

ENVIRONMENTAL HEALTH & SAFETY

SARS-CoV-2: Biosafety Guideline for Research Laboratories

This biosafety guideline is intended to assist laboratories in planning and implementing their research with SARS-CoV-2 (the causative viral agent of COVID-19) or related biological materials at the University of Toronto. This guideline is based on currently available scientific evidence, the Biosafety Advisory issued by the Public Health Agency of Canada (PHAC) and is subject to review and change as new information becomes available. SARS-CoV-2 has been classified as a Risk Group 3 (RG3) human pathogen by Health Canada Centre for Biosecurity.

Depending on the research activities, a Level 2 or Level 3 Biosafety permit, or amendment to these existing permits, is required for all proposed research with SARS-CoV-2, RNA or DNA from SARS-CoV-2 and samples or materials known or likely to contain SARS-CoV-2. Submitted permits/amendments will be reviewed by Local Biosafety Committee (LBC) members appointed to review submissions.). In addition, research may also require approval by the Research Ethics Board (for human samples), or by the local animal care committee (LACC) for animal protocols. Contact information and links to forms are provided at the end of this document.

Training

Personnel must have completed the following courses offered by the Environmental Health and Safety:

a) Biosafety training: EHS601 Laboratory Training (once)

EHS602 Biosafety Refresher (1 year after EHS601 and every year thereafter)

- b) WHMIS training: EHS101 WHMIS & Lab Safety (once) (EHS005 was an older version) EHS112 WHMIS Refresher (1 year after EHS101/EHS005 and every year thereafter)
- c) Blood Borne Pathogens Course: EHS603 for work with human or animal blood, body fluids, tissue or primary cells
- d) SARS-CoV-2 Course: EHS620 for work with SARS-CoV-2 or samples known/likely to contain SARS-CoV-2. Additional in-house training on specific SOPs must be provided and this training must be documented.
- e) Where respiratory protection is required: Respiratory Protection course (EHS532) and current (within 2 years) fit-testing. For more information: <u>https://ehs.utoronto.ca/training/respiratory-protection-training-fit-testing/</u>.

Note: Further specialized training is required prior to working in the Containment Level 3 facilities.

Medical Surveillance

Researchers must contact the <u>Occupational Health Nurse</u> prior to starting work with SARS-CoV-2 in the following cases:

- a) Researchers with any of the following pre-existing medical conditions
 - On Prednisone >5mg/day
 - Insulin-dependent diabetes mellitus or uncontrolled non insulin-dependent diabetes mellitus (fasting blood sugar > 12) and/or HbA1c > 7.0
 - Uncontrolled hypertension (>180/110)
 - On prescribed Biologics
 - On Chemotherapy or Radiation treatment
 - Severe chronic obstructive pulmonary disease
 - Liver, kidney, or heart issues
 - Haematologic disease
- b) Researchers planning to work with human blood, body fluids, tissue, primary cells.

Covid-19 Immunization Requirement

Occupational Health Services will file lab worker Covid-19 Vaccination proof from UCheck to lab worker medical file in Occupational Health & Safety Department.

A primary series is as follows:

- 2 doses of Health Canada approved* vaccines, or 1 dose of the Janssen vaccine
- 1 or 2 doses of a non-Health Canada approved vaccine AND an mRNA dose (Pfizer or Moderna)
- 3 doses of a non-Health Canada approved vaccine

*Health Canada approved vaccines are:

- Pfizer-BioNTech (Comirnaty, Tozinameran, BNT162b2)
- Moderna (Spikevax, mRNA-1273)
- AstraZeneca (Vaxzevria, COVISHIELD, ChAdOx1-S, AZD1222)
- Janssen/Johnson & Johnson (Ad26.COV2.S)
- Novavax (Nuvaxovid, SARS-CoV-2 recombinant spike (rS) protein)
- Medicago (Covifenz, plant based, virus-like particles (VLP) of SARS-CoV-2 spike (S) protein)**

People who have had COVID-19 infection should receive the recommended number of doses as outlined above. However, they are recommended to 6 months after having COVID-19 to get the next dose in their primary series or booster dose. Optimal timing can be discussed with a health care provider and depends on age, number of doses received, risk of exposure and health status.

Health Canada approved booster dose is strongly recommended every 6-months.

**The Medicago COVID-19 vaccine is not currently authorized for use as booster dose(s) in Canada. See Health Canada's website for the current list of COVID-19 vaccines authorized by Health Canada. <u>https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html</u>

COVID-19 Health Measures

Please follow current University Policy: <u>EHS COVID-19 information page (for general information about COVID-19 measures at the University)</u> Joint Provostial and Human Resources Guideline on Face Masks

The table below is taken from PHAC SARS-CoV-2 Biosafety Advisory (November 23, 2021) with some changes

Research Activities	Containment Level ^{**}
 Non-propagative diagnostic activities that do not result in the concentration or extraction of SARS-CoV-2 Example of these activities include, but are not limited to: clinical chemistry studies, urinalysis, and hematology and serology testing (e.g., analysis with automated platforms); visual examination of inactivated specimens or tissues (e.g., formalin-fixed); visual examination of bacterial and fungal cultures; routine staining and microscopic analysis of heat- or chemically-fixed smears; assays with virus-inactivated specimens; and preparation of specimens for packaging and distribution to diagnostic laboratories for additional testing. 	CL2
 Non-propagative diagnostic activities that may inadvertently concentrate or extract SARS-CoV-2 Examples of these activities include, but are not limited to: concentration of samples prior to inactivation (e.g., centrifugation of a bronchoalveolar lavage sample); and sample preparation for nucleic acid extraction, molecular testing of nucleic acids (sequencing, RT-PCR), and antigen and antibody assays. 	CL2+
 Propagative in vitro activities Examples of these activities include, but are not limited to: culturing specimens (e.g., propagated virus); preparatory work for <i>in vivo</i> activities; and processing a culture (i.e., propagated or cultivated) known to contain SARS-CoV-2 for packaging and distribution to laboratories. 	CL3
 <i>in vivo</i> work activities Examples of these activities include, but are not limited to: preparing inoculum; inoculating animals; and collecting specimens from experimentally infected animals. 	CL3

^{**}Refers to both infrastructure and operational practices

For any deviations from or clarifications to information in the table above, please contact ehs.biosafety@utoronto.ca

CL2+ Requirements (these are in addition to standard CL2 operational practices)

- The room must have consistent inward directional air flow (IDA).
- Personnel must wear a closed gown, double pair of gloves, and when appropriate, a face shield[†].
- Any procedure with the potential to generate aerosols or droplets must be performed in a certified Class II Biological Safety Cabinet (BSC). Such procedures include but are not limited to pipetting, plating, vortexing, cell sorting, ELISA plate washing
- After completion of work, BSCs must be decontaminated with an approved disinfectant for coronavirus (see section below on Decontamination).
- Centrifugation of specimens must be performed using sealed (aerosol-tight) centrifuge rotors or sample cups that are loaded/unloaded in a BSC. These rotors/sample cups must be surface decontaminated with an approved disinfectant before removal from the BSC.
- The use of sharps should be eliminated wherever possible.
- For waste disposal, see relevant section below.

Decontamination

Decontaminate work surfaces and equipment with appropriate disinfectants effective against SARS-CoV-2. Follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling. Based on current evidence, the following disinfectants are effective against SARS-CoV-2 for surface decontamination: 0.5% sodium hypochlorite (active ingredient in bleach), 70 % ethanol, and 0.5 % accelerated hydrogen peroxide.

Waste Disposal

For CL2+ all contaminated material [both liquid and solid (e.g., pipette tips, tubes, flasks, plates etc.)] must be fully decontaminated within the BSC prior to removal using the appropriate disinfectant (i.e. sodium hypochlorite).

- a) Solid waste should be soaked in a solution of 1 % sodium hypochlorite of a minimum of 30 minutes. Disinfectant is then poured off and solid waste placed in yellow biohazardous waste containers.
- b) For liquid waste, treat with a final of 1 % sodium hypochlorite for a minimum of 30 minutes before disposal into the sink.

Information on waste procedures (e.g. CL2) and the proper use of bleach can be accessed <u>here</u>.

[†] Face shield to be used when there is a potential for exposure to splashes

Emergency Response Plans

An emergency response plan must be in place and must include the following:

- a) Emergency contacts (e.g. PI, 24 hour emergency lab contact, campus police)
- b) Response procedures including those for biological spills, chemical spills, medical emergencies, occupational exposure.

Note:. Your plan must be available to lab personnel, your unit head (department), and managers of research facilities (where applicable) prior to commencing research.

Accident/Incident Reporting

Any accident or incident occurring at the university must be reported. Personnel are to contact their supervisor/PI and the supervisor/PI must submit an online Accident/Incident eForm. For further information, please refer to the information <u>here</u>.

Importing/Exporting

All transfers of SARS-CoV-2 samples (including but not limited to DNA, RNA, body fluids/tissue/cells) must be approved by the Biosafety Office prior importing or exporting; please send inquiries to <u>ehs.biosafety@utoronto.ca</u>. Please note that there are different requirements in place for domestic and international transfers.

Reminder: as applicable request a <u>Material Transfer Agreement</u> (MTA). The MTA is a contract between the provider of material and the recipient. It grants the recipient a license to use the proprietary material and ensures that both parties understand how the materials can be used.

Specimen Packing and Shipping

The transportation of SARS-CoV-2 specimens is subject to the Transportation of Dangerous Goods (TDG) Regulations, which include the packaging requirements stipulated in the standard CAN/CGSB-43.125. TDG certification is required for shippers/receivers.

Samples of SARS-CoV-2 specimens must be assigned to:

- UN2814, if they meet Category A criteria (i.e., propagated virus);
- UN3373, if they meet Category B criteria (i.e., patient/primary specimens); and
- UN3291, if the clinical waste contains Category B infectious substances (or it has low probability of containing virus).

In the event of an emergency involving dangerous goods, call CANUTEC at 1-888-CANUTEC (226-8832), 613-996-6666 or *666 on a cellular phone.

Contact Information

General Inquiries: <u>ehs.biosafety@utoronto.ca</u> Biosafety Permits and Amendments: <u>ehs.biosafety@utoronto.ca</u> Occupational Health Nurse: <u>ehs.occhealth@utoronto.ca</u> Environmental Protection Services: <u>hazwaste.ehs@utoronto.ca</u>

Links

University of Toronto Biosafety Website Level 3 Biosafety Permit – available upon request to Biosafety Office Level 2 Biosafety Permit Application Biosafety Permit Amendment Form Research Ethics Boards Ethics in Animal Research EHS COVID-19 information page (for general information about COVID-19 measures at the University) https://tc.canada.ca/en/corporate-services/acts-regulations/list-regulations/transportation-dangerousgoods-regulations

References

PHAC Advisory on SARS CoV-2 Health Canada's website for a list of COVID-19 vaccines authorized by Health Canada COVID-19 vaccine: Canadian Immunization Guide

Version History		
Version Number	Effective Date	Changes
1.0	April 23, 2020	Initial version
2.0	September 4, 2020	Section updated: Medical Surveillance
2.1	August, 2022	Sections updated: Introduction, Training, contact email, Immunization requirement, COVID-19 measures Reviewed by Biosafety Office, OHS (YTS and GL)