

CTRNet Standard Operating Procedure Immunization and Personnel Accident Reports			
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REVISION HISTORY

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6.1.002	2008	JdSH	1 st Release.

1.0 PURPOSE

All human specimens, independent of their state, should be treated with universal precautions. They should be handled as if infected with agents that may be pathogenic to humans. Precautions should be taken to safeguard personnel from potential infectious hazards. They should have up-to-date immunizations and report and document all accidents that they may be involved with at the biorepository.

2.0 SCOPE

The Occupational Health and Safety Procedures at the institution hosting the biorepository will have procedures that should form the basis of safety precautions and actions personnel should follow. However, this procedure covers basic steps that should be followed to ensure that personnel are adequately immunized and accidents are appropriately reported and documented.

3.0 REFERENCE TO OTHER POLICIES AND SOPS

1. CTRNet Policy: POL 007.001 Material and Information Handling Policy
2. CTRNet Policy: POL 005.001 Records and Documentation

4.0 ROLES AND RESPONSIBILITY

The policy applies to all personnel from CTRNet member repositories that work at the repository site and are responsible for collecting, processing and storing of repository samples.

Tumour Bank Personnel	Responsibility/Role	Site Specific Personnel and Contact Information
Phlebotomist/ Venipuncture nurse	Handle Human Biological Material	
Lab Technician	Collect and process biological material	
Pathologist/Pathologist assistant	Collect, Process and assess biological material	

5.0 MATERIALS, EQUIPMENT, AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

Materials and Equipment	Materials and Equipment (Site Specific)
Accident Reporting forms	
Occupational Health Records	

6.0 DEFINITIONS

Biohazard: Microbial or antigenic entities presenting risk or potential risk to the well-being of man, other animals, or plants, either directly through infection or indirectly through disruption of the environment.

Biohazardous Material: Any substance which contains or potentially contains biohazardous agents.

Safety: Processes, procedures and technologies to ensure freedom from danger or harm.

7.0 PROCEDURES

CTRNet repositories must follow Occupational Health and Safety Procedures at the institution at which they work. The procedure below is a guide for minimum precautions that should be taken to safeguard personnel from potential biohazardous/infectious agents they may encounter.

7.1 IMMUNIZATION

1. Personnel that handle human biological materials should receive appropriate immunizations or tests for the agents that may potentially be present in the lab or in the material handled.
2. Only personnel who have been advised of the potential hazards and appropriately immunized may access biological material or enter certain portions of the lab.
3. Provide personnel with access to the vaccine through the institutional occupational health department or compensate them for immunization they may have to obtain at external clinics.
4. Provide personnel with information about the pathogen and the vaccine (see below), and advise them of the possibility of vaccine failure or vaccine-related disease.

Hepatitis B Viral (HBV) vaccination is highly recommended for employees whose work activities potentially place them in contact with human blood or blood-contaminated body fluids. Employees have the right to refuse the HBV. Employees who refuse must complete the Hepatitis B Vaccine Letter of Declination for their employee file.

Tetanus vaccination: Tetanus (lockjaw, painful spasms of all muscles) is a serious disease caused by a germ that enters the body through a cut or wound. Employees working in health care or animal research environments should be knowledgeable of the date of their tetanus immunization- usually received in 3 doses during childhood. If one is unsure of the date, a booster dose is recommended as well as every 10 years thereafter to maintain protective antibodies against tetanus. Tetanus toxoid injection is often combined with Diphtheria vaccine (Td).

Always seek prompt medical attention for any wounds where a booster may be recommended sooner than 10 years.

5. Individuals declining vaccination must provide their reason(s) on a signed form of declination. Until the individual has been immunized, or has signed a form declining immunization, he/she must not work with human biological materials.

6. At minimum each personnel should have the following for their health clearance of immunizations— including diphtheria/tetanus within 10 years; polio and mumps; complete Hepatitis B vaccine series; and laboratory evidence (titer) of immunity to rubella, rubeola and varicella—and TB Mantoux clearance. Personnel who have not taken a TB skin test within the last twelve (12) months must take the two-step TB test (PPD).
7. If there are new licensed vaccines or medical prophylaxes available for the type of biological commodities potentially or actively being manipulated, personnel should have access to these immunization agents.
8. Maintain an active record (with updates) of personnel immunizations and vaccine booster treatments.

7.2 PERSONNEL ACCIDENT REPORTS

Laboratory events that might create hazards, exposures, or accidents requiring reporting could be classified in two categories:

Laboratory accidents during work with chemical hazards, biohazardous materials or in a biohazardous area that could result in physical injury, cuts, burns, abrasions, or fractures.

Other events occurring during the handling of biohazardous agents or infected specimens, that could allow release of the agent to the environment or its undesired transfer to employees or cultures.

In the first category the injury site could be contaminated with the biohazardous agent in use. In the second category illness or unwanted cross contamination could occur without physical injury. Mechanisms of infection typical of the second category are ingestion of contaminated fluids, exposure to aerosols, and penetration of agents through the unbroken skin. Therefore, for the purpose of controlling biohazards, all accidents, known exposures, and potential hazards should be identified and reported.

1. Familiarize all personnel with the location and use of safety showers, eye wash equipment and personal protective equipment.
2. If needed seek medical help immediately.
3. Prominently post emergency telephone numbers to be called in the event of fire, accident, flood, or hazardous or chemical spill in the repository.
4. Immediately inform the supervisor of the individual involved in the accident.
5. Have an internal accident-reporting system to help discover and correct unexpected hazards.
6. The internal reporting system should include provisions for investigating the causes of injury and any potentially serious incident that does not result in injury.

7. The goal of such investigations should be to make recommendations to improve safety, not to assign blame for an incident.
8. Beyond this follow institutional Occupational Health and Safety, federal, provincial or local reporting regulations and procedures as relevant.
9. In the event the worker is seriously injured and cannot report the accident, the supervisor with knowledge of the accident is still responsible for completion of the reports.
10. Document all accidents, investigations and outcomes.

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

1. Tri-Council Policy Statement; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, August 1998. <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
2. Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER). <http://www.isber.org>

9.0 APPENDICES

None