It is important to note that not all N95 respirators are tested for fluid resistance to be used as surgical N95s in the perioperative setting.

The Occupational Safety & Health
Administration (OSHA) may update guidance
related to masks as emerging pathogens arise
and new recommendations are developed.
Be on the lookout for updates by visiting
the OSHA website or consult your facility's
infection prevention or occupational health
department.

Learn more: www.osha.gov/SLTC/ respiratoryprotection/guidance.html

Do

- Check to make sure the N95 respirator has no defects such as holes or torn straps.
- Wear for protection against very small particles that float in the air (e.g., TB, measles, or chickenpox).
- Follow manufacturer's instructions for donning and doffing of N95 respirator.
- Ensure proper fit—making sure nose and mouth are completely covered. The N95 respirator must have a complete seal all around. Complete face seal check after donning the respirator.
- Mold the respirator over the bridge of your nose when putting it on to help keep the N95 respirator on and fitting properly. It is also helpful to press all around the face seal to be sure it is tightly in place.
- Tilt head forward and remove the N95 respirator by pulling bottom strap over back of head, followed by the top strap without touching the front of mask. Keep straps tight during the removal process.
- Discard an N95 respirator by touching straps only. Perform hand hygiene before and after use of an N95 respirator or any type of personal protective equipment, such as your gloves and gown.
- Remove the N95 respirator when no longer in clinical space and the patient intervention is complete.



- DON'T wear if wet or soiled; get a new N95 respirator.
- DON'T reuse; toss it after wearing once.
- DON'T let patients or visitors wear N95 respirators unless they've been fit tested to wear them.
- DON'T wear an N95 respirator that hasn't been properly fit tested. Proper fit is essential.
- DON'T use the N95 respirator if air leaks around the respirator edges.
- DON'T touch the front of the N95 respirator as it is contaminated after use. DON'T snap the straps, as that may spread germs.
- DON'T share your N95 respirator with others; germs can spread that way.
- DON'T leave an N95 respirator hanging around your neck.









Appendix G: Management of Known and Suspect Patients in the Operating Room

- 1) Because the Operating Room (OR) has recirculated air under positive pressure, whenever possible, surgery on patients with known or suspected TB should be postponed until TB has been ruled out or the patient is determined to no longer be infectious.
- 2) If surgery cannot be postponed then a portable HEPA must be placed in the room from the time the patient enters the room until after the room has been cleaned following the case, a minimum of 30 minutes after final cleaning. Use one portable HEPA per suite. The portable HEPA should be turned on and off following the instructions on the unit (if the instructions are missing call EHRS for assistance).
 - a. An alternative to a HEPA filter placement, surgery may be done in the designated OR that is negative pressure (OR9).
- 3) The case should be scheduled as the last case of the day.
- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) All employees entering the room or enclosed area must wear N95 respirator masks (or a CAPR). Since the OR is an area of low risk for TB transmission, fit-testing for the N95 respirator is not routinely required for the OR staff. In cases that suspicion for TB arises during surgery staff should replace their standard surgical masks with an N95 respirator without fit-testing or wear a CAPR. The N95 respirator mask provides acceptable temporary protection whether the employee is fit-tested or not. In cases where TB is suspected before the surgery, every effort will be made to identify those staff that will be working the particular OR suite and provide them with N95 respirator fit-testing prior to the procedure and or provide them with CAPR.
- 6) During postoperative recovery, the patient should be monitored and should be placed in a private room that meets recommended ventilation standards for TB isolation rooms (PACU isolation rooms are listed in Appendix D) or remain in the Operating Room with the portable HEPA filter still running.
- 7) Consult Appendix D for post-surgical room placement in an appropriate AII room.
- 8) In cases of known multi-drug resistant tuberculosis that require surgery, contact EHRS and Infection Prevention for coordination of additional engineering controls to be implemented by the Engineering and Operations HVAC division. Also contact Occupational Health to arrange for N95 respirator fit-testing for those employees working within the sterile field.

Appendix H: Management of Known and Suspected Tuberculosis Patients in the Cardiac Catheterization and Electrophysiology Laboratories

- 1) Because the Cardiac Catheterization Laboratory (Cath Lab) and the Electrophysiology Laboratory (EP Lab) lack an Airborne Infection Isolation procedure room, procedures on patients with known or suspected TB should be postponed until TB has been ruled out or the patient is determined to no longer be infectious.
- 2) If the procedure cannot be postponed then a portable high efficiency particulate air (HEPA) filter must be placed in the room from the time the patient enters the room until after the room has been cleaned following the case, a minimum of 30 minutes after final cleaning. The portable HEPA filter should be turned on and off following the instructions on the unit. Portable HEPAs are ordered through Distribution Services.
- 3) The case should be scheduled in an enclosed room and doors should be kept closed. The case should be scheduled as the last case of the day.
- 4) Bacterial/viral filters are used in the inspiratory and expiratory tubing of intubated patients with known or suspected TB.
- 5) All employees entering the room or enclosed area must wear an N95 respirator masks. If the employee was not able to be effectively fit tested a controlled air purifying respiratory (CAPR) designed for use in the OR if the employee works outside the sterile field must be worn. Since the Cath Lab and EP Lab are areas of low risk for TB transmission, routine fit-testing for the N95 respirator is not required. In cases that suspicion for TB arises during a procedure, staff should replace their standard surgical masks with an N95 respirator without fit-testing. A user seal-check should be performed. The N95 respirator mask provides acceptable temporary protection whether the employee is fit-tested or not. In cases where TB is suspected before the procedure, every effort will be made to identify those staff that will be working that particular case and provide them with N95 respirator fit-testing through Occupational Health or EHRS prior to the procedure.
- 6) During transport to and from the Cath Lab the patient is to wear a surgical mask. If possible, and the patient is not intubated, the patient is to wear a surgical mask during the entire procedure.

Appendix I: "High Burden Countries for Tuberculosis" Designated by the World Health Organization (WHO)(2022) and "Tuberculosis – United States, 2022" designated by the Centers for Disease Control and Prevention (CDC)

WHO updated the list in June 2021 and is valid until 2025. For the most current update, go to: https://www.stoptb.org/securing-quality-tb-care-all/high-burden-countries-tuberculosis

- 1. Angola
- 2. Bangladesh
- 3. Brazil
- 4. Central African Republic
- 5. China
- 6. Congo
- 7. Democratic People's Republic of Korea
- 8. Democratic Republic of Congo
- 9. Ethiopia
- 10. Gabon
- 11. India
- 12. Indonesia
- 13. Kenya
- 14. Lesotho
- 15. Liberia
- 16. Mexico
- 17. Mongolia
- 18. Mozambique
- 19. Myanmar
- 20. Namibia
- 21. Nigeria
- 22. Pakistan
- 23. Papua New Guinea
- 24. Philippines
- 25. Sierra Leone
- 26. South Africa
- 27. Thailand
- 28. Uganda
- 29. United Republic of Tanzania
- 30. Viet Nam
- 31. Zambia

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XI. MONITORING and APPROVAL

Approved:

- A. Annually, the Infection Prevention Department in conjunction with the Infection Control Committee (ICC), local Health Departments, Environmental Health and Radiation Safety and Occupational Health will complete a *TB Risk Assessment* and review the Tuberculosis Exposure Control Plan and Policy for evidence based best practice updated as needed.
- B. Approval will be through the ICC and the Medical Executive Committee of the Hospital.

/s/		
Michael Ellis, MD Chair, Infection Control Committee	Date	
/s/		
Puneet Sindhwani, MD Chair, Medical Executive Committee	Date	
/s/		
Michael Ellis, MD Chief Medical Officer	Date	