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TUBERCULOSIS PROTECTION IN RESEARCH ENVIRONMENTS

1. Background and Scope

Tuberculosis is a zoonotic disease that spreads rapidly in non-human primate colonies. Due to the devastating consequences of tuberculosis for non-human primates and the potential impact on associated research programs, personnel who enter non-human primate facilities will be screened anually to mitigate risk of infecting non-human primates with *Mycobacterium tuberculosis*.

The University of Pittsburgh also mandates semi-annual surveillance for *M. tuberculosis* exposure of all personnel who directly handle cultures of *M. tuberculosis*, animals infected with *M.tuberculosis*, or other specimens known to contain *M. tuberculosis* as part of this Tuberculosis Protection Program.

2. Procedure

All individuals, including visitors, entering non-human primate housing areas pose a risk of transmitting *M. tuberculosis* to the research animals, or of being exposed to animals with undiagnosed *M. tuberculosis* infections. Personnel handling unfixed primary tissues from non-human primates may be at risk of exposure to *M. tuberculosis*. All personnel who enter BSL-3/ABSL-3 facilities where research with *M. tuberculosis* is performed are also at risk for exposure.

All individuals at risk of exposure to *M. tuberculosis*, as described above, shall enroll in the University's Tuberculosis Protection Program.

3. Baseline Screening Guidelines

3.1. Baseline screening for *M. tuberculosis* exposure (TB screening) is required upon hire, or upon enrollment in the University Animal Exposure Surveillance Program or in the BSL-3 Occupational Health Program, if applicable, at Employee Health Services located in the UPMC MyHealth@Work clinic:

Medical Arts Building 3708 Fifth Ave, Suite 500 Pittsburgh, PA 15213 (412) 647-4949 Normal business hours 7AM – 3:30 PM, Monday-Friday

- 3.2. Personnel who have no written record of a TB screening within the past year (NHP users) or 6 months (*M. tuberculosis* workers) shall be screened via an Interferon-Gamma Release Assay (IGRA) or equivalent.
- 3.3. Personnel with a history of positive TB screening without knowledge of ever receiving Bacillus Calmette-Guerin immunization (BCG), or who know that they have received the BCG immunization *shall* inform Employee Health Services of this history.
 - 3.3.1.If the initial IGRA is negative and there are no other medical contraindications, the individual shall be cleared for work.

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- 3.3.2.If the IGRA is positive (e.g. latent TB), a chest radiograph and a medical history with a focus on symptoms suggestive of active pulmonary tuberculosis will be obtained. The participant may also be referred to the Allegheny County Health Department for follow-up at the discretion of the Employee Health Services.
 - 3.3.2.1. See Appendix 1 of this document for a summary of test result review and/or treatment procedures required for medical clearance of personnel where an IGRA screening test is positive.

4. Annual Screening Guidelines: Non-Human Primate Facility Entry, Non-Human Primate Tissue Handlers

- 4.1. All individuals entering non-human primate areas or handling unfixed non-human primate tissues shall undergo medical screening for active tuberculosis infection annually.
 - 4.1.1.Annual screening for personnel without prior history of positive Tuberculin Skin Test (TST) or BSC vaccination will be performed via TST or IGRA.
 - 4.1.1.1. If prior TST or IGRA was negative, and the current annual test is positive, this is considered to be a conversion. The individual will undergo medical evaluation and a chest radiograph will be obtained. Medical evaluation and clearance for work shall follow the steps outlined in Appendix 1.
 - 4.1.2.Personnel with a prior history of positive IGRA or positive TST (not BCG vaccinated) will be sent a Tuberculosis Health Questionnaire that asks the worker to self-identify any symptoms suggestive of active tuberculosis. The form must be completed, signed by the participant, and submitted to Employee Health Services annually. Medical evaluation of personnel indicating onset of symptoms suggestive of active tuberculosis is outlined in Appendix 1.

5. Semi-Annual Screening Guidelines: Mycobacterium tuberculosis Workers

5.1. All individuals directly handling cultures of, or animals infected with, *M. tuberculosis* shall undergo medical screening for active tuberculosis infection every six months. Semi-annual screening shall be via IGRA or TST (with no history of positive IGRA, TST, or BCG immunization). Personnel with history of positive TST or IGRA will be screened semi-annually with a Tuberculosis Health Questionnaire exclusively.

6. Implementation

6.1. Implementation of screening methods occurs in consultation with the University Attending Veterinarian, Principal Investigator and/or Environmental Health and Safety who assist the University Employee Health Services Medical Director in the evaluation of specific cases. If a consensus cannot be reached among these individuals, the final decision for work clearance will rest with the University Employee Health Services Medical Director (for *M. tuberculosis* research areas) and/or the University Attending Veterinarian (for research involving NHPs).

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- 6.1.1.Individuals refusing tuberculosis screening, declining the recommended clinical treatment, or failing to submit a completed Tuberculosis Health Questionnaire form shall be prohibited from entering non-human primate and/or *M. tuberculosis* research areas.
- 6.1.2.DLAR supervisors, Animal Facility Directors, and the Principal Investigator (or designee) are responsible for verifying current TB screening and clearance status of all entrants, including all visitors, into non-human primate or *M. tuberculosis* research areas under their supervision.
- 6.1.3.Individuals who manipulate non-fixed primary tissue from non-human primates who refuse tuberculosis screening, decline the recommended clinical treatment, or fail to submit a completed Tuberculosis Health Questionnaire shall be prohibited from handling unfixed non-human primate tissues.

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Appendix 1: Medical Clearance Procedures for Personnel with Positive IGRA, TST, or Tuberculosis Health Questionnaire Identified During Enrollment or Semi-Annual Screening

- 1. If the initial IGRA is positive upon enrollment, or if an Annual/Semi-annual screening results in a positive TST or Tuberculosis Health Questionnaire identifying symptoms suggestive of active tuberculosis, a chest radiograph and a medical history with a focus on symptoms suggestive of active pulmonary tuberculosis will be obtained.
- 2. If there is no clinical or radiographic evidence of active pulmonary disease and,
 - a. The individual <u>had</u> a documented negative IGRA or TST in the preceding 24 months, (e.g. latent TB; test result <u>represents a conversion</u>), the employee is restricted from contact with live non-human primates, or entry to *M. tuberculosis* research areas until appropriate medical evaluation and/or treatment plan (e.g. antibiotic therapy) has been completed, documented and reviewed by the Employee Health Services Medical Director. Clearance for return to contact with live non-human primates will be determined on a case-by-case basis, as applicable, by the University Attending Veterinarian in consultation with the Employee Health Services Medical Director.
 - b. In circumstances not described above, or where personnel are restricted from access to non-human primates, final clearance for beginning or returning to contact with live nonhuman primates will be determined on a case-by-case basis, as applicable, by the University Attending Veterinarian in consultation with the Employee Health Services Medical Director.
- 3. If there is clinical or radiographic evidence of active pulmonary tuberculosis, the employee is medically restricted.
 - a. This restriction is not removed until the individual provides documentation establishing that the clinical or radiographic findings can reasonably be attributed to a condition other than active pulmonary tuberculosis, or appropriate medical treatment has been initiated.
 - b. While on treatment the individual will be monitored by Employee Health Services for adherence to the treatment regimen.
 - c. These individuals will not be allowed to enter non-human primate or *M. tuberculosis* research areas until cleared by the University Employee Health Services Medical Director.
 - d. Further, the individual will not be cleared to return to any University workplace until the University Employee Health Services Medical Director is reasonably convinced that the individual does not represent a health risk.
 - e. If the medical recommendation is that the employee be prohibited from entry to non-human primate or M. tuberculosis work areas or from return to work at the University, the employee, supervisor, Human Resources and ACHD will be notified the day the decision is reached.