TRU Plan for Administrative Oversight for Pathogens and Toxins in a Research Setting.

Thompson Rivers University's (TRU) Biosafety Program was initially developed in 2009. As a result of the changes put forth by the Public Health Agency of Canada (PHAC) including the implementation of the Human Pathogens and Toxins Act (HPTA) and the Human Pathogens and Toxins Regulations (HPTR), TRU has developed the following Plan for Administrative Oversight (PAO) for Pathogens and Toxins in a Research Setting (henceforth called 'the Plan'). The purpose of this Plan is to facilitate the development of internal accountability structures and support accountability structures that currently exist by bridging gaps in the oversight of pathogens at an institutional level thus mitigating any biological risks to TRU. This Plan will be used by TRU as part of the license submission process.

This Plan is intended to provide an overview, from a high institutional level, of the mechanisms that are, or will be, in place at TRU to administratively manage and control biosafety and biosecurity risks. The Plan includes an overview of how the elements are, or will be, managed and represented.

List of Abbreviations

AHT	**Animal Health Technology**
AVP-RGS	Associate Vice-President of Research and Graduate Studies
ACC	**Animal Care Committee**
BSO	Biological Safety Officer
CBH	Canadian Biosafety Handbook
CBS	Canadian Biosafety Standard
CCAC	Canadian Council on Animal Care
CL	Containment Level (i.e. CL1, CL2, CL3, CL4)
HPTA	Human Pathogens and Toxins Act
HPTR	Human Pathogens and Toxins Regulations
IBSC	Institutional Biosafety Committee
JOHSC	Joint Occupational Health and Safety Committee
LRA	Local Risk Assessment
LRAs	Local Risk Assessments
OHS	Occupational Health and Safety
ORGS	Office of Research and Graduate Studies
PAO	Plan for Administrative Oversight
PHAC	Public Health Agency of Canada
PI	Principal Investigator
PSDS	Pathogen Safety Data Sheet
REB	Research Ethics Board
RG	Risk Group (i.e., RG1, RG2, RG3, RG4)

RGs	Risk Groups
RSS	Risk and Safety Services
SOPs	Standard Operating Procedures
SSBAs	Security Sensitive Biological Agents
TCPS2	Tri Council Policy Statement
TRU	Thompson Rivers University
VPAF	Vice President of Administration and Finance

Glossary of Terms/Definitions

Biohazardous material: material of biological origin that may be potentially harmful to humans, animals, plants, the economy or the environment. Biohazardous materials include:

- Pathogenic microorganisms such as viruses, fungi, parasites and bacteria;
- Biological toxins from microorganisms, plants and animals;
- Materials that may contain the above-mentioned agents (e.g. cell cultures; tissue, blood and body fluids from humans and animals; environmental samples);
- Certain proteins, nucleic acids (siRNA, miRNA, DNA from pathogenic organisms, oncogenes);
- Genetically modified organisms (GMO) that may be hazardous to the environment if released

Biological material: pathogenic and non-pathogenic microorganisms, proteins and nucleic acids, as well as any biological material that may contain them. Biological material that contains human or animal pathogens is referred to as "Infectious material".

Biological toxins: poisonous substances naturally produced by living organisms (microorganisms, plants and animals).

Biological safety officer (BSO): A specific individual designated for overseeing facility biosafety and biosecurity practices.

Biosafety: The application of containment principles, technologies and practices to prevent unintentional exposure to infectious material or toxins, or their accidental release.

Biosafety Manual: A facility-specific manual that describes the necessary core elements of a biosafety program (e.g. biosecurity plan, training, personal protective equipment).

Biosecurity: measures implemented to prevent the loss, theft, misuse, diversion or intentional release of infectious materials or toxins.

Containment: physical design parameters and operational practices that protect personnel, the immediate work environment and community from exposure to biological material.

Containment level (CL): The minimum required physical containment and operational practices for safely handling infectious material or toxins in laboratory, large scale production, and animal work environments. As defined by the CBS, there are four containment levels ranging from a basic laboratory (containment level 1 [CL1]) to the highest level of containment (containment level 4 [CL4]).

Controlled activities: Any of the following activities referred to in Section 7(1) of the Human Pathogens and Toxins Act: possessing, handling or using a human pathogen or toxin; producing a human pathogen or toxin, storing a human pathogen or toxin; permitting any person access to a human pathogen or toxin; transferring a human pathogen or toxin; importing or exporting a human pathogen; releasing or otherwise abandoning a human pathogen or toxin; or disposing of a human pathogen or toxin.

Decontamination: process by which materials and surfaces are made reasonably free of microorganisms or toxins, and thus are safe to handle. Decontamination may be achieved through disinfection, inactivation or sterilization.

Disinfection: A process used to eliminate most forms of living microorganisms.

Emergency Response Plan: A document that outlines the procedures to be taken and the parties responsible in emergencies such as spills, exposure, release of infectious material or toxins, personnel injury or illness, power failure, fire, explosion or other emergency situations (e.g. severe weather, hurricane, armed intruder).

Exposure: Contact with, or close proximity to, infectious material or toxins that may result in infection or intoxication respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.

Facility (plural: facilities): Structures or buildings, or defined areas within structures or buildings, where infectious material or toxins are handled or stored. This could include individual research and diagnostic laboratories, large scale production areas, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.

Good Microbiological Laboratory Practices: Basic laboratory practices applicable to all types of activities with biological material.

Human Pathogens and Toxins Regulations: Regulations which establish national requirements for the safe handling of human pathogens and toxins, and provide assurance that individuals with access to a prescribed list of security-sensitive human pathogens and toxins would hold an appropriate security clearance.

Human Pathogens and Toxins Act: An Act whose purpose is establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins.

Incident: An event or occurrence with the potential of causing injury, harm, infection, intoxication, disease, or damage. Incidents can involve infectious material, infected animals, or toxins, including a spill exposure, release of infectious material or toxins, animal escape, personnel injury or illness, missing infectious material or toxins, unauthorized entry into the containment zone, power failure, fire, explosion, flood, or other crisis situation (e.g. earthquake, hurricane). Incidents include accidents and near misses.

Infectious material: Any isolate of a pathogen or any biological material that contains human or animal pathogens.

Laboratory: An area within a facility or the facility itself where biological material is handled for scientific or medical purposes.

Local Risk Assessment (LRA): Site-specific risk assessment that identifies hazards based on the infectious material or toxins in use and the procedures being performed.

Medical surveillance program: A program for prevention and detection of illness related to laboratory exposure to infectious material or toxins. The program emphasizes prevention, but also provides a process through which potential infections are identified and treated before disease occurs.

Movement: The action of moving people, material or animals from one physical location to another in the same building. This can include movement within the same containment zone, to a difference containment zone, or to another location within the same building.

Overarching risk assessment: A broad risk assessment that supports the biosafety program as a whole and may encompass multiple containment zones within an institution or organization. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of pathogens and toxins.

Pathogen: An agent (e.g., a microorganism, nucleic acid or protein) that can cause disease or infection in humans and/or animals.

Pathogen risk assessment: The determination of the risk group and appropriate physical containment and operational practice requirements needed to safely handle the infectious material or toxins in question.

Pathogen Safety Data Sheets: Previously titled Material Safety Data Sheets for infectious substances, Pathogen Safety Data Sheets are technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting.

Risk: The probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

Risk Group (RG): The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of

Standard operating procedure (SOP): A document that identifies the hazards associated with a project and describes safe work practices and procedures to minimize or eliminate risk.

Toxins:

- Biological Toxins: poisonous substances naturally produced by living organisms such as microorganisms, plants and animals.
- Microbial Toxins: a subcategory of biological toxins. Microbial toxins are poisonous substances produced by microorganisms (bacteria, viruses, fungi).

Transportation: Shipping of infectious material or toxins to another building or location, within Canada or abroad, in accordance with the *Transportation of Dangerous Goods Act* and *Regulations*.

TRU Romeo: TRU's research administration tool that allows researchers and administrators to work collaboratively to manage internal and external grant applications throughout the life span of the research application.

Virulence: The degree or severity of a disease caused by a pathogen.

Waste: Any solid or liquid material generated by a facility for disposal.

PAO Elements:

Element 1: Commitment from Senior Management to manage and control biosafety and biosecurity risks at the institution/organization.

The current Biosafety Program has been in place since 2009 and was approved by the Associate Vice-President of Research and Graduate Studies (AVP-RGS). As a result of PHAC's new regulations and the incorporation of Enterprise Risk Management, this program is being reviewed and updated. A Biosafety Policy, which outlines the program, associated procedures, and responsibilities of the University, faculty, staff, students, Institutional Biosafety Committee (IBSC), and Biosafety Officer (BSO), has been developed

and has been posted on TRU's website. Prior to this, a biosafety program document which outlines many of the items in this Plan was already being followed and was part of the basis of this document.

Element 2: Delineation of the roles and responsibilities for committees, individuals, departments, etc., that have a role in the control/management of biosafety and biosecurity risks.

i. Institutional Biosafety Committee (IBSC)

This committee is comprised of members representing departments that conduct activities using biohazardous agents requiring containment level 2 (CL2) under the guidance of the Canadian Biosafety Standard (CBS), 3rd edition, 2022, and the Canadian Biosafety Handbook (CBH), 2nd edition, 2016. These departments include but are not limited to physical sciences, Biological Sciences, Natural Resources Sciences, Animal Health Technology Program, and the Biological Sciences laboratory technician. Subject matter expertise will be provided by terminal degree holding scientist committee members, the institutional BSO, and technical representatives from institutional microbiology and Animal Health Technology departments. Non-academic members will include the Director of Risk Management Services, the Associate Director of Safety and Emergency Management, and a designate from the Office of the AVP-RGS. Non-academic members will provide necessary administrative support and expertise to ensure committee concerns and recommendations are properly reviewed and addressed by senior institutional management. The BSO sits on this committee as well as the Joint Occupational Health & Safety Committee (JOHSC) and Animal Care Committee (ACC) and Research Ethics Board (REB) in order to provide continuity and consistent oversight for biosafety. Overarching financing of the institutional biosafety program operating budget is done at the beginning of the fiscal year by senior institutional administration. This includes provision of funds for major and minor biosafety enhancements deemed to be immediately necessary, as well as monies for those enhancements whose implementation may be safely deferred to a later date. For those enhancement funding judged to be immediately necessary, the BSO may submit a request for funding to the Associate Director of Safety and Emergency Management, who then brings the item to the immediate attention to the Dean of Science and the AVP-RGS for provision of funding. For those enhancements that can be safely deferred, enhancements are obtained by submitting a formal request to the Associate Director of Safety and Emergency Management, who then presents the request to the Director of Risk Management, the Vice President of Administration and Finance, the AVP-RGS, and the Dean of Science for review, evaluation, and decisions regarding provision of funding.

Members of the IBSC will be appointed by, and report to, the Director of Risk Management and the AVP-RGS for terms of 2 years. The IBSC will meet quarterly, at a minimum, to review risk assessments, permit applications, distribute new and relevant biosafety information to lab staff, provide technical advice to users of biohazardous materials and assist the Risk and Safety Services (RSS) with the development of policy, programs, procedures, manuals and training.

All research projects involving potentially hazardous biological materials will be registered with the RSS. Protocols requiring CL2 will be reviewed by the committee and approval granted through the RSS.

Membership of the JOHSC will consist of non-managerial worker, employee, resource, and in some cases, community representatives that will meet monthly to review and resolve health and safety issues in support

of the institutional occupational safety and health program. Worker representatives will be peer-selected by workers at the university who do not exercise managerial functions. Employee representatives will be selected from workers at the university who exercise managerial functions that have sufficient authority to act on matters agreed upon at a meeting. The risk management department will provide specialist resources to the committee who will act in an advisory capacity and will not participate in votes or stand as chairs. Additional non-voting members from the campus community may also attend periodic meetings in the capacity of a liaison, to present health and safety concerns for committee attention. Committee subject matter experts will be derived from both the worker and employee representatives. With the exception of community and RSS committee members, JOHSC members will serve 3 year terms. Worker representatives will provide relevant expertise via the institutional Safety and Biosafety Officers. Employee subject matter experts will be derived from senior representatives from the institutional Facilities, Human Resources, and Student Services departments, as well as instructors from institutional trades programs. Resource experts will consist of the Associate Director of Safety and Emergency Management and the Director of Risk Management, both of which are non-voting committee members. All committee members will serve as conduits through which employee health and safety concerns can be appropriately directed to the co-chairs who are then responsible for ensuring these issues are resolved within the committee, cooperatively. If this is not possible, co-chairs are responsible for bringing these issues to the attention of senior institutional management for appropriate resolution.

Members of the ACC are appointed by the University Senate Research Committee and biosafety subject matter expertise will be derived from a designated University Veterinarian, two faculty members from Biological and/or Natural Resource Sciences, a faculty member from another discipline experienced in animal care and use, a technical staff representative from AHT and the institutional BSO. Additional members will include a faculty or staff member who is uninvolved in animal work, a graduate student representative, two volunteer community representatives, and a non-voting designate from the Office of Research and Graduate Studies (ORGS), who will serve as a committee coordinator. The ACC will meet at least 3 times per year to review and resolve issues related to animal care and research compliance, as mandated by the Canadian Council on Animal Care (CCAC) Guidelines and Policies and commensurate with CBS and CBH standards. Any issues are to be reported to the Director of Risk Management and the AVP-RGS. The Chair is to be chosen from among the committee members. The Chair should normally be an animal user with experience in animal use and care, but not be directly involved in the management of the institutional animal facilities, nor be involved in the preparation of a significant number of the protocols to be reviewed by the committee, in order to avoid potential conflicts of interest. ACC members serve three-year terms with the exception of the student member who may serve a one-year term.

The Research Ethics Board (REB) operates to fulfill the University's ethical responsibilities concerning the involvement of human participants in research. This committee is empowered to ensure that all research involving humans, with which the University is affiliated, is conducted in accordance with the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the TRU Policy on Integrity in Research and Scholarship (ED 15-2). The REB will consist of at least 5 members, of whom at least two, will have relevant expertise and on-going experience in relevant research disciplines, fields and methodologies, the university BSO, an ethics expert, a member with relevant legal knowledge (but not the institution legal counsel or risk manager), a community member who is not affiliated with the institution,

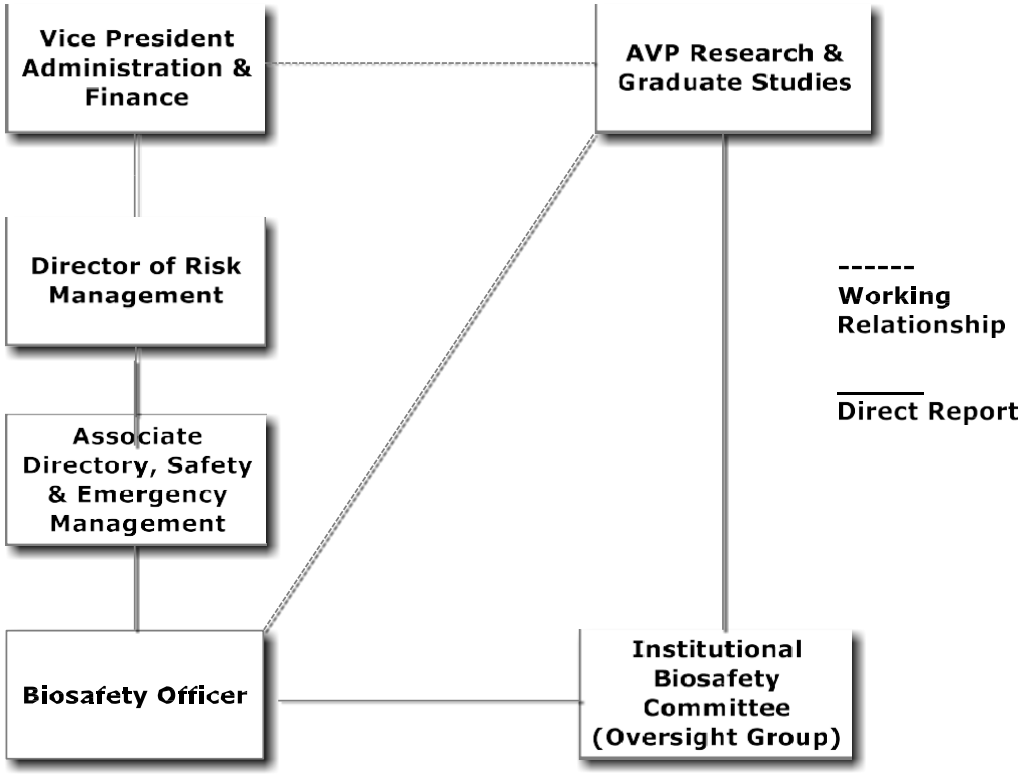
and a member from the ORGS to provide administrative support and research experience as required. Members of the committee are recommended by the REB and appointed by the Senate Research Committee. The Senate Research Committee shall select one faculty member representative of the REB to serve as Chair. The REB may also choose to elect a vice-chair to act on behalf of the chair in his or her absence. The REB chair is responsible for ensuring that the REB review process conforms to the requirements of the TCPS2. The role of the REB Chair is to provide overall leadership for the REB and to facilitate the REB review process based on institutional policies and procedures and the TCPS2. The REB chair is also responsible for reporting meeting minutes and any issues in need of attention to the Director of Risk Management and the AVP-RGS. Terms of members will be overlapping to preserve experience and continuity of function of the REB. All members of the REB are voting members. All members should have completed or commit to complete the tri-council Course on Research Ethics.

Terms of reference are located on the TRU website.

ii. Associate Vice President of Research and Graduate Studies (AVP-RGS)

The AVP-RGS is the License holder and holds grant funding until confirmation that all safety aspects are met i.e. the Principal Investigator (PI) has a valid TRU Biosafety Certificate.

TRU Biosafety Program Organizational Structure



iii. Biosafety Officer

Acts as the liaison between TRU and PHAC on regulatory issues. Responsible for the day-to-day operations of the biosafety program including but not limited to:

- Developing effective procedures for implementation of standards and guidelines;
- Ensuring compliance with regulation for the use of, or exposure to, biohazardous materials;
- Providing general training sessions on biosafety;
- Ensuring appropriate training is provided to persons using biological hazards;
- Notifying PHAC of any lab acquired infections, inadvertent possession of human toxins, pathogens or Security Sensitive Biological Agents (SSBAs) not received as expected;
- Conducting regular internal inspections and biosafety audits and reporting findings to the Manager RSS and the license holder via the IBSC;
- Informing the license holder of any non-compliance by a person conducting activities under the license;

- Establishing procedures for dealing with spills;
- Keep abreast of legislation concerning biohazardous materials and advise the ISBC and administration about potential impact on the University;
- Participating in investigations of incidents; and
- Authorizing purchase requests for biohazardous materials;

iv. Associate Director, Office of Safety & Emergency Management

Develop, coordinate and oversee the Biosafety Program and all its components; maintain records of accidents/incidents and carry out investigations as required; organize and maintain spill response and emergency procedures; and report to external compliance agencies.

This department reports up through to the Vice President of Administration and Finance (VPAF) which eliminates any potential perceived conflicts of interest that may arise by reporting to the AVP-RGS. As all PIs, researchers, faculty, instructors and technicians are affiliated with the Research and Academic Faculties, reporting to the VPAF allows the RSS to make unbiased decisions related to all safety issues at the university.

The RSS also collaborates with Facilities (who also report to the VPAF), and facility users in order to ensure that any new buildings, laboratories and renovations include relevant information specifically related to the requirements of the various health and safety regulations and guidelines as well as any that relate specifically to biosafety and biosecurity.

v. Director of Risk Management

The Director of Risk Management is a member of Senior Management and reports to the VPAF. All institutional safety matters are reported directly to the Director of Risk Management Services by the Associate Director of Safety and Emergency Management, when there is action required on institutional safety issues at the Senior Management level.

Summary

The Biosafety program is meant to be collaborative in nature with advice being sought and utilized from the IBSC, the BSO and senior management, but when there is an imminent health and safety risk, the BSO has the authority to stop work as appropriate under WorkSafe BC Legislation. The BSO would report these types of major non-conformance issues to the Chair of the IBSC and the Associate Director of the RSS, for immediate reporting up the senior management line. The BSO would then also report to PHAC and other agencies as required.

Element 3: Establishment of a single point of contact to provide guidance on the Plan and a senior level 'champion' who can represent biosafety issues at a senior level on his/her behalf.

The TRU BSO is the single point of contact for biosafety at TRU who provides guidance and updates on this Plan as needed. As outlined above, the BSO (who is a TRU safety member in the RSS), reports to the Associate Director of the RSS and advises both the Director of Risk Management and the AVP-RGS as well as the IBSC. In matters of biosafety and biosecurity, the BSO also acts as the liaison to regulatory authorities.

The AVP-RGS is the primary champion for biosafety at senior level meetings receiving technical information from the BSO and the IBSC. The Director of Risk Management is the secondary champion mainly when it comes to issues of safety and security.

The current contact information for the Director of Risk Management at TRU is:

Jacquetta Goy, 250-828-5362, jgoy@tru.ca

Element 4: High level overview of how biosafety and biosecurity risks are *identified* at the institution/organization.

All areas that deal with human, animal, plant or aquatic pathogens have been consulted as part of the original program and again when the new regulations were introduced. This allows the TRU program to be comprehensive, covering all areas where biohazardous materials are being used.

Prior to the initiation of any institutional CL-2 research activities, as per the 2nd editions of the Canadian Biosafety Standard (CBS) and the Canadian Biosafety Handbook (CBH), the Director of Risk Management and the AVP-RGS mandate that an overarching risk assessment is performed by the IBSC for review by senior administration and eventual Director of Risk Management and AVP-RGS approval. This broad assessment supports the organization as a whole and ensures identification of biological hazards and biosecurity risks and mitigation strategies though a systematic review of the type of biological material that is present, mandatory completion of LRAs, the location and state of proposed work areas and related infrastructure, and proposed investigative activities.

Local risk assessments (LRAs), identifying biosafety and hence biosecurity risks and measures to be implemented to mitigate these risks, are completed using TRU's online Biohazardous Material Use Application system, for any procedures involving work with biohazards as part of the permit application and review process.

These applications are completed by institutional researchers as part of project-specific LRAs prior to starting work activities and describe biological material by type, risk group classification, pathogenicity, intended laboratory manipulation techniques and infection/inoculation operations, proposed inventory lists, justified deviations from established protocols, and infection/exposure risk to personnel. These applications also outline hazard mitigation strategies, physical and engineering containment controls that will be in place, personal protective equipment that will be used, transportation strategies, decontamination and waste disposal protocols, and a description of any additional required permits. Provision of emergency exposure protocols will also be required and made available to all staff and students working with any proposed pathogenic material. These will include agent mode of transmission, incubation period, period of communicability, infectious dose, typical presenting symptoms, modes of decontamination, and emergency response protocols.

Once completed and submitted, LRAs are reviewed by the IBSC and biosecurity risks and hazard mitigation strategies are then identified using science, policy, and expertise. If biological materials and mitigation

strategies are deemed appropriate for use at TRU and in line with regulations described in the CBS and CBH, Biosafety Certificates with scheduled annual review dates will be presented to approved researchers by the Director of Risk Management and the AVP-RGS, and made available for all laboratory students and staff for reference.

Any changes to approved experimental procedures or in the nature of the biological materials that are to be used, must be submitted to the IBSC via the same online Biohazardous Material Use Application system and are subject to the same scrutiny as the biological materials and protocols that were described in the original project. Similarly, incidents or issues of non-compliance can also prompt a reevaluation of investigator activities via LRA resubmission including the appropriate changes.

Element 5: High level overview of how biosafety and biosecurity risks, including those from research with dual-use potential, are *assessed* once they have been identified at an institutional/organizational level.

Using the PHAC *'Decision Tree: Identification of Dual-Use Potential in Life Sciences Research'* (Figure 1), TRU does not conduct research with anything that has dual-use potential.

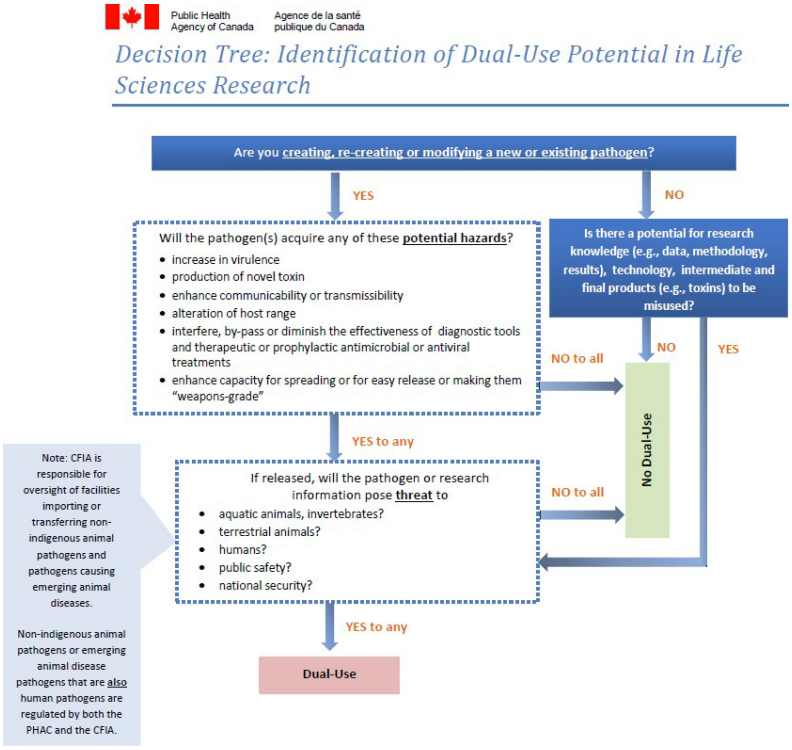


Figure1: PHAC Decision Tree which can be used to identify dual-use potential in life sciences research

The use of biohazardous materials has always been closely monitored at TRU. A biosafety risk identification and assessment was completed previously as part of the microbiology program which was developed and accredited by the Canadian Medical Association. Despite discontinuing the accredited program, these high

standards have been maintained. TRU has used information related to the biosafety risk group and containment requirements obtained through the 2015 CBS, 2015 CBH, and available Pathogen Safety Data Sheets (PSDS). Currently the biosafety risks at TRU have been classified as Risk Groups (RGs) 1 and 2 only.

Any new research project or laboratory sessions involving biohazards must undergo an LRA to ensure all hazards are identified and develop standard operating procedures (SOPs) to mitigate these identified risks. These are included in the biohazard permit application process which is reviewed and assessed by the IBSC. This process will then approve teaching or research protocols, ensure proposed procedures and location of use are appropriate then issue approval via the BSO.

Following overarching and local risk assessments, rigorous biosecurity assessments are conducted at TRU by the IBSC under the oversight of AVP-RGS and the Director of Risk Management. Biosecurity risk assessments are carried out at TRU to ensure adequate security measures are in place to prevent the loss, theft, misuse, diversion, or intentional release of infectious material or toxins or other laboratory assets. The IBSC also conducts biosecurity assessments on all approved stored and incoming biohazardous materials and laboratory equipment for approval by the Director of Risk Management and the AVP-RGS.

After overarching risk assessment is established by senior administration and the IBSC, and IBSC reviews submitted LRAs, biosecurity assessments at TRU begin with asset identification and prioritization by the IBSC. By establishing accurate inventory and storage lists, the IBSC can then prioritize asset protection based on the consequences of malicious use, the ease of use of the material, and the impact of loss of material on the facility. Under the oversight of the AVP-RGS and with the help of the Associate Director of Safety and Emergency Management and the Director of Risk Management, the IBSC then identifies asset vulnerabilities and evaluates the likelihood, motive, means, and opportunities of both internal and external threats to intentional asset misuse. Risk levels and mitigation strategies developed from these analyses consisting of a variety of engineering and administrative controls can then be summarized using risk statements and risk registers if it deemed necessary.

Upon their completion, all overarching and local risk assessments and biosecurity risk assessments are reviewed by the IBSC, the Director of Risk Management, and the AVP-RGS for accuracy and completeness.

Any changes to approved experimental procedures or in the nature of the biological materials that are to be used, must be submitted to the IBSC for review and approval via the same online Biohazardous Material Use Application. Additional triggers that can prompt reevaluation of work practices and risk assessments include changes in working areas, changes in means of laboratory security, breaches in laboratory security, misplaced or lost inventory, and laboratory incidents and issues of non-compliance.

Element 6: High level overview of how the biosafety and biosecurity risk are *managed and controlled* at the institutional/organizational level.

As stated in element 5, TRU does not conduct research with anything that has a dual-use potential.

TRU incorporates a combination of control components to limit non-compliance and potential for accidents/incidents. All labs use Risk Group 1 (RG1) organisms whenever possible however some Risk Group 2 (RG2) pathogens are used in teaching and research areas and are captured in TRU's control mechanisms.

The overarching control mechanism is TRU's Biosafety Program, many components of which have recently been reviewed and updated. The program encompasses many of the control mechanisms that are being used. These include:

- **Biosafety Manual** – is developed for individuals who handle or work in proximity to potentially infectious materials and toxins and is based on an overarching risk assessment of the protocols in use at TRU. Developed based on CBS and CBH, the manual incorporates institutional as well as biosafety specific information including laboratory-specific SOPs, containment standards, project registration and approval process, biosafety training, biosecurity, pathogen risk assessments and risk group classification, emergency response plan, incident reporting, ventilation and lab safety equipment, movement and transportation, medical surveillance, decontamination and waste management and laboratory decommissioning.
- **Biohazard Permit System** – consists of permit application, LRA Form, and SOPs. This process much be completed before beginning any activities with biological materials – for teaching or research use – or if there are significant changes (i.e. new materials or procedures) to a previously approved Biohazard Permit.
- **Linkage with AVP-Research and Graduate Studies (Research Approval Certificates) –** For funded projects, a Safety & Emergency Management Research Approval Certificate is required before the Office of the AVP-RGS will release research funds. These certificates are issues by the RSS following review and assessment of all hazardous materials and controlled products that are used in the laboratory and indicates that the PI or area is in compliance with all of the University's policies and procedures related to biosafety and biosecurity. If there are any compliance issues, grant funding can be stopped.
- **Biosafety Policy** – a draft policy is in the review stage and will be published on TRU's webpage once approved. This policy outlines the Biosafety Program, Responsibilities of the RSS, BSO, IBSC, Deans, Research Chairs, PIs and Researchers, Employees, Students and Visitors.
- **Institutional Biosafety Committee (IBSC)** – This committee meets on a quarterly basis to review and review and approve biohazard permit applications (submitted through the TRU Biohazard Permit System – Romeo) to ensure correct containment levels have been assigned and that the correct biosafety practices are in place.
- **Cross Committee Appointments** – as the BSO is cross appointed to other committees (i.e. Animal Care and Ethics Review Committees) any biosafety or biosecurity issues can be identified and rectified before potential unsafe work is initiated. This cross appointment has also built more awareness and collaboration across work units.
- **Internal Audit/Inspection Program** – the RSS conducts inspections on behalf of TRU on a regular basis to measure compliance with all federal, provincial, municipal and internal requirements and to continually improve the health and safety programs. A specifically designed inspection checklist has been created and approved by the IBSC. The outcomes of the inspections/audits can impact the

status of a biohazard permit. The RSS utilizes a compliance promotion approach with the goal to prevent non-compliance. As indicated in element 2, RSS can stop work based on imminent health and safety risks under BC Occupational Health and Safety legislation.

- **Training Program** – biosafety training is mandatory for all students, faculty, staff, volunteers and visitors working with biohazardous materials, as well as for anyone who oversees spaces where these materials are used or stored. Core training topics include definition and classification of biological agents; elements of risk assessment; policy, guidelines and regulations; laboratory management and operations; good microbiological laboratory practices; biosecurity; safety equipment; waste disposal and spill response procedures; safe work practices in the field and supervisor responsibilities. Records of training completion will be managed by the BSO as part of the RSS responsibilities. Specialized training for use of biological safety cabinets, safe handling of blood and transportation of dangerous goods is also provided as appropriate.
- **Accident/Incident Reporting** – this is a mechanism that facilitates reporting of all incidents at TRU. This online process has been in existence for many years and is well established. As per TRU Safety protocols all incidents are reported to the individual's supervisor and follow institutional reporting. If warranted, an investigation is initiated and consequent recommendations implemented. All incidents are tracked in our internal system and will be used to determine if further training or equipment is required.

Element 7: Coverage of all work areas (research areas, teaching, off-site, etc)

The areas at TRU where controlled activities with pathogens and/or toxins occur include:

Use	Risk Group	Lab Classification	Location
Teaching Area	RG1 and RG2	CL2	Science Building, Kamloops, British Columbia
Research Areas	RG1 and RG2	CL2	Science Building, Kamloops, British Columbia
Prep/autoclave/disinfection Common Area	RG1 and RG2	CL2	Science Building, Kamloops, British Columbia
Animal Area	CL1	CL1	Animal Health Technology Building, Kamloops, British Columbia

All work areas where biohazardous materials are used or stored are in the CL2 area which is controlled through a fob system which monitors who enters and leaves this area. Researchers' offices are locked. Security staff patrols these areas regularly.

Controlled activities with RG2 pathogens at TRU are only permitted in the Science building located at the Kamloops British Columbia TRU campus location. No controlled activities with RG2 pathogens or toxins are permitted at the Williams Lake British Columbia TRU campus location.

In the event that new work/research areas are needed, this Plan for Administrative oversight is to be reviewed and altered appropriately to maintain mandated provincial and federal compliance standards.

Element 8: Description of all individuals covered by the Plan (researchers, faculty, students, etc.)

The TRU Biosafety Program covers all researchers, faculty, graduate students, research assistants who work with human and animal pathogens and toxins. Each biosafety certificate is updated to include the person responsible for the area as well as anyone who works under that certificate.

Individuals who will be teaching in or conducting research in the CL2 area are referred to the BSO who outlines the training requirements as well as the institutional requirements – i.e. research Biohazard Permit application process and subsequent responsibilities. Anyone who is authorized access to the CL2 lab (key or fob) must undergo core training first – no one is allowed to work in the area until all aspects of training are completed.

Element 9: Summary of how the Plan is communicated.

The Biosafety Program and elements within this Plan are communicated to all impacted individuals utilizing a variety of mechanisms. Reports from the RSS are submitted to Senior Administration and the Board of Governors at the end of each semester that includes a specific section on the Biosafety Program. This report will include stats on the number of biosafety certificates, number of non-compliances, advances in the program, etc. Regularly scheduled meetings will include the Director of Risk Management, Associate Director of the RSS, an IBSC Co-Chair, and AVP-RGS to keep everyone informed of activities in real time, as well as provide the mechanisms for information from senior management to be provided back to the BSO. This will also allow senior management to provide input into the plan elements as well as be informed as to why certain mechanism are in place.

There is continual interaction and communication from the BSO and RSS to the researchers, faculties, instructors, technicians, staff and students. The BSO engages in continuous consultation with the IBSC to ensure that communication is consistent. The BSO acts a conduit between all of the committees involved (i.e., IBSC, JOHSC, Animal Care and Ethics Committees). The RSS also interacts with the Research and Scholarly Activities Administration Office by providing semi-annual lists of Research Approval certificate holders, as well as interacting with them on a case-by-case basis for grant funding releases.

RSS will use a multitude of communication tools to ensure that information is always updated and current. The TRU website will include all forms, policies, manuals, training requirements and documents etc. Minutes of safety and IBSC meetings are posted on the TRU website. All university-wide communications is distributed by the TRU Announcements system using primarily e-mail and web applications.

Element 10: Overview of the procedures to review and monitor the Plan.

The TRU Biosafety Program is under continuous review in order to ensure it remains consistent with federal, provincial, municipal and University requirements as well as keep up to date with current technologies. The BSO is responsible for ensuring the practices are current and bringing any required changes to the attention of the IBSC. This Plan is part of this review process; review of this document will be done on an annual basis to gather recommendations for improvement, efficiency changes, and suggestions from the IBSC and others involved. These recommendations will be gathered and presented at one of the quarterly IBSC meetings held each year. If any regulatory change occurs, the IBSC Chair, AVP-RGS, Director of Risk Management, Associate Director of Safety & Emergency Management and the BSO will discuss the impacts on the program and options for incorporation/change at TRU. Once this group determines the best path forward, the option will be presented to senior management and either the change will be made or further input will be provided. Any changes made to TRU's Biosafety Program that impact the elements presented in this Plan (e.g., change in roles or responsibilities of the IBSC) will be updated in the plan once all of the above recommendations and approvals are complete.

Any changes made to the Program will be communicated to all relevant stakeholders as needed. All areas and/or departments that play a role in the Biosafety Program are invited to provide feedback at any time.

The BSO continually reviews the incidents of non-compliances, to determine trends. Depending on the areas where the non-compliances tend to be occurring, changes may be made to the biosafety training, application process, inspection frequency, inclusion of specific info sessions or newsletters etc.