EAST CAROLINA UNIVERSITY

INFECTION CONTROL PLAN & BIOLOGICAL SAFETY POLICY

East Carolina University Respiratory Protection Program for Infectious Agents

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Approved by: Previously part of the Tuberculosis Control Plan

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Respiratory Protection Program: Tuberculosis and Other Infectious Agents

- Respiratory Protection

**Assignment of Responsibility**

The program is administered by the Office of Prospective Health. Prospective Health will evaluate ECU employees and medical students for use of respiratory protective devices for TB (and other infectious agents). Fit testing, and education about use and care of approved respiratory protective devices will be provided for clinical employees of departments with TB patient exposure potential, or exposure to other airborne diseases. Respiratory protection devices, in appropriate sizes and models, will be provided by the department to healthcare workers who may see patients in clinics with known or suspected TB or other airborne infectious disease. If exposure occurs at PCMH, respiratory protection devices will be provided by the hospital.

Research employees using infectious agents with potential for airborne spread may be included in a respiratory protection program when required by the ECU Biological Safety Committee.

All health care workers entering an enclosed area with a patient who has known or suspected tuberculosis or who is present when cough inducing procedures (e.g. bronchoscopy, transtracheal aspiration, administration of Pentamidine) are performed on patients with known or suspected tuberculosis, will wear a respiratory protective device that meets the OSHA recommended performance criteria. This device must be placed prior to entering the room and removed only after leaving the room.

Prospective Health will evaluate employees for ability to wear TB respiratory protection, via Respiratory Clearance questionnaire. (Refer to Appendix A). If needed, Prospective Health will evaluate employees via physical examination for respiratory clearance after review of their questionnaire. (Refer to Appendix B).

The TB respiratory protection program is administered by the Biological Safety Office. The Biological Safety Officer or designee will provide fit testing of respiratory protection devices and education in their use and care under the TB/Infectious Agent Respiratory Protection Policy.

**Worksite Specific Procedures**

I. Respiratory protection will be used in the following settings:

A. Research Use: When handling organisms spread by the airborne route (BL-3) or when creating aerosol of BL-2 organism outside
a biological safety cabinet AND when required by the
Institutional Biological Safety Committee review of the research
protocol.

B. Clinical Use:
1. When examining a patient known or suspected to be
infected with a micro-organism spread by airborne
route such as tuberculosis, smallpox and SARS. (See
Infection Control Policy for additional details on
isolation precaution and list of diseases or conditions
when respiratory protection must be used.
2. When handling clinical specimens from such a patient,
or manually cleaning a reusable device contaminated
with the secretions of such a patient.

C. Facilities Services:
1. Personnel involved in low-level remediation of mold
contaminated building materials
2. Area to be disrupted is less than 30 square feet in
surface area.

II. Respirator Selection:
A. Will be the responsibility of the office of Prospective Health. At
present, 3M N95 half-face masks will be used to protect against
tuberculosis and other airborne infectious disease in the clinical setting.
Healthcare workers who cannot be fitted, or who desire a higher level of
protection will use a powered air-purifying respirator (PAPR).

NOTE: The department of Pathology currently uses a 3M R95 filtering
face mask that provides protection from nuisance level organic vapors as
well as particulates, which is dimensionally identical to the 3M N95
mask and is CDC /NIOSH approved for Tuberculosis.

B. In order to facilitate the use of respiratory protection in both the ECU
Clinics and at Pitt County Memorial Hospital, BSOM mask selection
will be coordinated with the hospital.

III. Medical Evaluation:
Health care workers are screened to determine whether they are
physically able to wear an approved respiratory protective device. The
screening process is performed using the OSHA screening questionnaire
(Appendix A). There are few medical conditions that may be
compromised by the wearing of an approved N95 facemask in the
healthcare setting. The questionnaire is given to the employee or
medical student and is reviewed by Prospective Health. Employees
identified as having potential problems are further evaluated by the
Prospective Health physician or designee, via history and/or physical examination.

If Power Air-Purifying Particulate Respirators (PAPR) are used, education is provided on PAPR use. Fit testing of PAPR is not performed.

D. Fit Testing Procedure:
A qualitative fit test is used to determine whether a respiratory protective device adequately fits the particular health care worker. A qualitative fit procedure will be performed by the Office of Prospective Health outlined by the manufacturer of the Qualitative Fit Test Apparatus and per 29CFR 1910.134. Fit testing can detect only the face seal leakage that exists at the time of the fit testing. Face seal leakage can result from factors such as, incorrect face piece size or shape, beard growth on a wearer, incorrect positioning of a face piece on a wearers face, incorrect head strap tension or position, improper mask maintenance, and mask damage.

E. Categories of employees

Fit testing for masks to protect against Tuberculosis or other airborne infection is offered to all health care workers in clinical departments: Department of Medicine, Family Medicine, Pediatrics, Pathology, Radiation Oncology, Emergency Medicine, Surgery, OB-GYN, Physical Medicine, Rehabilitation, and ECU Medical Students.

Select Employees in Facilities Services who may encounter/remove moldy building materials will be fit tested

An interval history is done yearly on healthcare personnel at BSOM (Appendix C). Fit testing will be repeated on all users if the respiratory protection devices provided are changed, or if they experience a significant change in facial size or features. Each year a list of respiratory protective devices and sizes used will be sent to the departmental manager.

Per OSHA regulations, only those employees who enter tuberculosis isolation rooms or who perform high risk (cough inducing) procedures on known or suspected TB patients require frequent fit testing. Brody School of Medicine employees meeting this criteria would include Pulmonary specialists, intensivists, Infectious Disease specialists, some Surgeons and Gastroenterologist who do upper endoscopies and pathologist that do autopsies. These employees will be known as high risk or category A employees.
Tuberculosis is endemic to eastern North Carolina, so tuberculosis is frequently part of the differential diagnosis of patients seen in Brody clinics. All Brody School of Medicine clinical employees who have direct patient contact will be considered part of the Brody School of Medicine voluntary respiratory protection program for tuberculosis. Clinical employees who have direct patient contact would include physicians, nurses, physician assistants, nurse practitioners, medical office assistants, nurse assistants, phlebotomists, and physical therapists. These employees will be known as category B employees.

Both category A and B employees might encounter other airborne infectious diseases on rare basis, but this is not an expected occupational exposure.

All category A and B employees will receive a medical evaluation from Prospective Health and fit testing and/or training to use respiratory protection. Prospective Health will provide a list of respiratory protection sizes and devices to the department, after fit testing.

Category A and B employees will be medically screened once and fit tested upon employment. Both the employee and the employee’s manager will be provided with documentation of fit testing and N-95 mask size. Employees unable to pass the fit test will be instructed in the use and demonstration of the PAPR. Bearded employees will be instructed in the use and demonstration of the PAPR. Need for PAPR will also be conveyed to the ECU clinic manager.

Category A employees may be fit tested at regular intervals such as after every three years. Annual fit testing will be performed if required and enforced by OSHA.

Category B employees may be fit tested less frequently e.g. every five years.

Category A & B employees will be asked at their annual Employee Health update visit about facial changes that indicate that a change in mask size may have occurred. (Appendix C) Facial surgery, trauma, or a large amount of gained or lost weight may require employee to be re fit tested. Change in health status will be inquired about in employees with a past positive PPD to ascertain whether an updated medical screening is indicated (Appendix C).

Employees using respiratory protection for other airborne infectious agents, e.g. research labs, will be fit-tested as per category A for the
duration of the research project.

E. Training:
The user is trained in the proper use of the approved respiratory protective devices and their limitations. Training will provide the employee an opportunity to handle the protective device, have it fitted properly, test its face piece to face seal, wear it in normal air for a long familiarity, and finally wear it in a test atmosphere. Each user will receive fitting and instructions, including demonstrations and practice on how the protective device should be worn, and shown conditions that prevent a good face seal. Such conditions may be a beard, side burns, or temple pieces on glasses. Also, the absence of one or both dentures can seriously affect the fit of a face piece. To ensure proper protection, the face piece fit is checked by the wearer each time the wearer puts on the approved respiratory protective device. This is done by following the manufacturer's face piece fitting instructions. If the employee will use PAPR, similar demonstration and instruction will be performed.

Fit tests will be documented on the form in Appendix D. The annual bloodborne pathogen/tuberculosis training for employees will include information about use of respiratory protection. Mold training will be provided annually in conjunction with asbestos training for Facilities Services.

F. Respiratory Protective Device Inspection, Cleaning, Maintenance and Storage:

Each clinical area will provide a stock of respiratory protection devices in sizes or type needed by their employees. The devices will be stored in an area convenient to access and use. The N95 or R95 masks used are disposable. These should not be cleaned, but disposed of when contaminated, or after use.

The PAPR should be cleaned according to manufacturer’s instructions. PAPR hoods will be cleaned each use, as a non-critical item per ECU Infection Control Policy on disinfection. They will be stored in a containment area near the battery packs which will be kept charged at all times Respirators, training, and medical evaluations will be provided at no cost to the ECU employees.

G. Limitations:
The particulate respirator used for protection from microorganisms will not provide protection against gases or vapors and do not supply oxygen. They are not to be used in such situations. Employees who
need additional protection from Infectious agents, beyond that provided by the HEPA mask should use the PAPR. Use of the N99 masks minimally increases the effectiveness of the mask, while the PAPR provides 2.5X the effectiveness of a half facemask.

H. Program Evaluations
The respiratory protective program is evaluated at least annually. Elements of the program that are evaluated include: work practices and acceptance of respiratory protective devices, including comfort and interference with duties. Biological Safety will perform the annual program evaluation at the end of each calendar year. Results will be presented to the Infection Control Committee for clinical issues and/or to the Biological Safety Committee for research use issues.
Appendix A

ECU OSHA Questionnaire for Respirator Use for Tuberculosis or other Airborne Infectious Agents

For every clinical employee who will use an N-95 half-face mask or Powered Air Purifying respirator for TB prevention.

Part A Section 1

1. Today’s date: ________________________________

2. Your name: ___________________________ Department: __________

3. Your age: ________________________________

4. Sex: Male Female


6. Your job title: ___________________________ 7. Work Phone number ________

8. You may contact the Prospective Health professional who will review this questionnaire at 744-2070.

9. You may use either a:
   a. Disposable N-95 filter-mask, OR
   b. Powered-air purifying respirator.

10. a. Have you worn a respirator in the past? (circle one): Yes No
    If “yes,” what type(s): ________________________________
    b. Do you perform any of the following procedures in either the hospital or clinic setting on known or suspect TB patients?
       please check Yes, No
       Bronchoscopy ______ Emergency Dental Procedures ___
       Transtracheal Aspiration ______ Endoscopy ______
       Endotracheal Intubation ______ Autopsy _______
       Endotracheal Suctioning ______ Examine Patients with known
       or suspected Active TB ______ (in past 12 months)
Part A Section 2

1. Do you currently smoke tobacco, or have you smoked tobacco in the last month?  
   Yes  No

2. Have you ever had any of the following conditions?
   a. Seizures (fits)  
      Yes  No
   b. Diabetes (sugar disease)  
      Yes  No
   c. Allergic reactions that interfere with your breathing  
      Yes  No
   d. Claustrophobia (fear of closed-in places)  
      Yes  No
   e. Trouble smelling odors  
      Yes  No

3. Have you ever had any of the following pulmonary or lung problems?
   a. Asbestosis  
      Yes  No
   b. Asthma  
      Yes  No
   c. Chronic bronchitis  
      Yes  No
   d. Emphysema  
      Yes  No
   e. Pneumonia  
      Yes  No
   f. Tuberculosis  
      Yes  No
   g. Silicosis  
      Yes  No
   h. Pneumothorax (collapsed lung)  
      Yes  No
   i. Lung cancer  
      Yes  No
   j. Broken ribs  
      Yes  No
   k. Any chest injuries or surgeries  
      Yes  No
   l. Any other lung problem that you’ve been told about  
      Yes  No

4. Do you currently have any of the following symptoms of pulmonary or lung illness?
   a. Shortness of breath  
      Yes  No
   b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline  
      Yes  No
   c. Shortness of breath when walking with other people at an ordinary pace on level ground  
      Yes  No
   d. Have to stop for breath when walking at your own pace on level ground  
      Yes  No
   e. Shortness of breath when washing or dressing yourself  
      Yes  No
   f. Shortness of breath that interferes with your job  
      Yes  No
   g. Coughing that produces phlegm (thick sputum)  
      Yes  No
   h. Coughing that wakes you early in the morning  
      Yes  No
   i. Coughing that occurs mostly when you are lying down  
      Yes  No
   j. Coughing up blood in the last month  
      Yes  No
   k. Wheezing  
      Yes  No
   l. Wheezing that interferes with your job  
      Yes  No
   m. Chest pain when you breathe deeply  
      Yes  No
   n. Any other symptoms that you think may be related to lung problems  
      Yes  No
5. Have you ever had any of the following cardiovascular or heart problems?
   a. Heart attack       Yes No
   b. Stroke        Yes No
   c. Angina        Yes No
d. Heart failure       Yes No
e. Swelling in your legs or feet (not caused by walking) Yes No
f. Heart arrhythmia (heart beating irregularly)   Yes No
g. High blood pressure Yes No
h. Any other heart problem that you’ve been told about Yes No

6. Have you ever had any of the following cardiovascular or heart symptoms?
   a. Frequent pain or tightness in your chest   Yes No
   b. Pain or tightness in your chest during physical activity Yes No
c. Pain or tightness in your chest that interferes with your job Yes No
d. In the past year, have you noticed your heart skipping or missing a beat Yes No
e. Heartburn or indigestion that is not related to eating Yes No
f. Any other symptoms that you think may be related to heart or circulation problems Yes No

7. Do you currently take medication for any of the following problems
   a. Breathing or lung problems Yes No
   b. Heart trouble Yes No
c. Blood pressure Yes No
d. Seizures (fits) Yes No

8. If you’ve used a respirator, have you ever had any of the following problems?
   a. Eye irritation Yes No N/A
   b. Skin allergies or rashes Yes No
   c. Anxiety while wearing it Yes No N/A
d. General weakness or fatigue Yes No N/A
e. Any other problem that interferes with your use of a respirator Yes No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire? Yes No

For Prospective Health Use Only

Cleared to fit test   Needs PAPR

Needs exam   Other

Signature: _______________________________ Date: _________________
APPENDIX B
PROSPECTIVE HEALTH
PERIODIC MEDICAL EVALUATION FOR RESPIRATOR USE FOR TB

Employee Name: ____________________________ Date: ____________________________

________________________________________ ________________________________
Department: ____________________________ Supervisor: ____________________________ Phone#: ____________________________

Do you currently use a respirator? ______ What type(s)______________

Physical examination (if needed) BP_____/_____ Pulse_______
RR_______

Head and Neck:________________________________________________________________________________

Cardiopulmonary:_____________________________________________________________________________

Facial hair or anatomic problem:________________________________________________________________

Other:_______________________________________________________________________________________

Approval: This employee (is/is not) medically cleared for respirator use at ECU-HSC.
HEPA mask_______ PAPR_____

Employee signature:_____________________________________________ Date:________________________

Recommended Re-evaluation in ____ months ____________________________
Date_____________ Re-evaluation in 5 years____ Physician
APPENDIX C
OFFICE OF PROSPECTIVE HEALTH
188 LIFE SCIENCES BUILDING
BRODY SCHOOL OF MEDICINE
INTERVAL HISTORY-HEALTHCARE

Name _____________________________
Department __________________________ Phone __________
Date ______________________________________________________

1. Have you had any change in your health status?
   Yes  No

2. Have you developed any chronic illness in the past year?
   Yes  No

3. Have you developed any new allergies in the past year?
   Yes  No

4. Do any work activities cause you physical problems?
   Yes  No

5. Do you work with lasers?
   Yes  No

6. Are you taking any of the following types of medication (which might affect your susceptibility to infectious diseases)?
   a. Prednisone or other steroids?   Yes  No
   b. Anti cancer drugs?    Yes  No
   c. Anti rejection drugs for organ transplant? Yes  No

7. Do you experience any symptoms with use of latex gloves, such as rash, hives, wheezing, sneezing or runny nose?
   Yes  No
   If yes, are you now using a non-latex glove?
     Yes  No

8. a. Have you ever had a positive skin test for tuberculosis?
      Yes  No
     b. If yes, do you currently have any of the following symptoms?  Fever, night sweats, unexplained weight loss, chronic cough or coughing blood?
      Yes  No

9. For healthcare providers only:
   Have you ever been fit tested for TB respiratory mask?
     Yes  No  NA

10. Since your TB mask was last fitted, have you gained or lost 20 pounds, had surgery on your face or neck or had dentures installed or removed? Yes  No
    Grown a beard?       Yes  No

__________________________________________________________
Signature

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M. tuberculosis is carried through the air in either infectious droplets or as airborne bacterial particles. These droplets and particles may be generated when a person with infectious TB disease coughs, speaks, sings or spits. In an occupational setting, workers in close contact with persons with infectious tuberculosis disease are at increased risk of infection with TB. Certain high hazard medical procedures which are cough-inducing (e.g., bronchoscopy, suctioning) may further increase the risk of infection to health care workers. When it is not possible to avoid exposure by other means, respiratory protection (use of a mask) is required. SARS and smallpox are other airborne infectious agents

The 3M N95 (half-mask filtering face piece) Respirators have been approved by the Office of Prospective Health for use as required by the Tuberculosis Control Plan. Any respirator used at ECU for the protection against Tuberculosis must be approved by the Office of Prospective Health. Before use, you must receive medical clearance and be fit tested by the Office of Prospective Health. Should you experience any problem using this respirator, inform your supervisor or the Office of Prospective Health (744-2070) immediately.

I. Use of disposable N95 respirator mask.

1. Follow all instructions and be aware of the limitations regarding use of these respirators. Failure to wear mask during all times of exposure can reduce effectiveness and result in sickness or death.
2. If the respirator becomes damaged or breathing becomes difficult, leave the contaminated area and discard and replace the respirator.
3. These respirators are NOT for use against gases, vapors, asbestos, sandblasting, paint spraying operations, or atmospheres containing less than 19.5% oxygen.
4. Do not use if you have a beard, other facial hair, or a condition that prevents a complete seal between your face and the edge of the respirator.

II. Fit check your mask each time respirator is worn.

1. Gently pre-bend nosepiece to conform mask to face.
2. Separate the headbands with index fingers.
3. Cup the mask under the chin and bring the headbands over the head. Place the first band at the neck. Pull the remaining band up and place at the crown.
4. Form the nosepiece tightly across bridge of nose and face. Adjust mask to achieve a facial seal.
5. Face seal should be checked to assure proper fit. Adjust nosepiece if there is air leakage around the nose. Reposition bands to secure facial seal around edges of respirator.
6. Any mask which appears to be physically defective (torn material, broken straps) should not be used.

III. Storage and Disposal

The N95 masks are designed to be a reusable/disposable negative pressure respirator. These masks will be treated as disposable for use at East Carolina University. This eliminates problems associated with storage and reuse.

I have read and understand the information presented here and have been provided ample opportunity to ask questions.

Signed: ___________________________ Date: ________________

Name (print): ___________________________

Dept: ________________________________

FIT TEST

After medical clearance via OSHA questionnaire (all negative responses) or cleared by medical professional if positive response(s) fit testing will be performed. Men with beards, and anyone who cannot pass the fit test will use a powered air purifying (helmet) respirator.

Respirator To Be Used

_____ 3M N95, size (circle)  Small  Regular

_____ Powered Air Purifying Respirator (PAPR)

Recommend Re-Evaluation for Fit Test

_____ 12 months
 _____ 5 years
 _____ Other

_____ Using PAPR, no reevaluation needed

Prospective Health Staff  Date