

Working with Human Blood, Tissue, Body Fluids

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Section 1. ADMINISTRATIVE OVERVIEW

A. PURPOSE- The Purpose of this bulletin is to ensure that all U of M lab and clinical research personnel are aware of the hazards of working with human blood, tissues and body fluids and understand the safe-work practices required to protect themselves and others.

B. SCOPE-

- The biological agent risk assessment and biosafety operational practices apply to personnel (staff, students, visitors) working in laboratories and clinical research areas in U of M owned buildings who have **reasonably anticipated occupational exposure or exposure as part of university course work to human blood, body fluids or tissue (including primary human cell culture) or other potentially infectious material (OPIM) as listed.**
- Information related to the biological agent risk assessment and containment level biosafety practices for work with human cells in continuous established cultures is discussed in another Bulletin.
- ***New for 2014:*** *The U of M Biosafety Advisory Committee has determined that the collection and simple manipulation of human samples as typically carried out in a clinical research or exercise physiology setting is covered by the U of M Biosafety Policy/Procedure and requires a Biosafety Permit. A 'Clinical Biosafety Permit' has been developed.*

C. POLICY-

- All work with human blood, other body fluids and tissues will be done according to the Public Health Agency of Canada's (PHAC) **Containment Level 2 (CL2)** facility design and operational standards as described in the most current version of the Canadian Biosafety Standards (and Guidelines), unless the tissue/fluid is known to contain a pathogen of a higher risk group (i.e., greater than Risk Group 2).
- Exceptions may apply to work done under a Clinical Research Permit as based on a local risk assessment (LRA) and in consultation with the Biosafety Officer (BSO).

- Clinical Permits are not available for areas where human pathogens are extracted immunoprecipitated, concentrated, collected, amplified, cultivated, refined, cultured, and/or grown from such samples.
- Phlebotomy procedures (involving human participants) will be compliant with the U of M Human Ethics Resource Committee (HERC) document '[Guidelines for the collection of blood samples \(phlebotomy\) in research involving humans](#)'.

D. RESPONSIBILITY- It is the responsibility of the Principal Investigator, Laboratory Supervisor, and responsible owners of these materials to:

1. obtain the appropriate U of M Biosafety Permit before beginning work.
2. develop site-specific protocol (safe work practices, PPE, decontamination and disposal practices) and ensure lab staff are trained in the procedures.
3. develop site-specific procedures to document training by involved personnel.
4. ensure staff are given the opportunity to protect themselves through immunizations as per the U of M Policy/Procedure: Immunization Standard and to document immunization and/or risk-of-exposure counselling.

Section 2. PATHOGEN RISK ASSESSMENT

Related to human blood, body fluids and tissue

Given the number of pathogens that can potentially be associated with human blood and tissues, human body fluids or human-derived products, there is no known screening technique that can offer complete assurance that such materials are free of pathogens.

Universal and standard precautions are terms that were developed in the health care setting to describe safe work procedures with human blood, blood products and certain fluids in order to prevent infection from the pathogens that they may contain. These procedures were developed using the assumption that it was prudent to assume a hazard, including more serious pathogens such as Hepatitis B and C and HIV could reasonably be expected to be present, rather than attempting to screen for all or suspected pathogens.

In the laboratory setting, this approach assumes that Risk Group 2 biological agents are present and Containment Level 2 facility design and operational standards are to be in place. Extreme care must be taken to avoid aerosol producing procedures, spilling and splashing when working with any of these materials. Pathogens should be presumed in/on all equipment and devices that come into direct contact with any of these materials.

It is still important to additionally obtain as much information as possible about your sample before beginning work, in order to develop specific safe work practices for the work in your lab or possibly even determine that a different (i.e., higher) containment level is required.

A further risk assessment of your specific material will include collection of information on the following items:

1. Tissue/Sample Origin

1.1 Blood and Blood-related Material

As discussed there are **pathogenic microorganisms** which **are generally associated with human blood**. These are often also referred to as Blood-Born Pathogens (BBP).

In addition to blood samples, these BBPs may also be found in:

- semen, vaginal fluids and secretions,
- CSF- cerebro-spinal fluid,
- other specimens containing visible blood (fresh swabs of a wound, sputum, etc.),
- unscreened or inadequately treated blood products,
- serum-derived fluids or products,
- saliva,
- unfixed tissues and organs.

The BBPs of most concern include, but are in no way limited to, Hepatitis B or Hepatitis C virus and human immunodeficiency virus. A brief discussion of these viruses can be found below. Additionally, the [Pathogen Safety Data Sheets](#) (previously known as Material Safety Data Sheets or MSDSs for infectious material) for these pathogens should be available for reference when working with the human blood, tissues and body fluids listed above.

Hepatitis B virus (HBV)- This is a virus that infects the liver. While there are several types of hepatitis, Hepatitis B infection is transmitted primarily through exposure to infectious body fluids (blood, blood products, CSF, serum-derived fluids, saliva, semen, vaginal fluids, unfixed tissues and organs). It initially causes an inflammation of the liver but can lead to more serious conditions, such as cirrhosis and liver cancer. It is the most frequently occurring laboratory-associated infection; the incidence of Hep B in some categories of lab workers is 7 times greater than that of the general population. A vaccine is available for HBV prevention.

Human immunodeficiency virus (HIV)- This is a virus that infects the immune system, weakening it so that it is ineffective in fighting other diseases as well as HIV. HIV can be found in blood, semen, vaginal secretions, CSF, other specimens containing visible blood, unscreened or inadequately treated blood products.

Noe: For work with known HIV positive samples refer to the 2014 [Biosafety Directive for Human Immunodeficiency Virus \(HIV\) and Human T-cell Lymphotropic Virus Type 1 \(HTLV-1\)](#) available on the PHAC website.

1.2 Other Human Material that is Potentially Infectious (often referred to as OPIM)

Human samples may also contain other micro-organisms based on the tissue/sample origin. For example, **fecal samples** may contain a variety of bacteria and viruses, **respiratory samples** may contain TB or influenza, neurological tissue may contain prions, cervical samples may contain Human Papilloma Virus. Further research with a clinical infectious diseases reference book or medical consult by the worker and their PI may be required. This will help determine additional hazards and the most likely routes of transmission of any potential pathogens. Again, once potential pathogens are identified, Public Health Agency of Canada (PHAC) Pathogen Safety Data Sheets (PSDSs) should be referenced.

2. Donor Population and Health Status

Universal precautions are based on the assumption that the health status of the donor is unknown. However, when possible you should try and obtain as much information as possible about the donor population and determine if a pathogen is known to be, or highly likely to be present. For example is the sample from a normal donor pool, a clinical sample from patients with specific symptoms or from donors known to be positive with a certain virus or bacterial infection? Is there an accompanying impact on the micro-organism load or concentration?

Again, if a pathogen is known or highly likely to be present, a [PSDS](#) for that specific agent should be available and referenced to develop safe work practices.

3. Types of Procedures

All procedures should be evaluated for the ability to transmit pathogens due to any of the four main routes: **inhalation, inoculation, ingestion, and contact with mucous membranes**. For example does the procedure provide the opportunity for:

- direct contact with contaminated sharp objects.
- direct contact with mucous membranes via splashes etc.
- production of aerosols that can be inhaled or produce droplets that can land at a distance from the procedure and be transmitted to mucous membranes or ingested due to indirect contact.

3.1 Aerosol Producing Procedures

Procedures which may produce aerosols include: pipetting, spills and splashes, loading needles, discharge from animals or ectoparasites, operation of a centrifuge, homogenization, plating cultures.

Operational practices and techniques used to control the production of aerosols include but are not limited to: emptying of pipette down the side of tubes, use of cooled or disposable loops to plate culture, use of a lab-grade blender or homogenizer, use of sealed safety cups and rotors with centrifuging.

At Containment Level 2, all aerosol-producing procedures should be done in a Biosafety Cabinet (BSC).

3.2 Procedures related to work with Blood-Borne Pathogens

Blood-born pathogens are primarily transmitted by inoculation and contact with mucous membranes. Evaluate all procedures for the following types of incidents:

- Accidental puncture** by a contaminated sharp object. In the lab, examples of such tasks could include using needles/syringes, razor blades, glass tubing, pipettes, pipetteman tips, and handling waste and trash.
- Contamination of skin and mucous membranes:**
 - **Direct contact** with contaminated material through open cuts or skin abrasions, or to mucous membranes (e.g. unprotected mouth, eyes, nose) through unanticipated splashes, e.g. opening tubes of uneven pressure, tubes, bottles breaking releasing liquid hitting a hard surface.
 - **Indirect transmission** to open cuts or mucous membranes (eyes, mouth, nose, genitals) through transfer by hand/glove contact of unknowingly contaminated surfaces. i.e. created by splashes or **aerosols** that land at a distance from the source procedure.

Note:

- Hepatitis B Virus can survive in dried blood for long periods (weeks) and can remain stable on environmental surfaces for at least 7days at 25°C. Therefore, attention to surface disinfection after spills and at the end of the working day is critical.
- For HIV, survival in the environment is not as much an issue. Drying in the environment causes a rapid 90-99% reduction in HIV concentration (within several hours). Keep hands away from the eyes, nose and mouth in order to avoid potential exposure of the mucous membranes; eye goggles or face shields may assist in accomplishing this objective.

3.3 Procedures related to work with Other Potentially Infectious Material (OPIM)

Depending on the procedures in use, the type of sample and the potential presence of other contaminating pathogens (e.g. fecal samples contaminated with pathogenic *E. coli*, or respiratory samples contaminated with influenza virus), lab workers should additionally consider transmission by the following routes.

a) Ingestion:

Exposure could be due to direct contact or indirect contact by the following actions.

- unconscious hand-to-mouth actions
- placing contaminated articles or fingers in the mouth
- eating, drinking or smoking in the laboratory or failing to use proper hand hygiene
- mouth pipetting

b) Inhalation:

Breathing aerosols unknowingly generated by **aerosol-producing procedures** (sonicating, grinding, blending, and flaming a transfer loop) can give rise to contaminated aerosols.

Some surveys indicate that up to 80% of laboratory-acquired infections were transmitted by aerosols.

Section 3. CONTAINMENT LEVEL 2 REQUIREMENTS

Related to work with human blood, body fluids and tissues

As indicated in the policy statement of this document, at the U of M we have opted to follow the Public Health Agency of Canada's (PHAC) 'Canadian Biosafety Standards (CBSG)' for all work with human blood, body fluids and tissues. Exceptions for some individual requirements may apply for human blood, body fluids, tissues excluded from licensing under the Human Pathogens and Toxins Act but only if **based on a local risk assessment and in consultation with the Biosafety Officer**. **

Containment Standards include both **Facility Design and Operational Standards**. The CL2 facility design and operational standards have been extracted to a separate document found on the [Biosafety Program](#) website. The operational standards as described in Chapter 4.0 of the Guidelines are adapted below to reflect the requirements for work with human blood, body fluids and tissues in the context of in eight (8) standardized sections.

***Background: Regulation of work with human blood, body fluids and tissues by The Human Pathogens and Toxins Act (HPTA) excludes work with a human pathogen or toxin in an environment in which it naturally occurs, as long as it has not been cultivated or intentionally collected or extracted. <http://www.phac-aspc.gc.ca/lab-bio/requ/sai-di-1-eng.php>. The HPTA does apply to any human pathogen and toxin that have been extracted immuno-precipitated, concentrated, collected, amplified, cultivated, refined, cultured, and/or grown from such samples.*

A. FACILITY-DESIGN STANDARDS

Refer to all requirements for CL2 facility design requirements in Chapter 3 of the [CBSG](#) (1st Edition) or the relevant section of the most current edition.

B. OPERATIONAL STANDARDS

NOTE- Until the transmissible pathogen is inactivated appropriately, all of the following operational standards apply to the handling of human-derived material that contain or could potentially contain human pathogens. Inactivation may include disinfection or decontamination steps (e.g. autoclaving or surface disinfection with 70% ethanol) or **inactivation using heat or another chemical** that is part of the experimental procedure.

1. Training

- a. The PI is to provide training on this SWP, First aid and the U of M [Post Exposure Protocol](#), [biological agent incident response and reporting](#) or site specific alternate training.

- b. The PI is to identify the location of spill-control material and safety equipment including eyewash and shower that are available on site.
- c. Phlebotomy procedures involving human participants will be compliant with the procedures and training requirements in the U of M Human Ethics Resource Committee (HERC) document '[Guidelines for the collection of blood samples \(phlebotomy\) in research involving humans](#)'.

2. Access Control and Biosecurity

- a. Doors to the containment zone where the work is done must be closed at all times.
- b. Access to the containment zone to be limited to authorized personnel and authorized visitors. Refer also to the Basic Lab Biosecurity Plan in the Biosafety Guide.
- c. A [U of M Workplace Hazard Information Placard \(WHIP\)](#) is required with current contact info, Containment level 2 and biohazard logo/clinical permit icon and any other pertinent entrance requirements. The signage can be acquired by selection of appropriate information on the EHSO website at http://umanitoba.ca/admin/human_resources/ehso/geninfo/signage.html
- d. Donning and doffing of PPE dedicated to the containment zone in accordance with SOPs and based on a LRA.
- e. Personnel to wash hands after handling infectious materials and when exiting the containment zone.

3. Immunization

- a. Vaccines are currently available for Hepatitis B Virus (HBV) and are recommended for all personnel working with BBP as part of their research project. The vaccine is not currently provided free-of-charge to all Manitobans, but is available at a cost as needed for potential occupational exposure.
- b. **Following are the requirements for HBV vaccination for all workers with occupational exposure to human blood and body fluids and tissues at the U of M:**
 1. The PI/Departments/responsible owners of these materials will ensure that all current and new lab personnel working with Blood-Born Pathogens must be informed of the option to protect themselves with Hep B vaccinations. Hep B vaccination can be required as a condition of employment or acceptance into a program for new personnel. Consult with Human Resources to include this in any offers of employment or study. Please also review the [U of M Procedure: Immunization Standard](#) for a more complete discussion of the requirements.
 2. *Where the exposure will only be to human cells in established continuous cultures, potential staff or students will be provided with the information and be given the opportunity to accept or decline vaccination.*
 3. All workers should additionally be advised :
 - a. to consult with their personal health care provider to ensure that their general immunization status meets with current Manitoba Health/Canadian Immunization Guidelines.
 - b. **that safe-work procedures and post-exposure procedures are also critical factors in protecting workers from all potential BBPs.**
 4. U of M does not currently have a central office for providing immunization services. For **current** staff, the Principal Investigator can document the risk assessment on the form http://umanitoba.ca/admin/human_resources/ehso/media/090205RiskAssessmentForm.doc and send the person to their personal health care provider along with the completed Risk Assessment form and the 'Immunization Record' form found at http://umanitoba.ca/admin/human_resources/ehso/media/ImmunizationAppAug06.pdf
 5. The health care provider will use these to document the immunization, or document that the staff member has been counselled but has declined to receive the immunization.
 6. All vaccination records, declinations and counselling documents should be kept with the personnel files in the department (and protected by FIPPA/PHIA).
 7. If you need help in completing the form or require a further consultation, please contact the Occupational Health Coordinator, Judy Shields at 474-6438.

4. Exposure Control

4.1 Avoid exposure by Accidental Puncture

- a. Identify and develop a site-specific protocol for all sharps that may come in contact with the potentially infectious material (PIM). The protocol must comply with the U of M [Biohazardous Waste Chart](#) and requirements for waste disposal in the Biosafety Guide.
- b. Replace glass with plastic where possible.
- c. Strictly limit the use of needles, syringes and other sharp objects. Replace procedures using needles and scalpel blades with alternate, less hazardous tools where possible. Refer to the Biosafety Program Guidance Document found at http://umanitoba.ca/admin/audit_services/media/Sharps_Safety.pdf
 - Safety-Engineered sharps should be used in research and clinical labs whenever suitable for the task.
 - **Safety-Engineered sharps used in clinical research areas must follow the Manitoba Workplace Safety and Health Act [WS& H Act Part 45.1](#).**
 - Avoid auto-inoculation and the generation of aerosols during use and disposal.
 - Do not bend, shear, recap or remove a needle from the syringe.
 - Promptly place syringes with attached needles into a puncture-resistant sharps container.
 - Fill sharps containers only 2/3 full.

4.2 Avoid exposure by Direct Contact

- a. Bench work is acceptable at Containment level 2 with certain provisos. **Working inside a BSC is often recommended or required by the BSAC.**
- b. Take extreme care to avoid spilling and splashing infected materials, to minimize creation of aerosols, and to contain a spill using appropriate devices/lab-bench absorbent covers, etc.
- c. At Containment Level 2 all aerosol producing procedures should be done in BSC. A risk assessment will determine which procedures and materials require the use of the BSC.
- d. Wear the Personal Protective Equipment (PPE) prescribed in the document or by your PI.
- e. Wear Gloves (e.g., latex, vinyl, co-polymer) for all procedures that might involve direct skin contact with potentially infectious material.
- f. Primary barriers are recommended for use during procedures performed on the bench top, where there is a high potential for creating splashes, splatters or generating droplets. An example of a primary barrier would be PPE such as lab coat, gloves and face shield or safety goggles and a facemask. Other scenarios are to work behind a splash shield.
- g. Keep hands away from the eyes, nose and mouth in order to avoid potential exposure of the mucous membranes.
- h. **Hand washing is a critical component of exposure control. Wash your hands after removing gloves, before leaving the laboratory and at ANY time after handling materials known or suspected to be contaminated.**
- i. **Cover open wounds, cuts, scratches, and grazes with waterproof dressings and gloves. If you exhibit any open wounds (broken skin) in areas that can not be covered by dressings or clothing, re-evaluate the work in process. Suggestions for mitigating the exposure in the case of broken skin that cannot be covered include, for example where the wound is on the face, work with a full face shield; work in the BSC, or have someone else do the work.**
- j. Do not eat, drink or smoke or store food, personal belongings, or utensils in the lab AT ANY TIME.
- k. Do not apply cosmetics, or insert or remove contact lenses. Wearing contact lenses is permitted only when other forms of corrective eyewear are not suitable.
- l. Wearing jewellery is not recommended in the laboratory. For example, large rings can puncture gloves, and watches and necklaces can hang into and be contaminated by your cultures and thereby be a source of further environmental and personnel contamination.
- m. Oral pipetting of any substance is prohibited in any laboratory.

- n. Tie back or restrain long hair so that it cannot come into contact with hands, specimens, containers or equipment.

4.3 Avoid exposure by Indirect Contact

- a. Separate paperwork and report writing from work areas where biological agents are in use.
- b. Clean and decontaminate work surfaces with a suitable disinfectant at the end of the day and after any spill of potentially biohazardous material.
- c. Do not wear protective laboratory clothing in non-laboratory areas
- d. Do not store laboratory clothing in contact with street clothing.
- e. Decontaminate and label or tag-out contaminated materials and equipment leaving the laboratory for service or disposal. Follow the U of M [Decommissioning Procedure](#) and the [Final Disposal of Lab Equipment Guidance Document](#), and [Biohazardous Waste Disposal Chart](#).

5. Biohazardous Waste Disposal

- a. Post and follow the U of M [Biohazardous Waste Disposal Chart](#) or alternate site specific procedures developed in consultation with the BSO.
- b. For a more complete discussion of the requirements refer to the section on the disposal of Biohazardous Waste in the U of M [Biosafety Guide](#), Section 8.6.
- c. Note the disposal requirements for potential sharps (items that have the potential to puncture the skin) and are contaminated with human blood and body fluids.

6. Disinfection and Decontamination

- a. Use disinfectants effective against the agents. These must be available at all times within the areas where the biohazardous material is handled or stored.
- b. Refer to the MSDSs for other acceptable disinfectants, for example, for HBV and HIV.
- c. Refer to Section 8.5 in the Biosafety Guide to select appropriate concentrations and procedures for using bleach and alcohol. Note the short shelf life of bleach. Working solutions should be made fresh weekly; daily recommended.

7. Personal Protective Equipment (PPE)

Wear the PPE as prescribed by your PI or as found, below. Refer also to Biosafety Guide Section 8.4 and Generic WHMIS and Basic Lab Safety PowerPoint presentation for more information.

7.1 Shoes

- a. Wear shoes with a closed toe and heel (i.e. no sandals or clogs) in the lab at all times.

7.2 Lab Coats

- a. A clean lab coat should be available at all times in case one becomes contaminated.
- b. It is preferable that legs and arms are covered, for example by long pants, socks, a buttoned-up lab coat with long sleeves with cuffs.
- c. If any clothing is exposed or suspected of exposure, decontaminate the clothing before laundering. For example autoclave lab coats or treat the spill with bleach. This is necessary unless laundry facilities are inside the containment area of the lab and have been proven effective in decontamination.
- d. **A back-closing gown may be preferable to a front-closing lab coat or it may be required for some work, such as that in a BSC or in cleaning up a spill.**
- e. U of M [Guidelines for Lab Coats](#) – Selection, Use and Care.

7.3 Face Protection

- a. Wear safety glasses for all **bench work** involving human tissues or fluids.
- b. Wear face protection (full face shield; or safety glasses and mask) for bench procedures that are likely to generate droplets of blood or body fluids. This will prevent exposure of mucous membranes of the mouth, nose and eyes to potential infectious agents, for example during spill clean-up.

7.4 Gloves

- a. Wear gloves (e.g., latex, vinyl, co-polymer, nitrile) for all procedures that might involve direct skin contact with potentially infectious material. Have gloves available in sizes required by lab personnel.
- b. Wear gloves if you have dermatitis or other lesions on the hands even when you anticipate having only indirect contact with potentially infectious material.
- c. Inspect gloves for tears and punctures before and after putting them on.
- d. Do not touch contaminated surfaces with bare hands when removing your gloves.
- e. **Wash your hands immediately after removing gloves.**
- f. **Always** remove gloves when leaving the lab, and before touching clean surfaces in the lab such as a phone, computer, light switch, door handle or book.
- g. Gloves that have been in contact with biohazardous material should be considered contaminated and should be decontaminated before disposal.
- h. Nitrile gloves are preferable due to the lower frequency of allergic responses by people wearing nitrile compared to latex gloves. It should also be noted that nitrile gloves will not maintain their integrity when punctured, and that their use means lab personnel will be able to identify potential exposures sooner.

8.0 Emergency Response

8.1 Post Exposure Protocol (PEP)

- a. The U of M [Post Exposure Protocol](#) or your alternate appropriate site-specific procedure should be posted in the lab in a visible place, for example next to the phone.
- b. Resource document: [Biological Agent Incident Response and Reporting](#).
- c. **Note: Non-U of M employees working in U of M owned buildings (e.g. HSC staff working in HSCRF) should report incidents to their own employer.**

8.2 First Aid

If a known or suspected exposure occurs:

- a. Wash the areas immediately (see guidelines b-d below), and follow the [Post Exposure Protocol](#). **Seek medical assistance within two hours.** Take along the your site-specific or the U of M Post Exposure Protocol, any available MSDS or lab-specific information if available, and any remaining sample involved in the exposure, if available and safe for transport.
- b. **Eyes:** use the eye wash according to directions to thoroughly flush the area.
- c. **Any small intact areas of skin:** initiate first aid by washing skin surfaces thoroughly and immediately with soap and water.
- d. **Large skin areas:** activate the emergency shower.

8.3 Spill Clean up

- a. Have suitable disinfectants available in the lab at all times.
- b. Refer to the spill clean-up procedures in the [Biosafety Manual](#). General [Biohazardous Spill Response](#) and [Biohazardous Spill Clean-up Job-Aid](#).
- c. General Procedures:
 1. Wear all the stated PPE including double gloves and full shoes and cover your legs. In addition, wear a back-closing gown and full-face protection when cleaning up any large spills of human tissue or fluids or their extracts, or when splashes or sprays of the materials are possible.
 2. Pick up contaminated broken glassware using a brush and dustpan, tongs or forceps.
 3. Move carefully during spill clean-up to avoid splashes and/or self-contamination.
 4. If a known or suspected exposure occurs to any clothing, treat that item as contaminated. It must be decontaminated before laundering, for example by autoclaving lab coats or

treating a spill with bleach. This is true unless laundry facilities are available inside the containment lab and have been proven as effective in decontamination of fabric.

5. Report spills, accidents or exposures as soon as possible to the laboratory supervisor/PI. A written record of such incidents must be maintained, and the results of incident investigations should be used for continuing education. [Biological Agent Incident Response & Reporting guidelines](#).

Section 4. RISK ASSESMENT WORK SHEET

Related to work with human blood, body fluids and tissues

The following is a useful way of evaluating risks of using samples from human blood, body fluids and tissues. This information can guide your safe use of these materials for research.

A. Pathogen Risk Assessment

1. Unfixed Material/Sample type:

- | | | |
|---|--|---|
| <input type="checkbox"/> Semen | <input type="checkbox"/> Synovial fluid | <input type="checkbox"/> Feces |
| <input type="checkbox"/> Vaginal secretions | <input type="checkbox"/> Pericardial fluid | <input type="checkbox"/> Urine |
| <input type="checkbox"/> Breast milk | <input type="checkbox"/> Cerebrospinal fluid | <input type="checkbox"/> Sweat |
| <input type="checkbox"/> Amniotic fluid | <input type="checkbox"/> Pleural fluid | <input type="checkbox"/> Tears |
| <input type="checkbox"/> Sputum | <input type="checkbox"/> Peritoneal fluid | <input type="checkbox"/> Bones or teeth |
| <input type="checkbox"/> Nasal secretions | <input type="checkbox"/> Other: specify | |

- Human blood and/or blood products

Specify all in use: *e.g. serum, PMNLs,, platelets*

- Human tissues or organs.

Specify all in use *e.g. lung, brain, placenta, muscle*

- Fixed tissues or organs

Specify all in use and describe how they are fixed.

2. Material Sample Source:

- Clinical samples
- Clinical samples with diagnosed illness/known pathogen –name:
- Normal Donor Pool
- Tissue Bank
- Other: *specify*

3. Largest amount used: _____ Typical amount used: _____

4. Have the samples been screened for any pathogens? Yes No

If Yes – specify:

5. For tissue or organ samples can the material be reasonably expected to contain any characterized pathogen in addition to the typical BBP? Yes No

If Yes – specify and provide and complete pathogen risk assessment:

B. Personnel Risk Assessment:

6. All personnel working with or near any of the above material in the lab of PI _____
- Have had the recommendation to get Hep B vaccinations verbally communicated to them.
 - Have had the recommendation to get Hep B vaccinations verbally communicated to them and the department has a record of vaccination being received OR being declined with counselling.
 - Are required to provide documentation of Hep B vaccination as part of entrance into graduate program or position acceptance OR provide record of declination of vaccination with counselling..
 - Other medical surveillance plan in place. Describe:
7. All lab personnel working with or near any of the above material have received documented training as per this risk assessment as well as a program-specific training, describing the routes of exposure, signs/symptoms of disease, treatments, U of M Post Exposure Protocol and the requirement to report for medical attention if symptoms appear?
- Yes No

8. Indicate the related PSDSs available and referenced. **At a minimum the PHAC PSDSs for Hep B, C and HIV should be available.**

C. Facility Design Compliance

9. All work with human source material is conducted at Containment Level 2 facility design and operational practices as per the PHAC Canadian Biosafety Standards and U of M Biosafety Guide?
- Yes No

D. Operational Practices Risk Assessment

10. Will sharps be used? Yes No
- If YES, are you using safety engineered sharps? Yes No

If not, explain:

Needle and syringe assemblies will be placed into a puncture-resistant, autoclavable sharps container with a secure lid, without attempting to clip or recap the needle until being treated by autoclaving at _____oC for at minimum _____of minutes. Yes No N/A

If No, explain sharps disposal procedure:

11. How and at what stage of the experiment is the infectious agent inactivated or lysed? OR What is the method of terminal inactivation?

12. All work done in a BSC? Yes No
 If NO, indicate the type of procedures that will be done on the open bench and describe steps taken to reduce aerosol producing procedures, splash and spill and protect personnel and the environment.

Procedures that would increase the hazard include:

- Aerosol producing procedures including cell sorting, sonication, centrifuging in open containers, shaking or vigorous mixing or pipetting. Blending grinding, opening containers whose internal pressures may be different from ambient pressure?
- Procedures that create a splash, spill hazard
- Procedures with a sharps hazards

13. Will your experiments involve centrifugation? Yes No
 If yes, are sealed rotors, or sealed centrifuge safety cups, or screw-top tubes in available for use?
 Yes No

14. Specify disinfectants and decontaminants and decontamination procedures in use.

Surface Disinfection				
List all decontaminants used in the laboratory to surface disinfect hard surfaces and laboratory gloves:				
Disinfectant	Working Concentration	Contact Time (min)	Preparation Frequency	Used Against