

**WADSWORTH CENTER  
NEW YORK STATE DEPARTMENT OF HEALTH**

**SARS-Coronavirus and Highly Pathogenic Influenza Virus  
Laboratory Occupational Health Protocol**

**Table of contents**

Introduction		2
Section 1	Required laboratory documentation for recognition of an event	3
Section 2	Reporting of events and illnesses	4
	2.1: Reporting of events	4
	2.2: Reporting of illnesses	4
Section 3	Responding to exposure events	5
	3.1: If the initial risk assessment identifies no risk of exposure	5
	3.2: If the initial risk assessment identifies a low risk of exposure	5
	3.3: If the initial risk assessment identifies a moderate to high risk of exposure	6
Section 4	Responding to fever or respiratory symptoms in laboratory workers	7
	4.1: Scenario 1: Symptoms with no risk of exposure	7
	4.2: Scenario 2: Symptoms with low risk of exposure	7
	4.3: Scenario 3: Symptoms with a documented exposure event	9
	4.4: Medical evaluation for potential SARS Co-V exposure	9
	4.5: Medical evaluation for potential HPI virus exposure	10
Section 5	Initiation of laboratory testing	11
Section 6	Basis for “stand down”	13
Section 7	Risk assessment	13
Section 8	Laboratory biocontainment and safety practices	14
Section 9	SARS and HPI laboratory access	14
Section 10	Required occupational health practices	15
Section 11	Medical costs and leave	16
Section 12	Administrative considerations	16
	12.1: Protocol review	16
	12.2: Training	16
Attachment 1	SARS/HPI Daily Monitoring Log of Laboratory Personnel	
Attachment 2	CDC Algorithm for management of fever or respiratory symptoms when SARS-CoV transmission is occurring in the world	

# **SARS-Coronavirus and Highly Pathogenic Influenza Virus Laboratory Occupational Health Protocol (An Appendix to SARS and HPI Laboratory Biosafety Protocols)**

## **Introduction**

The international scientific community moved with remarkable speed to identify the causative agent of Severe Acute Respiratory Syndrome (SARS) and to develop assays to detect the SARS coronavirus (SARS-CoV). These steps, along with isolation and quarantine, helped limit transmission of the newly identified public health threat and contain the outbreaks to parts of Canada and the Far East. However, recent cases of laboratory-acquired SARS infections in Beijing, Singapore and Taipei, have raised concerns about laboratories becoming the sources of new outbreaks. The emergence of highly pathogenic avian influenza viruses that have been transmitted to humans has also increased the biocontainment burden on laboratories performing research with these agents.

Work with these agents presents unique challenges because biocontainment and exposure management is critical, not only for the health of laboratory personnel, but also to prevent escape and potential infection of the local human and animal populations. The severe consequences to public health and agriculture of accidental release of these agents make early detection and containment of laboratory infections critical. In parallel, the rapid discrimination of work-related infections from the inevitable commonplace respiratory infections that occur in laboratory staff is essential. Thus, the medical monitoring and event-response protocols must be designed so as to support valuable research and also protect public health.

While we cannot guarantee that a laboratory accident will never occur, we do have a responsibility to ensure that the work is performed at the highest appropriate biosafety level, that laboratory accidents are fully documented and that potentially exposed staff are monitored to minimize the risk that a work-related infection will go undetected and spread to family and community contacts. While laboratory safety protocols exist for working with SARS-CoV and highly pathogenic influenza (HPI) viruses, there is a need to expand the guidance on how to respond both to exposure events and to respiratory illness in laboratory workers. The situation is exacerbated by the limited information on routes of transmission and the viral dose required for infection. Because of the adverse public health consequences of a laboratory infection spreading to the community, the natural tendency will be to plan very conservatively and to err on the side of caution. While this is the appropriate approach given our current lack of knowledge we, nonetheless, do not want to place unnecessarily restrictive limitations on the scientists performing this important research. Given the pre-existence of comprehensive laboratory safety protocols, we therefore consider that the critical component of this plan is the formation of a Risk Assessment Group that is composed of individuals with the appropriate expertise to allow evaluation of the potential for infection. A detailed description of the Risk Assessment Group can be found in Section 7 of this protocol. It is the role of this group to review all factors leading up to the event or illness, and to determine the appropriate response. Because it is not possible to address every possible scenario in a written protocol, good practice will depend heavily upon the exercise of good judgment by the Risk Assessment Group. We believe that if this protocol is followed in a timely fashion, the risk of spread of infection will be greatly minimized.

This protocol is divided into sections that reflect the sequence of actions and outcomes that will occur following either a laboratory event creating a potential exposure or the development of respiratory illness in a laboratory worker.

## **Section 1: Required laboratory documentation for recognition of an event**

Procedures at several levels will ensure that there is available a clear record of activities with infectious viruses and that laboratory accidents and potential exposures, collectively referred to as “events”, are well documented and appropriately communicated.

### **1.1: Documenting events**

- 1.1.1: All individuals entering the BSL-3 laboratory must record date and time of entry and exit on the log sheet as well as a short description of the work performed indicating that there were no breaks of protocol or equipment failures recognized during the session. The entry must also note the occasions of entry when no work with infectious material was performed.
- 1.1.2: As far as possible, work with infectious virus will be performed in the BSL-3 laboratory with two personnel present. On some occasions, it may be necessary to work alone, but this is only permissible for highly experienced individuals (as determined by the Principal Investigator). Whenever possible, a responsible individual should be informed of their work plan.
- 1.1.3: All events, however minor, must be documented in an Event Log, which will be maintained in the accessible entry area of the BSL-3 laboratory. Events will include small spills in the biological safety cabinet or a vessel breakage within the biological safety cabinet while wearing personal protective equipment. These minor events should be reported to the Supervisor/Principal Investigator upon completion of the work. See Section 1.1.4 for exposure events.
- 1.1.4 An exposure event is defined as any laboratory event that creates a potential for exposure to SARS-CoV or HPI virus including, but not limited to, all uncontained releases, occupational exposures, and equipment failures in the laboratory. Examples of exposure events include a spill of infectious material outside the biological safety cabinet, tube leakage in a centrifuge, splashes to mucous membranes, needle stick, and power failure of a biological safety cabinet. Such events should result in termination of the work, personal decontamination, and exit from the contaminated area. The event will be recorded in the Event Log and reported to the Supervisor/Principal Investigator immediately upon personal decontamination and exit from the contaminated area.
- 1.1.5 Personal decontamination may include removal of contaminated clothing, thorough scrubbing and rinsing of known contaminated body surfaces, determined by the nature and extent of the contamination.

## **Section 2: Reporting of events and illnesses**

All events and illnesses will be reported. The extent of reporting is dependent on the assessed risk to the individual and the environment.

### **2.1: Reporting of events**

- 2.1.1 All events entered into the Event Log (Sections 1.1.3 and 1.1.4) will be reported by the employee to the Supervisor/Principal Investigator. Exposure events will be immediately reported to the Supervisor/Principal Investigator, whereas all other events will be reported upon completion of the work.
- 2.1.2. All exposure events will be assessed by the Supervisor/Principal Investigator in conjunction with the Biosafety Officer to initially evaluate the exposure risk and need for notification of the Wadsworth Center Administration. Those judged to have a low, moderate or high risk must be reported to the Laboratory Chief or Division Director. A Wadsworth Center Incident Report will be filed by the employee. Examples of such events include, but are not restricted to: a needle-stick injury, a spill outside the biological safety cabinet while the individual is wearing full personal protective equipment and negative pressure is maintained, or a failure in the exhaust system leading to positive pressure of the laboratory. The Laboratory Chief/Division Director will notify the Wadsworth Center Administration and the Safety Office.
- 2.1.3 If the Wadsworth Center senior administration (WC Director, WC Deputy Director or the Division Director) considers it warranted, the Risk Assessment Group will be notified of the exposure event.
- 2.1.4. If the Supervisor/Principal Investigator or Biosafety Officer believes there is a high risk of exposure and cannot immediately reach the Wadsworth Senior Administration, the Risk Assessment Group must be notified directly.

### **2.2: Reporting of illnesses**

- 2.2.1 Personnel who have worked in the BSL-3 laboratory will report any fever or respiratory symptoms to the Supervisor/Principal Investigator or Laboratory Chief. If the clinical signs are compatible with the laboratory pathogen or the employee has worked in the BSL-3 laboratory within the last 14 days, the Supervisor/Principal Investigator will, in turn, make an immediate report to the Division Director, who will notify Wadsworth Center senior administration.
- 2.2.2 If the Wadsworth Center senior administration (the Director, Deputy Director or Division Director) considers that it is warranted, the Risk Assessment Group will be notified of the illness and any associated exposure event.
- 2.2.3 If the Supervisor/Principal Investigator believes there is a high risk of a work-related illness and cannot reach the Wadsworth Center senior administration, the Risk Assessment Group must be notified directly.

### **Section 3: Responding to exposure events**

As described in Sections 1.1.3 and 1.1.4, all events will be documented in an Event Log and reported to the Supervisor/Principal Investigator. These events must be immediately investigated to determine root causes. Periodic reviews also should be performed to assess for trends. Prevention efforts, such as addressing knowledge deficits or workload issues that may have contributed to the breach, must be undertaken, and any changes in protocol must be evaluated for efficacy.

An initial risk assessment will be performed for each exposure event based on the assessed procedural risk and the nature of the breach, i.e. exposure potential. Initial determination of exposure risk after reporting of an exposure event will be performed in-house by the Supervisor/Principal Investigator and the Wadsworth Center Biosafety Officer, and if determined appropriate, the Risk Assessment Group will be activated via the Wadsworth Center senior administration (see Section 2.1.3). The Risk Assessment Group will consist of:

- An infectious disease medical provider
- A Department of Health epidemiologist
- Two Wadsworth Center personnel i.e., the individual's immediate supervisor plus another scientist with relevant pathogen or BSL-3 laboratory experience
- The Wadsworth Center Biosafety Officer

If the risk is determined to be low, moderate or high, the NYSDOH Bureau of Communicable Disease Control will be contacted. Criteria used for risk assessment are described in Section 7.

#### **3.1: If the initial in-house risk assessment of the exposure event by the Supervisor/Principal Investigator and the Biosafety Officer identifies no risk of exposure:**

- 3.1.1 The employee may continue to work and no further action is necessary. The Risk Assessment Group need not be convened.
- 3.1.2 The employee should be reminded to report any fever or symptoms of respiratory infection to the Supervisor/Principal Investigator as per the standard protocol.

#### **3.2: If the initial in-house risk assessment of the exposure event by the Supervisor/Principal Investigator and the Biosafety Officer identifies a low risk of exposure:**

- 3.2.1 A Wadsworth Center Incident Report will be filed by the employee.
- 3.2.2 The Local Health Department and NYSDOH Bureau of Communicable Disease Control will be notified.
- 3.2.3 The Risk Assessment Group will be notified that a potential exposure event has occurred (see Section 2.1.3).
- 3.2.4 The completion of the Daily Monitoring Log of Laboratory Personnel (Attachment 1) will be implemented. The Log will be monitored daily by the facility-designated person in conjunction with the Wadsworth Center Biosafety Officer and in frequent consultation with the consulting Infectious Disease Medical Provider. For ten days following the event, the individual will report to the Laboratory Chief or Division Director to record presence/absence of the

following symptoms: fever  $\geq 100.4^{\circ}\text{F}$ , lower respiratory symptoms (cough, shortness-of-breath), sore throat, rhinorrhea, chills, rigors, myalgia, and/or headache. Additionally, diarrheal illness may be present with SARS and influenza. On work-days the employee will contact the Laboratory Chief or Division Director before reporting to work. On weekends or holidays the Laboratory Chief or Division Director will be called at home.

- 3.2.5 If any of the above symptoms develop within the ten day period, laboratory personnel should follow the illness protocol in Section 4, Scenario 2 below.

**3.3: If the initial in-house risk assessment of the exposure event by the Supervisor/Principal Investigator and the Biosafety Officer identifies a moderate to high risk of exposure:**

- 3.3.1 A Wadsworth Center Incident Report will be filed by the employee.
- 3.3.2 The Local Health Department and NYSDOH Regional Epidemiology Central Office will be notified.
- 3.3.3 The Risk Assessment Group will be notified that an exposure event has occurred (see Section 2.1.3) and completion of the Daily Monitoring Log of Laboratory Personnel (Attachment 1) will be implemented.
- 3.3.4 The laboratory worker will be placed on leave for 10 days post-event and will maintain home isolation. Surgical masks and a thermometer will be supplied by the Wadsworth Center. The Local Health Department will be consulted on home isolation procedures.
- 3.3.5 The log will be monitored daily by the facility-designated person in consultation with the Infectious Disease Medical Provider if symptoms develop.
- 3.3.6 If any symptoms develop follow Section 4, Scenario 3 below.

## **Section 4: Responding to fever or respiratory symptoms in laboratory workers**

Upon onset of fever or respiratory symptoms, the employee will immediately make an initial contact with the Supervisor/Principal Investigator or Laboratory Chief. If at home, the employee will not report to work, pending further evaluation and instruction. If at work, the employee should don a surgical mask, notify the Supervisor and return home without using public transportation. Should onset of fever >100.4°F and severe respiratory symptoms occur while the employee is in travel status, away from the Capital District, the Supervisor will collect supporting information and contact one of the Risk Assessment Group members immediately to gain guidance on response. If a moderate to high risk exposure event has occurred in the 14 days prior to planned travel, the employee will be placed on leave at home, and travel will be cancelled.

When an illness is reported to the Supervisor/Principal Investigator and/or the Risk Assessment Group has been activated, they will use all available information to determine the level of risk of exposure and then follow the appropriate algorithm that may include medical monitoring, laboratory testing and isolation or quarantine.

### **4.1: Scenario 1: Symptoms with no risk of exposure**

**Background:** An example of this scenario would be an employee who has not worked in the BSL-3 laboratory within the previous 14 days but who has now developed fever of 100.4°F or greater and respiratory symptoms. (The 14 day period is based upon the high likelihood that beyond that period following an exposure, disease would not develop.) The employee calls in indicating he/she has relevant symptoms.

#### **Action taken:**

- 4.1.1 The employee should not report to work, pending further evaluation and instruction.
- 4.1.2 The laboratory entry log will be reviewed by the Supervisor/Principal Investigator to determine the last day the employee worked in the BSL-3 facility. It should be confirmed that the employee has not worked with either live pathogen within the last 14 days.
- 4.1.3 Surveillance will be enhanced for other respiratory and/or febrile illness among laboratory workers to determine if the laboratory may have been contaminated. If no other illness is identified, no further action is necessary. Employees who are not well enough to work will remain at home on sick-leave, and will be seen by a personal physician at their own discretion. If illnesses are identified in other laboratory staff working in the BSL-3 laboratory, the Risk Assessment Group should be consulted to determine further action.

### **4.2: Scenario 2: Symptoms with low risk of exposure**

**Background:** Examples of a low risk of exposure would be an employee who has worked in the BSL-3 laboratory within the previous 14 days without an exposure event and who has now developed specific respiratory symptoms.

In this scenario, given no serious documented laboratory event, a non-work-related respiratory infection should be strongly considered.

**Action taken:**

- 4.2.1 The employee will not report to work pending further evaluation and instruction. The Event Log will be reviewed by the Supervisor/Principal Investigator to determine the last day the employee worked in the BSL-3 laboratory, and the Event Log should be checked for documentation of events in the preceding 14 days. The Wadsworth Center senior administration (WC Director, WC Deputy Director or the Division Director) and Biosafety Officer will be notified.
- 4.2.2 If the employee's symptoms are compatible with SARS-CoV or HPI virus, the Risk Assessment Group will be notified through the Wadsworth Center senior administration.
- 4.2.3 The Risk Assessment Group may require the employee to remain at home and monitor symptoms using the Daily Monitoring Log of Laboratory Personnel (Attachment 1). The log should be monitored daily by the facility-designated person in consultation with the Infectious Disease Medical Provider.
- 4.2.4 The Local Health Department and the NYSDOH Regional Epidemiology Central Office will be notified.
- 4.2.5 If symptoms resolve within 72 hours, the employee, after consultation with the Risk Assessment Group, will return to work (see Section 6). Monitoring will continue for the remainder of the 10-day period.
- 4.2.6 If symptoms persist or worsen, the Infectious Disease Medical Provider, in consultation with the Risk Assessment Group, will initiate diagnostic testing for respiratory pathogens including SARS-CoV or HPI virus. In this case, CDC Algorithm 2: Algorithm for management of fever or respiratory symptoms when SARS-CoV transmission is occurring in the world [www.cdc.gov/ncidod/sars/clinicalguidanceframe2.htm](http://www.cdc.gov/ncidod/sars/clinicalguidanceframe2.htm) (Attachment 2) will be followed using Standard Respiratory Precautions during transportation to and at the Healthcare Facility.
- 4.2.7 Specifically, the employee should be provided with a surgical mask and instructions on its use and disposal. For patients who cannot wear a mask, tissues and instructions on when to use them (e.g. when coughing, sneezing or controlling nasal secretions) should be provided. The employee should be instructed on how and where to dispose of used tissues and of the importance of hand hygiene after handling this material.
- 4.2.8 Transport to the Healthcare Facility should be arranged such that the employee does not use public transportation.

**4.3: Scenario 3: Symptoms with a documented exposure event**

**Background:** In this scenario a documented exposure event has already occurred (Section 3). The Risk Assessment Group and the Local Health Department have been notified that a potential exposure has occurred. Examples of exposure events would be a spill of virus-containing material outside of the biological safety cabinet, failure of the biological safety cabinet while infectious virus is being handled and a powered air purifying respirator is not being worn, or splashes of infectious materials onto mucous membranes. The development of

symptoms has been monitored using the Daily Monitoring Log of Laboratory Personnel (Attachment 1).

**Action taken:**

- 4.3.1 If symptoms do appear after an exposure event, the Risk Assessment Group will be consulted and the employee will be referred to the Infectious Disease Medical Provider for further medical evaluation. Algorithm 2: CDC Algorithm for management of fever or respiratory symptoms when SARS-CoV transmission is occurring in the world (Attachment 2) will be followed using Standard Respiratory Precautions during transportation to and at the Healthcare Facility (Section 4.2.7 and 4.2.8 above).

**4.4: Medical evaluation for potential SARS Co-V exposure:**

- 4.4.1. **Symptoms deemed *not significant* by the Infectious Disease Medical Provider and public health authority:**
  - a. If symptoms progress, follow Algorithm 2 (Attachment 2) for management of fever or respiratory symptoms.
  - b. If no significant symptom progression occurs during 10 days following exposure, after consultation with the Risk Assessment Group, discontinue medical evaluation and monitoring (Section 6).
- 4.4.2. **Fever or respiratory symptoms or other symptoms considered significant by the Infectious Disease Medical Provider and the Bureau of Communicable Disease Control:**
  - a. Follow Algorithm 2 (Attachment 2) for management of fever or respiratory symptoms when SARS transmission is occurring in the world.
  - b. Identify and monitor contacts daily in coordination with the Local Health Department. The laboratory will identify and monitor laboratory contacts. The Local Health Department will identify and monitor community contacts.
  - c. If not hospitalized, the Local Health Department will assess appropriate placement for home isolation.

**4.5: Medical evaluation for potential HPI virus exposure:**

- 4.5.1 **For other than fever or respiratory symptoms:**
  - a. If medical findings are deemed significant, follow recommendations outlined for SARS above (Section 4.3, Scenario 3).
  - b. If medical findings are unrelated or are deemed *not significant* by the Infectious Disease Medical Provider and public health authority, continue medical follow-up to monitor for symptom progression. If symptoms progress to fever or respiratory symptoms, follow guidance for SARS-CoV above (Section 4.3, Scenario 3). If no symptom progression occurs during the 10 days following the event, in consultation with the Risk Assessment Group, discontinue medical evaluation and monitoring (Section 6).

4.5.2 **If not hospitalized:**

- a. The Local Health Department will assess appropriate placement for home isolation for 14 days after the onset of illness or until an alternative diagnosis is established.
- b. Testing for pertinent influenza A strains will be made on a case-by-case basis. This decision will be made by the Infectious Disease Medical Provider, in consultation with the Risk Assessment Group.
- c. The laboratory will identify and monitor laboratory contacts.
- d. The Local Health Department will identify and monitor community contacts.

4.5.3 **If hospitalized with milder illness:**

- a. Implement infection control precautions as above.
- b. The Infectious Disease Medical Provider, in consultation with the Risk Assessment Group, will initiate diagnostic testing for respiratory pathogens including influenza A strains currently used in the laboratory.

4.5.4 **If hospitalized with unexplained radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS) or severe respiratory illness:**

- a. Implement Standard, Airborne and Contact Precautions, including the use of eye protection when within 3 feet. Continue these precautions for 14 days after onset of symptoms or until an alternative diagnosis is established.
- b. The Infectious Disease Medical Provider, in consultation with the Risk Assessment Group, will initiate diagnostic testing for respiratory pathogens including influenza A strains currently used in the laboratory.

## **Section 5: Initiation of laboratory testing**

Laboratory testing will be performed at the Wadsworth Center when the Risk Assessment Group indicates that it is warranted. For these assays, there will be no cost to the employee or their health insurance. If the employee requests testing, but the Risk Assessment Group does not feel it is warranted, a decision will be made by the Wadsworth Center senior administration as to whether or not to proceed. Annual serological screening of staff will be performed for evidence of previous or current infection, even in the absence of reported exposure events or compatible illness.

Samples required for laboratory testing will be taken by designated staff at the designated Healthcare Facility and tested at the Wadsworth Center. Recommended samples for influenza testing are nasal pharyngeal/oropharyngeal (NP/OP) swabs (collected in viral transport medium), bronchial lavage or sputum. Serum should also be submitted for serologic testing.

The appropriate samples to eliminate a diagnosis of SARS by both RT-PCR and serology are dependent on the time after onset of illness and are shown in the table below.

<b>Specimen</b>	<b>&lt;1 week Post-onset</b>	<b>1-3 weeks post-onset</b>	<b>&gt;3 weeks post-onset</b>
Serum for serology	++	++	++*
Blood (EDTA/purple top tube)	++	+	–
Respiratory samples including NP/OP swabs, sputum and bronchial lavage. Sputum preferred.	++	++	+
Stool	-	++	++

\*Serum must be collected >28 days post-onset to rule out SARS serologically.

++ Indicates a priority specimen

- Indicates not recommended

The priority of the tests performed will depend on which pathogen the employee has worked with, e.g., SARS-CoV or HPIV. The primary samples will not be inoculated into cell culture in a BSL-2 laboratory until SARS or HPI has been ruled out.

- 5.1: For SARS-CoV the Wadsworth Center's real-time RT-PCR assay will be performed first. In addition, acute sera will be tested for the presence of SARS IgM in the Diagnostic Immunology Laboratory using the CDC/LRN ELISA assay.
- 5.2: For influenza, the first test performed will be a Directigen Rapid Antigen Detection assay. The antigen detection assay is not particularly sensitive on primary diagnostic samples but it will be performed because, when positive, it provides a rapid result. Irrespective of the result, the Wadsworth Center's real-time RT-PCR assays for influenza A and B will be performed. If a positive result is found for influenza A, a conventional RT-PCR-based typing assay will be performed. It should be noted that the limit of detection of this conventional RT-PCR assay may not allow typing without prior amplification in cell culture.

5.3: Test interpretation and testing for alternative agents

- 5.3.1 A positive PCR result for SARS-CoV or HPI virus should be confirmed by a qualified second laboratory to ensure that this result is not an artifact of laboratory contamination. Positive results will be confirmed by repeat testing of the same aliquot and separate aliquots of the original specimen and by testing the specimen in an independent laboratory. The Wadsworth Center will also send the specimen to the CDC for repeat testing.
- 5.3.2 A negative PCR result in a given patient sample does not rule out SARS-CoV infection in the patient due to the low viral load that is present in some clinical specimens. SARS-CoV infection can only be ruled out by a negative antibody result on a serum specimen collected >28 days post-onset of illness.
- 5.3.3 The significance of negative PCR results for SARS-CoV and HPIV will be reinforced by confirming the presence of another agent. Once the absence of SARS-CoV and HPI virus **in a particular sample** has been confirmed by RT-PCR, the Wadsworth Center Virus Reference and Surveillance Laboratory and the Bacteriology Laboratory will perform further testing using a combination of real-time PCR and culture. Priority will be given to molecular assays because of speed, and to avoid amplifying a potentially harmful pathogen. Detection assays will be performed for pertussis, mycoplasma, chlamydia, respiratory syncytial virus, parainfluenza virus, enterovirus, adenovirus and human metapneumovirus.

## **Section 6: Basis for “stand-down”**

The Risk Assessment Group will re-assemble when assay results are available and when the rate of progression of symptoms in the staff member has been assessed. The decision to allow the employee to return to normal duties or to continue isolation will be made by the Risk Assessment Group based on all factors. Important supporting evidence would include an alternative diagnosis that explains the symptoms or negative PCR results for SARS Co-V and HPI virus and the resolution of symptoms. Laboratory workers may be asked to be seen by the Infectious Disease Medical Provider prior to return to work.

## **Section 7: Risk assessment**

The Risk Assessment Group will consist of an infectious disease medical provider, a DOH epidemiologist, two Wadsworth Center scientists i.e., the individual’s immediate supervisor plus another scientist with relevant BSL-3 laboratory experience and the Wadsworth Center Biosafety Officer. The Risk Assessment Group will be activated by Wadsworth Center senior administration in one of six situations.

1. An exposure event has occurred such that there may be a low or moderate to high risk of exposure of an individual or the environment to the pathogen.
2. An individual working in the BSL-3 laboratory within the last 14 days has developed symptoms consistent with the case definition of SARS or HPI (fever  $\geq 100.4^{\circ}\text{F}$ , lower respiratory symptoms [cough, shortness of breath], sore throat, rhinorrhea, chills, rigors, myalgia, and/or diarrheal illness).
3. An individual working with the pathogen within the last 14 days requests specimen testing.
4. When test results are available.
5. When the staff member’s symptom progression indicates risk assessment is necessary.
6. Following resolution of symptoms in an ill worker, to evaluate clinical course, laboratory results and other diagnoses, to advise on removal of isolation practices, and to authorize return to work.

The Risk Assessment Group will take all information into account to determine whether there is high/moderate, low, or no risk of exposure and to determine what level of testing and isolation may be required.

Risk assessment criteria may include:

- Was there a documented exposure event?
- Is there evidence of compatible symptoms?
- Is there medical examination/laboratory data supporting a diagnosis of SARS, HPI or other illness?
- Did the individual work with an infectious agent within a time period prior to onset of symptoms that is compatible with the incubation period for SARS-CoV or HPI virus?
- Did the individual use a laboratory procedure likely to cause aerosols?

- Is there illness in other laboratory workers?
- Is there a high prevalence of respiratory disease in the community?

## **Section 8: Laboratory biocontainment and safety practices**

Laboratory biocontainment and safety practices are enumerated in the SARS, Arbovirus Pathogenesis Laboratory and HPI Laboratory Safety Protocols to which this protocol is an appendix. BSL-3 biocontainment practices (as described in *Biosafety in Microbiological and Biomedical Laboratories*, CDC 1999) will be met or exceeded and will be strictly enforced. Work with these agents must be performed in laboratories reserved for BSL-3 designated agents exclusively. Additional information regarding biosafety and biocontainment can be derived from:

- A. Wadsworth Center Safety Protocol –  
<http://info.wadsworth.org/ssg/safety/manual/index.htm>
- B. SARS-specific CDC medical surveillance guideline for laboratory workers –  
<http://www.cdc.gov/ncidod/sars/guidance/f/app5.htm>
- C. SARS-specific WHO protocol [http://www.who.int/csr/sars/biosafety2003\\_12\\_18/en/](http://www.who.int/csr/sars/biosafety2003_12_18/en/)

## **Section 9: SARS and HPI laboratory access**

General laboratory safety training and familiarity with the Wadsworth Center safety guidelines, BSL-3 and specific SARS and Influenza Research Laboratory training and experience are required for admittance to the laboratory. Additional qualifying training and experience is required for authorization to work alone in the laboratory under conditions described in the SARS and Influenza Research Laboratory Safety protocols. Annual influenza vaccination is recommended unless contraindicated (e.g., egg allergy).

It is recommended that employees with any of the following be discouraged from work in the BSL-3 laboratory or be reassigned to other duties:

- pregnancy
- known immunosuppression
- febrile illness (>100<sup>0</sup> F)
- open wounds or skin lesions that cannot be adequately protected
- chronic asthma, emphysema or severe respiratory conditions
- current use of clinically directed medications known to reduce dexterity or reaction time.

## **Section 10: Required occupational health practices**

The following ongoing occupational health practices will be performed for all employees working in the SARS and HPI laboratory.

- 10.1 An initial and annual serum sample will be tested, and an aliquot stored in the Wadsworth Center staff serum banking facility.
- 10.2 Education for all employees working in the SARS or HPI laboratory regarding the details and implementation of this protocol must be provided prior to admission to the laboratory and should include discussions of information management during events or illness in the interest of open communications as well as rumor control.
- 10.3 There may be an initial physical examination to establish baseline physical parameters that may be useful in evaluation of respiratory infections developing during periods following potential exposure. The respirator program, or other regular examination at the Department of Civil Service Employee Health Center may serve this purpose.
- 10.4 Unexplained employee absenteeism will initiate a supervisor inquiry to rule out an unreported respiratory illness requiring a risk assessment response.
- 10.5 In the interest of both optimizing patient management practices and supporting public health practices, a review of relevant employee medical records by the infectious disease medical provider may be necessary. The employee should be made aware of this prior to working in the BSL-3 laboratory, and documentation that the employee has been apprised of this possibility should be on file. Consent forms may be completed upon assignment to the BSL-3 laboratory.
- 10.6 Surgical masks and thermometers for home monitoring use will be provided by the Wadsworth Center upon assignment to the BSL-3 laboratory, as will recording forms.
- 10.7 The Wadsworth Center Safety and Security Office will coordinate some aspects of medical services, maintain some records and interpret and enforce workplace health regulations.
- 10.8 The Infectious Disease Medical Provider, in conjunction with the County and DOH epidemiologists will arrange for required imaging, isolation, hospitalization, and patient transport.
- 10.9 Initial and continuing education of all BSL-3 laboratory staff in laboratory safety and occupational health practices is the basis for proper execution of the provisions of this protocol.

## **Section 11: Medical costs and leave**

A system to manage medical costs for the evaluation and treatment of employees with symptoms requiring follow-up (as per approved medical protocols) must be developed by the institution in the context of its overall benefits package. This system may include a combination of paid leave benefits, workers compensation and health insurance benefit coverage dependent on the particular circumstances of the incident and on the employee's health insurance plan.

Prompt and accurate reporting of events or symptoms will ensure containment of disease and protection of the public health. To facilitate and encourage prompt reporting, the employer will assure that initial costs involved in this risk evaluation will be covered with no out-of-pocket costs to the employee.

A system must also be developed to provide for required routine medical surveillance such as serum banking and medical clearance for respirator use. This should be provided on work time and at no charge to the employee.

A document describing the NYSDOH-specific approaches to Medical Costs and Leave issues can be obtained upon request.

## **Section 12: Administrative considerations**

### **12.1: Protocol Review**

12.1.1 This protocol will be reviewed by the responsible scientists, Wadsworth administrative staff, Wadsworth Biosafety Officer, the Bureau of Communicable Disease Control, and the NYS DOH Occupational Health and Safety Director annually and upon all significant applications.

12.1.2 The Risk Assessment Group will be convened after each application but no less than semi-annually to discuss approaches and create written recommendations for implementation or changes to the protocol.

### **12.2 Training**

12.2.1 Initial training and annual retraining sessions on the practices described in this protocol will be required and arranged by the Principal Investigator and the Wadsworth Center Safety and Security office.

2 Attachments