

# Disease Surveillance Reporting

## I. PURPOSE AND APPLICABILITY

This policy implements [Boston Public Health Commission's \(BPHC\) "Guidelines for Implementation and Enforcement of Boston Public Health Commission's Disease Surveillance and Reporting Regulation."](#) The BPHC Guidelines require laboratory registration and a medical surveillance program for research laboratories working with High-Risk Agents. The Guidelines are designed to ensure that BPHC receives timely access to information regarding incidence of disease syndromes, any outbreak or cluster of a disease, and potential exposures to reportable diseases deemed harmful to the public health.

This policy sets forth the roles and responsibilities of researchers and of compliance staff at Boston University (BU) and Boston Medical Center (BMC) as mandated by the BPHC Guidelines.

This policy supplements but does not replace or supercede any other existing BU or BMC policies or procedures. For example, additional procedures relating to laboratory safety are set forth by the Boston University Environmental Health and Safety Department (EHS) in the EHS Manual, and other subsidiary EHS documents. This policy also supplements but does not replace or supercede [reporting requirements relating to industrial accidents for employees of either BMC \(PDF\)](#) at or [BU \(PDF\)](#)

## II. DEFINITIONS

**EHS Director** means the Director of Research Safety in the Environmental Health & Safety Department of Boston University and Boston Medical Center.

**OccHealth Officer** means, at Boston University and at Boston Medical Center, the physician who is the Occupational Health Officer of Research Occupational Health Program (ROHP). The OccHealth Officer may also name a designee to perform occupational health assessments or evaluations, provided that the designee is also a licensed physician experienced in occupational medicine or a registered nurse experienced in occupational health nursing.

**Expose or Exposure** means any situation arising from or related to the work operation of BU or BMC where an employee or a community resident may ingest, inhale, absorb through the skin or eyes or otherwise come into contact with any High-Risk Agent.

**High-Risk Agent** means

- a. Select Agents, as defined below;
- b. agents in risk group RG- 4 as specified in the National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules and Biosafety in Microbiological and Biomedical Laboratories published by the US Centers for Disease Control and Prevention and the National Institutes of Health and the amendments and rulings made

relative thereto from time to time. Please also see [Biosafety in Microbiological and Biomedical Laboratories](#) and [Classification of Human Etiologic Agents on the Basis of Hazard](#);

- c. highly pathogenic avian influenza;
- d. SARS Co-V; and
- e. any other agent identified by the Director of BPHC on a list to be posted on the [BPHC's website](#) or appearing on [Reporting Form \(PDF\)](#).

**Select Agent** means microbial and toxic agents listed at 42 CFR 73.4, 42 CFR 73.5, and 9 CFR 121.2 and the rulings made by the US Centers for Disease Control and Prevention and US Department of Agriculture relative thereto as amended from time to time. Please also see [HHS and USDA Select Agents and Toxins list \(PDF\)](#) and the [Office of Research Services website](#)

**Research Laboratory** means a workplace or a work area of a workplace which is used primarily for research, development, non –routine testing or experimentation activity in which any High-Risk Agent is used by or under the direct supervision of a technically qualified individual.

**Work Area** means a defined space, or a room or rooms, or other area where infectious agents or substances are produced, stored, or used, and where employees are present in the course of their employment. A work area may include an entire workplace.

**Workplace** means an establishment or business of an employer at one geographic location at which work is performed and containing one or more work areas.

### III. EHS REGISTRATION OF RESEARCH LABORATORIES

- A. The EHS Director will be responsible for registering with BPHC all Research Laboratories possessing, producing, storing, or otherwise working with any High–Risk Agent.
- B. Such registration shall be on a form provided by the BPHC's Office of Environmental Health and shall include the following:
  - 1. Name of the High–Risk Agent;
  - 2. The location of each High–Risk Agent (but only if such disclosure is consistent with federal, state, and institutional security restrictions and policies concerning Select Agents or High Risk Agents).
  - 3. Principal Investigator responsible for the High–Risk Agent(s);
  - 4. Title and a brief description of the nature of the project;
  - 5. Grant identification number or other unique institutional identifier number for the project;
  - 6. Contact information of the Institutional Biosafety Committee (IBC); and,
  - 7. Name and contact information of the OccHealth Officer.
- C. The information in the registration form shall be updated, on a form provided by the BPHC's Office of Environmental Health, twice a year, every July 31 and January 31 (or on the next business day if it falls on a holiday or weekend) following registration.
- D. The EHS Director shall inform the OccHealth Officer of all High-Risk Agents as they are identified at Boston University or Boston Medical Center and shall provide the

OccHealth Officer with a copy of each registration and update, simultaneously with filing.

#### **IV. RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS, SUPERVISORS, LABORATORY DIRECTORS AND THE IBC**

##### **A. Insure Registration Prior to Project Commencement**

The Principal Investigator, Supervisor, or Laboratory Director of any research project that proposes to possess, produce, store, or otherwise work with any High-Risk Agent must first contact the OEHS Director and ensure that a registration for the Research Laboratory is properly filed by OEHS with the BPHC.

##### **B. Develop Approved Plan Prior to Project Commencement**

1. The Principal Investigator, Supervisor, or Laboratory Director of any research project that proposes to possess, produce, store, or otherwise work with any High-Risk Agent must:
  - a. develop a plan jointly with the OccHealth Officer that will enable the Principal Investigator, Supervisor, or Laboratory Director to determine whether a significant exposure of personnel has occurred in the Research Laboratory and that will set forth a protocol for monitoring significantly exposed employees. (See Section VI.A.2. below); and
  - b. indicate in writing that the Principal Investigator, Supervisor or Laboratory Director, and the OccHealth Officer have each approved the plan.
2. The plan must also be approved by the EHS Director and the IBC before researchers on the project will be allowed access to a High-Risk Agent.

##### **C. Mandated Reporting to OccHealth Officer and EHS Director**

1. The IBC, Principal Investigator, Supervisor and/or Laboratory Director shall promptly report to the **OccHealth Officer**:
  - a. any diagnosis of any disease caused by a High-Risk Agent; and
  - b. any laboratory employee or other individual having access to a Research Laboratory that possesses, produces, stores, or otherwise works with any High-Risk Agent *who is absent from the work place due to illness for a period of two or more consecutive work days.*
2. The IBC, Principal Investigator, Supervisor and/or Laboratory Director shall report to the **EHS Director** and the **OccHealth Officer** any violation or breach of any laboratory procedures or any other incident which the IBC, Principal Investigator, Supervisor or Laboratory Director *should reasonably believe resulted in exposure to a High Risk Agent in the workplace or released any High-Risk Agent beyond the work area.*

The manner of reporting to Research Occupational Health Program is set forth in section VII below

## **D. Follow Up on Reporting Requirements of Laboratory Workers**

Principal Investigators, Supervisors and/or Laboratory Directors who learn of laboratory workers with reporting responsibilities as outlined in Section V below must confirm that such employees have reported to Research Occupational Health Program *before returning to work* and that the employees have a written release to return to work provided by Research Occupational Health Program.

Principal Investigators, Supervisors, and/or Laboratory Directors, should refer any ill employee who has had access to a High-Risk Agent to Research Occupational Health Program for evaluation.

## **V. RESPONSIBILITIES OF LABORATORY EMPLOYEES, TRAINEES, STUDENTS AND OTHERS WHO HAVE ACCESS TO HIGH-RISK AGENTS**

### **A. Mandatory Reporting to OccHealth Officer and EHS**

Laboratory workers or other individual having access to a Research Laboratory that possesses, produces, stores, or otherwise works with any High-Risk Agent who are exposed to a High-Risk Agent from a spill or a breach in laboratory practices must immediately contact the OccHealth Officer and to EHS Director to receive instructions as to appropriate immediate steps to be taken.

### **B. Mandatory Medical Evaluations**

1. Any laboratory employee or other individual having access to a Research Laboratory that possesses, produces, stores, or otherwise works with any High-Risk Agent *and*
  - o who has been diagnosed with, is exhibiting symptoms of, or may have been exposed to, any High-Risk Agent, or
  - o who has been absent from the work place due to illness for a period of two or more consecutive work days, must report to the OccHealth Officer prior to returning to work, for medical evaluation *before, and as a condition for, returning to work.*
2. Laboratory workers are *encouraged* to report *any* illness to the OccHealth Officer if working with High-Risk Agents, even if the illness does not result in a two-day workplace absence.

The manner of reporting to Research Occupational Health Program is set forth in section VII below.

## **VI. RESPONSIBILITIES OF THE OCCUPATIONAL HEALTH OFFICER**

### **A. Medical Surveillance of Employees Working With High-Risk Agents**

1. The OccHealth Officer is responsible for having in place a general plan to determine whether employees working with various High Risk Agents have had a significant exposure to a High Risk Agent and a plan to monitor significantly exposed employees.

2. The OccHealth Officer will work with the Principal Investigator, Supervisor, or Laboratory Director of any research project that proposes to possess, produce, store, or otherwise work with any High-Risk Agent to:
  - a. develop the project-specific plan described in Section IV.B.1., above, which will enable the Principal Investigator, Supervisor, or Laboratory Director to determine whether a significant exposure of personnel has occurred in the Research Laboratory and which will set forth a protocol for monitoring significantly exposed employees; and
  - b. insure that the project-specific plan is approved by EHS and the IBC before researchers have access to a High-Risk Agent.

## **B. Reporting to BPHC**

The Occupational Health Officer will immediately notify the BPHC of all presumptive LAI's followed by a confirmatory report once additional information is available. In the event of any incident the Occupational Health Officer will act as a single point of contact and coordinate all Occupational Health activities and notify other agencies as appropriate.

The OccHealth Officer is responsible for generating the following reports and reporting to the BPHC as indicated:

1. **Report of Diagnosis, Symptoms or Exposure** The OccHealth Officer shall perform an occupational health assessment for any laboratory employee or other individual having access to the laboratory who
  - o has been diagnosed with;
  - o is exhibiting symptoms of; or
  - o may have been exposed to, any High-Risk Agent.

The findings of the assessment shall be immediately reported to the BPHC, but in any event not later than one business day after completion of the assessment. Please download the [Reporting Form \(PDF\)](#).

The OccHealth Officer will conduct a follow-up assessment and provide information requested by BPHC regarding isolation and/or quarantine issues. If the determination is made that the illness is caused by a High-Risk Agent, BPHC will be consulted before an ill worker is allowed to return to work.

The OccHealth Officer will send BPHC documentation that an exposed person has been cleared to return to work within 3 business days of clearance.

2. **Report of Workplace Absence Due to Illness** The OccHealth Officer shall perform an evaluation of any laboratory employee or other individual having access to a Research Laboratory that possesses, produces, stores, or otherwise works with any High-Risk Agent *and* who has been absent from the work place due to illness for a period of two or more consecutive work days. The evaluation shall be completed prior to the employee's return to work. If the OccHealth Officer has a reasonable suspicion that the employee's

illness may be related to an exposure to any High-Risk Agent, the OccHealth Officer shall immediately notify the BPHC. If OccHealth determines that the illness was caused by a High-Risk Agent and may be work related, the BPHC must be consulted at least three business days prior to the employee's expected return to work.

3. **Report of Diagnosis of Disease** The OccHealth Officer shall report to the BPHC any diagnosis of any disease caused by a High Risk Agent. This report shall be made within one business day of the diagnosis.
4. **Report of Violation of Laboratory Procedures Resulting in Release of High Risk Agent** The OccHealth Officer shall report to the BPHC any violation or breach of any laboratory procedures or any other incident which the OccHealth Officer should reasonably believe released a High Risk Agent beyond the work area. This incident shall be reported to BPHC within one business day of the breach or incident.
5. **Notification to EHST** The OccHealth Officer shall provide the EHS Director with written notification of all reports made to the BPHC.

## **VII. MANNER OF REPORTING TO Research OCCUPATIONAL HEALTH Program (RohP)**

All Reports to Research Occupational Health Program shall be made in accordance with the following: Contact Research Occupational Health Program (ROHP) at (617) 414-7647

## **VIII. RESPONSIBILITIES OF BMC EMERGENCY DEPT. PERSONNEL**

BMC Emergency Department (ED) Personnel work closely with Research Occupational Health Program (ROHP) for reports that require ED services:

- BMC ED Personnel (or other providers at BMC or outside the Boston area), who evaluate Workers for potential or actual exposure in connection with illness, absence, or breach in laboratory practices that is potentially related to work with a covered agent *must also contact the Occupational Health Officer of the Research Occupational Health Program at the 24-hour contact telephone: (617)414-7647.*
- BMC ED Personnel should also contact Environmental Health & Safety and the Chair of the IBC by using the 24 hour contact telephone: (617) 638-4144. Information to be provided should include the name of the caller, the person(s) involved, the type of situation and a call back number.
- BMC ED Personnel should contact the Hospital Epidemiologist, Dr. Carol Sulis, Tel: (617) 414-5037, Pager: (617) 638-5795, ID # 6402, or should page the Boston Medical Center Infectious Disease Consultant on call at (617) 638-5795, ID # 8902 for the Harrison Avenue Campus, or pager ID # 8903 for the East Newton Campus