Biosafety Permits

After a mid-term review of the Biosafety Permit process, (currently a five-year term), the Biosafety Program, under the direction of the Biological Safety Advisory Committee (BSAC), is implementing some minor changes to the Biosafety Permit process. Please review the items below to find any pertinent to your program.

Clinical Area Permits

At a recent BSAC meeting the committee was in agreement that the U of M Biosafety Policy & Procedure applies to clinical research spaces and health care providing units engaging in work with human blood, body fluids or tissue. These areas are now required to register this work with a Biosafety Permit.

Even though the identified risks/hazards of working with human blood, body fluids and tissue in a clinical research or health care setting is considered work with Risk Group 2 biological agents, it was recognized that not all of the current PHAC Canadian Biosafety Standards and Guidelines (CBSG) Containment Level 2 requirements were applicable in these areas.

In response, a ‘Clinical’ Biosafety Permit has been developed that allows flexibility for some of the permit conditions (facility design, access control, training) as based on a local risk assessment and in full consultation with the Biological Safety Officer (BSO). Similar to the regular biosafety permits, the Clinical Biosafety permits will be valid for five years and will require amendments to be submitted if pertinent permit information changes.

Biosafety Program staff will be contacting identified areas individually, to help them work through the permit application process and requirements.

Note:

To compliment this, the guidance document ‘Working with Human Blood, Tissues and Body Fluids’ has been updated to include information on Clinical Biosafety Permits and expectations for phlebotomy procedures involving human participants.

All phlebotomy procedures at the U of M must follow the U of M Human Ethics Resource Committee (HERC) document: ‘Guidelines for the collection of blood samples (phlebotomy) in research involving humans’.
Core Platforms
A number of faculties and departments operate or provide specialty equipment or services, to other researchers internal and external to the U of M, often on a fee-for-service basis.

Any work with biological material undertaken within the ‘Core Platform’ must now be registered with a Biosafety Permit. (Biological material as defined under the Biosafety Policy/Procedure)

Typically these Core Platforms are run by current Biosafety Permit holders. These Biosafety Permits must now be updated to include all the locations, personnel and scope of work associated with the core platform. Some Core Platforms have already been registered. Please contact Steve.Cole@umanitoba.ca for information if this is applies to you and you have not been contacted.

Permit Terminations and Decommissioning
Researchers ceasing work with their biological agents in U of M owned buildings, due, for example, to retirement or relocation to another academic institution are required to:

1. Submit a permit termination application on the EHSA database
2. Submit a Biosafety Permit Declaration of Decommissioning indicating that all of their biological agents have been destroyed or transferred to another location.

Where the leave is sudden and the PI doesn’t have the opportunity to complete the required process, the responsibility for ensuring the process is completed will go to the department head. Detailed instructions can be found on the Biosafety Permit website.

Note: In anticipation of the changes with the full implementation of HPTA/HPTR and new license requirements (Dec. 2015) some Canadian institutions/BSOs are already requesting HPTA registration numbers when RG2 agents are transferred to or from their institution. A "Biohazardous Agent Transfer Notification" form has been developed and is currently available on the Biosafety program website.

Human Pathogens and Toxins Act (HPTA)& Regulations (HPTR) and the Canadian Biosafety Standards (CBS) 2\textsuperscript{nd} Edition

The comment period for the draft HPTR and draft CBS closed September 4, 2014 and the final version of these regulations and standards are now being prepared. Although the full effect of the HPTA, HPTR and CBS will not take full effect until December 2015, Parliamentary approval and release of the final versions is expected in February 2015, allowing for institutions to initiate any required changes.

The Biosafety Program is committed to keeping permit holders informed of the proposed regulatory changes. For a better understanding of the Regulatory framework of the HPTA/HPTR, information is available here. FAQs on the Canadian Biosafety Standards

Some of these changes will be implemented over the coming months so that the university will be in compliance by December 2015. The Office of Biosecurity has shared that all license holders will be inspected once during the term of their new license(s).
What will be new?

Some of the general program changes will include:

- With the full force of the HPTA/HPTR institutions will need to file separate licenses for Risk Group 2, 3, 4 pathogens and Security Sensitive Biological Agents and Toxins (SSBA or aka ‘Prescribed Agents’). (Currently under the HPTA, institutions are only required to register with PHAC) For information on prescribed agents and toxins refer to the Draft HPTR 10.2.
  - It is expected that the U of M Responsible Official will file a RG2 and a RG3 license.
  - No work with prescribed agents or toxins over the regulated quantities is currently known to be ongoing at the U of M. If you work with any of these regulated material please contact us as soon as possible; the security clearance and program requirements for regulated materials is quite stringent.

- BSO duties are identified under the Regulations. Persons authorized to work under the license will be expected to support the BSO in the performance of these duties.

- License applications will require submission of a biosafety and biosecurity management plan. Plans will be at a high (institutional) level and are intended to facilitate the development of internal accountability structures or support accountability structures that currently exist.
  - Biosecurity plans require a documented risk assessment and are developed to include information on defined elements.
  - EHSO is working with Office of Risk Management and the pertinent stakeholders to develop and document the biosecurity risk assessment and plan.

- A key license condition will be mandatory compliance with the applicable requirements set out in the CBS. Note the new Containment Zone 2 definitions and authorized access statements in the draft CBS. EHSO Biosafety program members will be visiting departments starting in the Spring of 2015 to clarify the expectations.

- All persons working with biological agents under a license will be required to report exposures and potential exposures to the BSO. The BSO in turn is required to ensure that an incident investigation is undertaken and if the exposure results in a worker infection, that the incident is reported to the PHAC. (Names of the individual or institution are not required to be included in the report.)

- With the full force of the HPTA, the Human Pathogens Importations Regulations (HPIR) will be repealed and Federal importation permits will no longer be available as an internal control mechanism. Workers under a HPTA license holder will now be responsible to notify the BSO:
  - When a human pathogen or toxin is lost in transit.
  - Inadvertent production of or release of a biological agent or toxin not covered by the current license.
  - Of their intentions to import human pathogens or toxins or to receive one by transfer from another licensed institution in Canada.
  - Before arrangements are made to send a human pathogen or toxin to another licensed institution or another country. See the Note in the Permit Terminations and Decommissioning section.
'What will be new?' continued

- The biosafety program will be required to conduct regular lab inspections or biosafety program audits which are to be reported to the license holder, including any issues of unresolved non-compliance.

Scope of the HPTA

There has been much enquiry over the biological agents covered by the scope of the HPTA. The Centre has developed four Statements of Administrative Intent (SAI) to provide a clearer understanding.

- **Cell and Cell Lines**: Explains that Cell and Cell lines are derived from human and animal sources and that when a Cell or Cell Line contains a Risk 2, Risk 3 or Risk Group 4 human pathogen or toxins as defined in the HPTA then it is controlled under its authority.

- **Exclusions from the Human Pathogens and Toxins Act (HPTA)**: When a human pathogen and toxin is found in the natural environment or in a regulated drug then it is not subject to the HPTA.

- **Defining the term Micro-organism in the context of the HPTA**: Defines the term microorganism as an organism which is too small to be visible to the naked eye (i.e., microscopic). It also specifies that when a microorganism meets the definition of Risk Group 2, Risk Group 3, or Risk Group 4 as defined in the HPTA then it is human pathogen and is controlled under its authority.

- **The HPTA Application to Helminths**: Specifies that when a Helminth meets the definition of Risk Group 2, Risk Group 3, or Risk Group 4 as defined in the HPTA then it is human pathogen and is controlled under its authority.