Biosafety Approval - FAQs

For Research and Clinical Trials

All research projects and clinical trials with biosafety implications involving AHS patients or resources must receive biosafety approval issued by AHS (in addition to APL, as needed). This new requirement ensures AHS practices are in line with the federal Human Pathogens and Toxins Act, the Canadian Biosafety Standards, and other national and international best practices for biosafety.

Research and clinical trials are increasingly making use of biological materials – including microorganisms, proteins, and nucleic acids – to investigate disease, develop new treatments, and offer novel therapeutics to patients.

In order to responsibly offer new research and clinical trial opportunities to its patients, AHS is committed to the safe handling, use, storage and containment of biological materials to protect patients, the public, staff, and the environment.

Does my research project/clinical trial require biosafety approval?

Prior to initiating a study, a biosafety approval issued on behalf of AHS is required if your research/clinical trial involves any of the following:

1. Investigational products consisting of, or derived from, a biological material.
2. Human pathogens and toxins classified as a risk group 2 or higher, as defined by the federal Human Pathogens and Toxins Act.
3. Genetically modified products generated using human pathogens and toxins such as, but not limited to, viral vector systems including CRISPR-based technologies, which have the capacity to target specific stretches of genetic code and edit DNA at precise locations.
4. Activities that purposely, or may inadvertently, amplify, concentrate, isolate, or aerosolize a human pathogen or toxin.

If you are unsure of whether or not your research project or clinical trial requires biosafety approval, or you have any biosafety questions, please email AHSBiosafety-Research@ahs.ca

How do I obtain an AHS biosafety approval?

If your study or trial involves any of the materials listed above, a biosafety approval must be obtained prior to initiating research, including clinical trials. A biosafety approval is issued by AHS (in addition to APL, as needed).

To initiate a biosafety review of a research project or clinical trial, either:

1. **Contact an AHS/APL biosafety program.**

   For the Cancer Care biosafety program in Edmonton and Northern Alberta: biosafety.cci@ahs.ca

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For the Cancer Care biosafety program in Calgary and Southern Alberta: biosafety.tbcc@ahs.ca

For Alberta Precision Laboratories biosafety program: aplbiosafety@aplabs.ca

AHS provincial biosafety program for research: AHSBiosafety-Research@ahs.ca

Or

2. Apply for research ethics board approval for your project.

All research ethics board-approved research studies involving AHS data, resources, and/or facilities are automatically forwarded to AHS Health System Access (https://www.albertahealthservices.ca/research/page8579.aspx) for administrative review and approval. During the administrative review process, research studies will be assessed for a required biosafety review and biosafety approval by an appropriate biosafety program.

The process of biosafety review and approval may be expedited by providing the following information when contacting an AHS/APL biosafety program or including it in a Research Ethics Board application:

a. All involved biological materials, associated biological material activities, and contexts in which biological materials will be acquired, possessed, handled, used, produced, stored, transferred, and disposed when conducting your research.
b. AHS' involvement in the research, including all of the proposed AHS sites where biological materials will be acquired, possessed, handled, used, produced, stored, transferred and disposed

Is an AHS biosafety approval required if a clinical trial has received a No Objection Letter from Health Canada?

Yes.

A No Objection Letter issued by Health Canada primarily considers the impact to, and the safety of, the patient, which involves weighing the risks of treatment in the context of the patient's disease/condition. A biosafety approval ensures the safety of the public, staff and environment are appropriately addressed.

How can I learn more about biosafety in AHS?

AHS has developed a suite of freely available biosafety training courses. AHS staff can access courses through MyLearningLink on Insite.

Biosafety Core Training – Introduction

Biosafety Core Training – Biohazardous Spill Response & Reporting

Biosafety Core Training – Biosecurity, Security Sensitive Biological Agents (SSBAs) and Dual-Use

Biosafety Core Training – Risk Group and Containment Levels

Biosafety Core Training Exposures, Lab Acquired Infections (LAIs) and Incident Reporting

Biosafety – Autoclave Safe Use

Biosafety – Biological Safety Cabinet Use

Biosafety – Clinical Trials – Clinical and Laboratory Staff

Biosafety – Genetic Modifications and Viral Vector Systems

Biosafety – Lab Safety Training

Biosafety Core Training – Exposures, Lab Acquired Infections (LAIs) and Incident Reporting

Biosafety training is also available to employees, students, and other AHS affiliates through:

University of Calgary

https://www.ucalgary.ca/risk/environment-health-safety/training

University of Alberta

https://www.ualberta.ca/human-resources-health-safety-environment/environment-and-safety/training/index.html.