1 Introduction

This Biosafety Standard Operating Procedure (BSOP) outlines procedures and techniques for working safely with primary **human samples**, which includes blood and blood products, body fluids, cells and tissues. These procedures will ensure that Memorial University of Newfoundland (MUN) personnel are aware of the hazards associated with human samples and the controls required to safely work with these samples.

The infectious agents of primary concern are the blood-borne pathogens (BBP) Human Immunodeficiency Virus (HIV, the virus that causes AIDS) and Hepatitis viruses B (HBV) and C (HCV). However, any infectious agent of disease present in the material can be transmitted by improper handling or accidental exposure to infected material. Blood is the body fluid of highest risk and the main subject of this SOP. However, all primary human samples should be handled as if they have the potential to transmit disease.

2 Scope

This BSOP applies to all MUN personnel performing procedures with human samples (tissues, fluids, cells) at containment level (CL) 2 or above.

3 Responsibilities

This section outlines responsibilities within the university for the implementation of this BSOP.

a. Environmental Health and Safety (EHS)
- Review and amend this BSOP as necessary.

b. Unit Heads
- Ensure that the requirements outlined in this BSOP are communicated to all applicable members of the unit/department.
- Ensure that the components of this BSOP and the applicable legislation are implemented in all facilities under the Head's authority.

c. Laboratory Supervisors/Principal Investigators
- Ensure that the personnel working with human samples are aware of the risks associated with the work (and that this training is documented in the personnel training log).
- Ensure that the personnel working with human samples abide by the requirements of this BSOP.
- Provide applicable immunizations for personnel prior to the commencement of work with human samples.

- Ensure that all incidents of exposure to human samples are reported to the Biological Safety Officer (BSO) as outlined in this BSOP.

d. Laboratory personnel (staff/students)
   - Understand the risks of working with human samples prior to commencing work.
   - Follow the procedures for safely working with human samples, as outlined in this BSOP.
   - Immediately notify your immediate supervisor of any incident with human samples. If this results in an exposure to biohazardous materials, immediately notify the Biological Safety Officer (BSC).

4 Definitions

Blood-borne pathogens (BBP): micro-organisms in blood and certain body fluids that cause disease in humans; the viruses of most concern are HIV, HBV and HCV.

AIDS: acquired immune deficiency syndrome, caused by infection with HIV.

HIV: Human immunodeficiency virus that causes the disease Acquired Immune Deficiency Syndrome (AIDS). HIV attacks the immune system, resulting in a chronic, progressive illness and leaving infected people vulnerable to opportunistic infections and cancers. The median time from infection to AIDS diagnosis now exceeds 10 years. AIDS is a chronic, potentially fatal disease that requires complex and ongoing medical management. There is no prophylactic vaccine for HIV.

Hepatitis B Virus: A blood-borne virus (HBV) that causes liver inflammation (hepatitis) with severity ranging from unapparent cases to fatal acute hepatic necrosis (or becomes a chronic infection). HBV it is most frequently occurring blood-borne pathogen and historically has been the most frequent laboratory-associated infection. There is no cure for disease from HBV. There is a prophylactic vaccine for HBV.

Hepatitis C Virus: A blood-borne virus (HCV) severity ranges from unapparent cases in approximately 90% of infections, to rare fulminating, fatal cases. Up to 90 per cent of infected persons carry HCV indefinitely. Over the long term, they are at risk of such illnesses as profound fatigue, cirrhosis, and liver cancer (chronic liver disease with fluctuating or persistently elevated liver enzymes is common). HCV is potentially treatable although treatment is toxic and not always successful. There is no prophylactic vaccine for HCV.

Hepatitis A Virus: The virus (HAV) causes acute hepatitis A, and is transmitted by the oral-fecal route, ingestion of contaminated food (i.e., shell fish) and water (hands may play an

important role in the direct as well as the indirect spread of HAV). HAV is characterized by an abrupt onset with fever, malaise, anorexia, nausea and abdominal discomfort, followed within a few days by jaundice. Illness can be mild (1-2 weeks) to severely disabling (6-9 months period). There is a prophylactic vaccine for HAV.

Tetanus (lockjaw): Infection by *Clostridium tetani* bacterial spores introduced into the body through a wound contaminated with soil, street dust or feces, or injected street drugs (also through lacerations, burns and trivial wounds). *C. tetani* produces a potent neurotoxin which causes painful muscular contractions (primarily of neck muscles, secondarily of trunk muscle, abdominal rigidity, generalized spasms with a 30-90% case fatality rate. There is a prophylactic vaccine for tetanus.

Universal Precautions: A set of steps to protect yourself from infectious agents in blood and body fluids.

5 Exposure types and risks

The risk of infection is related, in part, to the probability that the source material contains the infectious agent and also to the type of exposure that occurs. It is important that you know as much as possible about the biological material that you are working with, and that you convey this information to medical personnel to assist them in decision making about appropriate treatment following an incident. If you know the identity of the person who was the source of the blood or other material, then this "source" person can be approached by medical personnel to request that they be tested for blood borne pathogens.

Those in research laboratories work with unfixed human material from different sources, and often do not know the identity of the donor. The risk that the material contains blood borne pathogens varies greatly. Some laboratories use samples that have been screened and found negative for HIV, Hepatitis B and Hepatitis C, making the risk that these agents are present extremely low. However, it is important to know how long the time was between the negative screen and obtaining the sample, in order to determine the likelihood that the source might have changed status to infected. Other research laboratories work with fresh or frozen (unfixed) human material that has been donated by apparently normal, healthy donors. In this case the frequency of contamination of the material by blood borne pathogens would be the same as for that particular type of biological material in the general population. If you do not know that the sample is negative for HIV, HBV and HCV and do not know the identity of the donor, but do have a sample to which you have been exposed, then take the sample with you when you seek medical attention to determine if it can be tested for viral content.

The potential for additional pathogenic micro-organisms should be considered as part of a risk assessment for particular tissues and donor populations. For example, the intestines contain large numbers of bacteria and also may contain viruses, some of which may be pathogenic (eg.

Hepatitis A). The cervix can be infected by human papilloma virus (HPV). Universal precautions should be used and immunizations that are advisable should be identified and provided to personnel (in addition to Hepatitis B).

Note that only certain established human cell lines grown under certain conditions are capable of supporting the growth of the common blood borne viruses in culture. Thus, these viruses are not a general risk for those working with human cell lines. However, individuals should know whether the cell lines that they are using are infected with any of the blood borne pathogens or other human pathogens. Take appropriate precautions and seek medical attention promptly if exposed, informing the doctor about the risk.

a. Types of Body Fluids and Risks of Transmitting Blood-borne Pathogens

i. **Blood or any body fluid/tissue contaminated with blood** - these are the only fluids that have been implicated in occupational infection.
ii. **Semen and vaginal fluids -** these fluids have been implicated in sexual transmission.
iii. Cerebral spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial
iv. **fluid and amniotic fluid** - The risk of transmission of HIV from these fluids has not yet been determined.
v. **Saliva**:
- if HBV infected and associated with a bite that breaks the skin (with or without the presence of blood in the saliva), or
- if HIV or HCV infected and associated with a bite (with the presence of blood in the saliva).

Note: The risk of transmission from screened, donated blood, and manufactured blood products is negligible in Canada. Feces, nasal secretions, sputum, tears, urine, and vomitus are not implicated in the transmission of HBV, HCV, and HIV unless visibly contaminated with blood. However, feces can be a source of Hepatitis A from an individual infected with this virus.

b. Types of Injuries/Exposures that may Result in Transmitting Blood-borne Pathogens

i. **Percutaneous Injury** - needle-stick or cut/puncture with a sharp object.
ii. **Contact with Mucous Membranes** - splash to eyes, nose or mouth.
iii. **Contact with Non-intact Skin** - prolonged or extensive contact of exposed skin which is chapped, abraded, or afflicted with dermatitis, with blood or other infections body fluid. Includes a bite that breaks the skin.

Needle-stick contaminated with virus	Risk of Infection
HBV	6-30%
HCV	3-10% (approx.)

HIV	0.3-0.4%

6 Mitigating Risks Associated with Human Material

a. Universal Precautions

"Universal Precautions" are a set of steps to protect yourself from the blood and body fluids, by making the assumption that the material is infected with blood-borne pathogens. It includes:

- Engineering controls to reduce exposure to the material and to contain aerosols (eg. Biological Safety Cabinet when feasible, capped tubes, sealed centrifuge cups, etc.).
- Personal protective equipment (PPE) including lab coat/gown, gloves and goggles, and may include a mask or face shield depending on the activity.
- Thorough hand washing with detergent soap immediately upon removing gloves.
- Disinfection of surfaces using the appropriate disinfectant (note that they type of disinfectant must be effective against the pathogen(s) you intend to kill – refer to BSOP-03).
- Appropriate disposal of material in contact with blood or body fluids (refer to BSOP-01).
- Appropriate clean-up of spills – using freshly diluted 10% bleach or other general disinfectant (refer to BSOP-03).
- Limited use of sharps (i.e. substitute methods that do not require needles, use blunt forceps); use of safety-engineered sharps when feasible; no recapping of needles; correct disposal of sharps.

b. Immunizations

Refer to the Canadian immunization guide for information on available vaccinations.

c. Post-exposure prevention

i. HIV - there is no cure or immunization for HIV infection but infection can be prevented by taking antiviral drug therapy soon after an exposure incident, preferably within 2 hours [called prophylactic antiviral therapy because it is intended to prevent infection, not to cure infection; also called post exposure prophylaxis (PEP for short)].

ii. Hepatitis B – if not immune or if antibody titres low, infection can be prevented by immunoglobulin treatment within 48 hours of exposure.

iii. Hepatitis A - prophylactic immunoglobulin can be administered if infected individual/sample is contacted.

iv. Tetanus - if more than 10 years since last booster immunization then individual should get a booster when wounded and/or receive Tetanus Immune Globulin (TIG).

7 Post exposure response procedure

The following in an expanded version of the post-exposure response procedure described in the Biosafety Emergency Response Plan and Biological Safety Manual.

Following a definitive exposure to potentially infected human samples (i.e. personal contamination, exposure to aerosols, needle-stick, etc.), three basic steps must be followed in order:

1. **Emergency first aid/Reporting** – If emergency first aid is required, it should take precedence over everything else. Contaminated clothing should be removed and both the exposed person and responding person should thoroughly wash and disinfect hands prior to first response.
    - **Percutaneous injury or contact with non-intact skin**: allow the puncture, cut or abrasion to bleed freely, and wash well with soap under running water for 5 minutes. (Use an antiseptic if available).
    - **Contact with mucous membranes** (eyes, nose, mouth): flush thoroughly with water for 10 to 15 minutes.

    If emergency first aid is not required, immediately inform your supervisor of the details of the exposure. The supervisor must complete an investigation and submit an accident/incident report outlining the details of the exposure (see below).

2. **Medical testing/treatment** – As soon as possible, report to the emergency department of the closest local hospital for prescribed testing/treatment.

    - Consider the infectious potential of the source material and the nature of the contact. If the material is **from an unscreened** (i.e. has not been certified negative for HIV, HBV and HCV) or **known positive source** and the **contact is mucosal, associated with a wound (e.g. contaminated needle-stick or scalpel), on chapped skin, or a large volume or prolonged contact on intact skin then immediately following first aid, go to the nearest emergency department**.
        - **To expedite treatment,** inform the triage nurse in the Emergency Department that you have been involved in an occupational incident with potentially infected human material, how long it has already been since the incident, and that you are concerned that if antiretroviral drugs are to be given to prevent HIV infection then to be most effective therapy should be started as soon as possible, preferably within **two hours** of the incident.
    - If wounded and your tetanus booster was not within the last 10 years then inform your attending physician. Wounds that are large and/or have environmental contamination should be carefully cleaned and may require a booster the same day if more than 10 years since your last booster.

3. **Accident/incident reporting** – Your immediate supervisor (i.e. biosafety certificate holder) should be informed of the exposure as soon as possible. Together, you will complete an incident report via Memorial's Incident Management System (MIMS) within 24 hours by following the link below:

    http://www.mun.ca/MIMS/

MUN's BSO must be informed as soon as possible, as a condition of MUN's Human Pathogen and Toxin license.

The incident report should include details about the circumstances that led up to the incident as well as potential controls to prevent reoccurrence of similar incidents. Incidents can also be reported using the MUNSafe app. Please note that incidents requiring immediate response should be reported to Campus Enforcement and Patrol (864-4100).

4. **Follow-up** – The BSO will follow up with the individual exposed and his/her supervisor to review the accident/incident report. During this follow-up, the root cause(s) of the exposure will be identified, and preventative measures (i.e. controls) put in place to minimize the likelihood of reoccurrence.

Version History:

Version	Date	Author(s)	Notes
1.0	2021-08-18	Rod Hobbs	First writing. IBC approval.