University of Prince Edward Island	Policy No. admordgnl0012	Revision No. 0
Policy Title: Medical Surveillance Plan for Research Involving Biohazardous Materials		Page 1 of 6
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Authority: Board of Governors	Responsibility: Vice-President, Research Services & Graduate Studies	WWW Access: Yes

1. Purpose

1.1 The purpose of the plan is to prevent illness related to the exposure of laboratory personnel to infectious materials, biological toxins, and animal allergens in the course of their research. Preventive measures include:

1.1.1 Immunization and/or protective titre verification that may be required (example: rabies, Hepatitis B);

1.1.2 The identification of required personal protective equipment (PPE);

1.1.3 Ensuring the education of personnel on potential routes of exposure, response procedures if exposed, and symptoms of infection to aid in early detection of potential disease;

1.1.4 The required reporting of all potential exposure, incidents, near misses, and laboratory acquired infections;

1.1.5 The development of mitigation strategies for personnel working with animals in research which pose an allergen risk.

2. Scope

2.1 This Medical Surveillance Plan applies to those individuals working with Risk Group (RG) 2 human/zoonotic pathogens, potentially infected materials (including human tissue, blood, and body fluids), as well as those who may be exposed to animal allergens within a research environment.

3. Responsibilities

The Vice-President, Research Services and Graduate Studies has overall responsibility for the Medical Surveillance Plan, including its implementation and review.

3.1 Duties and Responsibilities

3.1.1 Department Chairs must:

3.1.1.1 Inform department members of the Medical Surveillance Plan and promote compliance.

3.1.2 Supervisors/Principal Investigator (PI) must:

3.1.2.1 Conduct a local risk assessment of their project. Anyone planning to begin a research project which involves a human/zoonotic pathogen, potentially infected materials, or human tissue, blood or body fluids must submit a Biosafety Permit application. The Biosafety Permit application must include an Exposure Control Plan that must be read, understood, and instituted by all individuals listed. Their understanding of the plan and their intention to comply with the plan must be confirmed by their signature on the form. This application process serves as the laboratory based risk assessment and determines, among other things, the pathogen(s) of concern, the potential for exposure, potential health concerns of staff, and the consequences of infection should exposure occur. Any research that involves the use of laboratory animals requires an Animal Use Protocol;

3.1.2.2 Comply with all requirements for biosafety permit approval from the Biosafety Committee;

3.1.2.3 Determine in advance the category of risk for any parenteral exposure to human blood/tissue/body fluids prior to working with these materials. PIs must be prepared to follow up any such exposures with the post exposure prophylaxis protocol that is recommended by the PEI Department of Public Health;

3.1.2.4 Ensure that all personnel have been informed about the potential risks of the planned project, and that the required safety measures are implemented, including the preparation of a post exposure prophylaxis plan if working with human blood, tissue, and/or body fluids;

3.1.2.5 Identify personnel requiring vaccination and/or verification of a protective titre, and ensure no work begins before the immunization verification process is complete, or a vaccination waiver has been signed. Costs associated with vaccination and titre checks will be covered by the University;

3.1.2.6 Ensure all required training (such as blood borne pathogen training) is completed before work commences;

3.1.2.7 Consult with the Biosafety Officer, University Veterinarian, Biosafety Committee or Animal Care Committee, as appropriate, on the application of this policy to the proposed research;

3.1.2.8 Discuss, in confidence, any personal health issues self-identified by personnel that could increase personal risk as a result of exposure to the biohazardous material(s) and/or animal allergens listed on the UPEI Exposure Control Plan, and discuss mitigating strategies that could be

instituted. Inclusion of a medical professional recommendation may be required;

3.1.2.9 Provide all required PPE and safety equipment to personnel as listed in the Exposure Control Plan and approved by the Biosafety Committee (refer to the PPE section in the UPEI lab safety manual);

3.1.2.10 Immediately inform the Biosafety Officer about personnel who have been exposed to biohazardous materials;

3.1.2.11 Submit an Incident Report Form for potential exposure, incidents, near misses, and any laboratory acquired infections.

3.1.3 Research Personnel must:

3.1.3.1 Adhere to the Medical Surveillance Plan;

3.1.3.2 Comply with the Exposure Control Plan, including use of PPE, operational practices and Universal Precautions, as required. Be aware of and follow the post exposure prophylaxis protocol if human blood/tissue/body fluids are handled;

3.1.3.3 Complete any required vaccination program and/or titre check and provide documentation of immunization and/or protective titres to the Biosafety Officer before beginning work. Individuals with concerns about vaccination are encouraged to discuss with their health care provider the risks and benefits of vaccination. If vaccinations are refused, a vaccination waiver must be completed and submitted to the office of Research Services and Graduate Studies in advance of beginning work;

3.1.3.4 Complete all required training before working with the infectious agent/toxin;

3.1.3.5 Report any exposure to biohazardous materials, incident, near miss, or illness that may be associated with the work to the supervisor or PI, and submit an Incident Report Form as soon as possible;

3.1.3.6 Report to the supervisor any medical or health condition (e.g. immunosuppressive medications, pregnancy, or illnesses that could compromise immune status) that could potentially change the employee's risk if he/she were exposed to the biohazardous materials involved in the research project.

3.1.4 Biosafety Committee

3.1.4.1 Must review all biosafety applications to determine if medical surveillance is required. If it is required, then the Committee must ensure that the information provided by the PI is complete;

3.1.4.2 The Committee may require changes to the application, based on the risk assessment. These changes are mandatory and may include, but are not necessarily limited to, revisions to protocols, PPE to be worn, disinfectant to be used, and training to be completed before work begins;

3.1.4.3 Employees listed on the Exposure Control Plan who decline to be vaccinated would be asked to sign a waiver, or may not be permitted to work on the project, depending on the outcome of the Biosafety Committee's review of the risk assessment;

3.1.4.4 When medical surveillance is required, the Committee will award the Biosafety permit after all requirements have been met.

3.1.5 Biosafety Officer must:

3.1.5.1 Provide biosafety training and biosecurity training;

3.1.5.2 Provide blood borne pathogen training;

3.1.5.3 Provide advice in advance of application submission, when requested;

3.1.5.4 Inform the Biosafety Committee when individuals have received the necessary immunization(s), signed waivers or verified titres;

3.1.5.5 Conduct incident investigations with the Health and Safety Advisor and/or other individuals such as the University Veterinarian, or those with specialized training (e.g. medical professionals);

3.1.5.6 Maintain a confidential file of all records pertaining to vaccination and immune status.

3.1.6 Animal Care Committee must:

3.1.6.1 Identify Animal Use Protocols that may require medical surveillance and direct this information to the Research Compliance and Awards Coordinator, Research Services;

3.1.6.2 Provide direction on dealing with research animal related allergies.

3.1.7 University Veterinarian must:

3.1.7.1 Assist with incident investigations when experimental animals are involved;

3.1.7.2 Provide education on the risks of allergen exposure, and educate on procedures, PPE, and equipment that may be beneficial to the individual's health.

3.1.8 Health and Safety Advisor must:

3.1.8.1 Conduct incident investigations with the Biosafety Officer.

4. Policy

4.1 The University of Prince Edward Island requires that all principal investigators/faculty members assume the primary administrative responsibility for the implementation and adherence to this Policy as it applies to their research.

In addition, all individuals working under this plan must adhere to the procedures outlined by this Policy. No research requiring medical surveillance may be undertaken until the Biosafety permit has been obtained, and medical surveillance requirements have been met. All activities require compliance with the following:

Canadian Biosafety Standards and Guidelines, 2nd edition
http://canadianbiosafetystandards.collaboration.gc.ca/

UPEI Biosafety Policy
http://www.upei.ca/policy/adm/ord/gnl/0007

UPEI Laboratory Safety Manual
http://www.upei.ca/hr/health-and-safety/lab-safety

AVC Rabies Vaccination Program
http://avc.upei.ca/dvm/incoming-students

PEI Occupational Health and Safety Act
http://www.gov.pe.ca/psc/index.php?number=1033036&lang=E

CCAC Guide to the Care and Use of Experimental Animals, Vol. 1 (1993)
http://www.ccac.ca/en_/standards/guidelines

Public Health Agency of Canada: Canadian Immunization Guide
http://www.phac-aspc.gc.ca/publicat/cig-gci/

5. Review

5.1 This plan is to be reviewed every 5 years or earlier, if necessary, by the Office of Research Services and Graduate Studies.