London Regional Genomics Centre Biosafety Policy

Revised 2019 Oct

The London Regional Genomics Centre (LRGC) is a multi-user facility where many different samples from varied cell sources are sequenced. These samples may contain known or unknown human pathogens. The safety of our genomics facility staff and users is of utmost concern. Information about the sample sources and potentially infectious agents is critical for effective biosafety measures. In an effort to ensure adequate biosafety procedures are followed within the LRGC, the following biosafety policy has been in effect since October 1, 2019. This policy ensures compliance with Western's Biosafety Guidelines, and was first reviewed and approved by Western's Biohazard Subcommittee on March 27, 2009. (For more information about Western's Biosafety policies and guidelines, please visit https://www.uwo.ca/hr/safety/topics/biosafety/index.html).

Each principal investigator is responsible for supplying the LRGC with a completed Biosafety Information Form for EACH cell/sample type to be sequenced in the facility, BEFORE experiments are begun.

It is the principal investigator's responsibility to ensure that all proposed cell/sample types are listed on an approved **University of Western Ontario Biological Agents Permit Application (BAPA) or equivalent Lawson/LHSC Biological Agents Permit Application.** For any cell type that has been virally transformed, transfected, transduced or infected with a non-viral agent (eg. bacteria), the information about the manipulation must be listed on the Biosafety Information form and the approved BAPA, in addition to the information about the parental cell type. Samples NOT listed on an approved BAPA will not be assigned a LRGC Biosafety Identifier, and will not be permitted to enter the facility.

This biosafety information form must be completed electronically in Microsoft Word. It is the principal investigator's responsibility to confirm the completeness and accuracy of each form. For each cell/sample type, a completed PDF of the full application, and a scanned copy of the signed signature page (page 2), must be submitted to the LRGC via email, at ngs@robarts.ca. For any sample transduced/infected with a virus/viral vector, the LRGC must be provided with a PDF copy of their approved BAPA along with the completed LRGC Biosafety Information Form (until the Western BAPA electronic database is online).

Upon receipt, complete Biosafety Information Forms will be reviewed by the LRGC, and will be forwarded to the Western Biohazard Subcommittee if further risk assessment is deemed necessary. Upon approval, each sample type will be given a Biosafety Identifier specific to a particular lab (i.e. TXG001). This designator MUST be included on all sequencing appointments and all request forms. Samples will not be processed and sequenced until this document is complete.

This policy will allow the facility to track the biosafety level of samples run in the lab as well as to maintain a record in the event of a facility audit by Federal or Provincial regulatory authorities. The information provided is the ultimate responsibility of the Principal Investigator. Please ensure that records are accurate and up to date.

Specific questions regarding this policy should be directed to David Carter (LRGC Manager) or Dr. Robert A. Hegele (LRGC Director). If necessary, these issues will be taken to Western's Biohazard Subcommittee for further discussion and resolution.

An electronic copy of the Biosafety Information Form can be obtained from the LRGC by sending an email to ngs@robarts.ca.

Thank you,

Management of the London Regional Genomics Centre

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Application Date (YYYY-MM-DD):

Applicant Information:

*List all users in your laboratory, including the Principal Investigator, who are authorized to conduct these experiments. *Must supply valid UWO/Robarts/LHSC/SJHC email address (eg. @uwo.ca or @robarts.ca)*

Principal Investigator	**Email***	**Phone**
Authorized user(s)	**Email**	**Phone**

Institutional Biosafety Review / Approval

It is the principal investigator's responsibility to ensure **all samples** to be processed for sequencing in the LRGC are listed on an **approved University of Western Ontario Biological Agents Permit Application form (or Lawson/LHSC equivalent)**. Samples not listed on an approved BAPA form will not be assigned a Biosafety Identifier, and will NOT be approved for sequencing in the LRGC.

Is this project listed on an APPROVED Western Biological Agents Permit Application or other institutional equivalent?

☐ Yes ☐ No ☐ Submitted for approval (date submitted:)

If YES, provide the following information:

Researcher:

Biosafety Approval Number:

Expiry Date:

If NO, refer to Western's Biosafety website for more information: https://www.uwo.ca/hr/safety/topics/biosafety/

Download the latest copy of Western's Biological Agents Permit Application form or Modification Form, and follow instructions for submission & review. You may not bring these cells into the facility until your submission has been approved by Western's Biosafety Committee. After approvals are obtained, provide approval number & date on a revised Biosafety Information Form, and re-submit to the LRGC at ngs@robarts.ca

☐ **I have read and understand the questions below and certify that the information provided is correct.**

Principal Investigator: Date:

Signature: _____

Please submit a scanned copy of THIS page with signature and date, along with a PDF of the full information form.

Project Information

Project Title:

Summary/Description of Project -- *Provide details related to cells that will be processed for sequencing (1 paragraph):*

Sample Information ** PLEASE COMPLETE A SEPARATE FORM FOR EACH CELL/SAMPLE TYPE **

Sample source:

☐ whole cells ☐ nuclei

If other than whole cells, please describe source:

Species:

☐ human ☐ mouse ☐ rat ☐ non-human primate ☐ yeast ☐ other (specify):

Cell/tissue type:

Sample origin (select option that best applies):

☐ Primary cells/tissue

☐ Cell line established from long term culture of primary cells:

Name(s): Source: ☐ Generated in-house ☐ PDF attached

Please attach a .pdf of the paper describing the protocol for the line's origin/generation, or provide a written description of the method used. ☐ PDF attached, or description:

☐ Commercially available/established cell line:

Name: Source/Company/Supplier: ATCC # / Commercial designation:

Planned application(s) of these cells at the LRGC

☐ single cell RNA sequencing ☐ single cell ATAC sequencing ☐ V(D)J Immune cell sequencing

For single cell barcoding and sequencing

Have the cells been transduced with a viral vector in a process requiring CL2+/CL3 containment?

☐ Yes ☐ No

If *YES,* **AT THE TIME OF SAMPLE PROCESSING** what will be the required containment level for these cells?

☐ CL1 ☐ CL2

NOTE: Cells requiring CL2+ or CL3 containment may not submitted to the LRGC.

OTHER INFORMATION

Please provide any additional information or comments that will help in assessing any risk/biohazard associated with single cell sequencing of this sample type under the above protocol:

Biosafety Information:

Provide the containment level (CL) classification of:

- the naïve/parental cell type: ☐ CL1 ☐ CL2 ☐ CL2+ ☐ CL3*
- the genetically modified cell type(s): ☐ CL1 ☐ CL2 ☐ CL2+ ☐ CL3*

Does the sample contain any known infectious agents?

☐ Yes ☐ No ☐ Unknown *If YES, list agents below:*

	Health Canada/CFIA Containment Level →	1	2	2+	3 *
Infectious Agent 1:		☐	☐	☐	☐
Infectious Agent 2:		☐	☐	☐	☐
Infectious Agent 3:		☐	☐	☐	☐

Describe the nature of the infectious agent(s) — *for example: wild-type, attenuated, replication-competent, rendered defective for viral replication*:

Were human blood donors screened for blood borne pathogens (*eg: HIV, HBV, HCV*)?

☐ Yes ☐ No ☐ N/A ☐ Unknown *If YES, provide test results below:*

	Positive	Negative
Test 1:	☐	☐
Test 2:	☐	☐
Test 3:	☐	☐

Could these samples contain other known human pathogens? ☐ Yes ☐ No *If YES, please describe:*

Have cell cultures been tested for mycoplasma and/or viral infection (*eg: HIV, HBV, SIV, EBV, HSV*)?

☐ Yes ☐ No ☐ N/A *If YES, provide test results:*

		Positive	Negative
Date:	Test 1:	☐	☐
Date:	Test 2:	☐	☐
Date:	Test 3:	☐	☐

Cellular transformation:

For cell line establishment, were cells transformed using a virus or part of a virus genome such as EBV, HTLV-1, herpes saimiri, SV40, Adenovirus, retroviral or cellular oncogene?

☐ Yes ☐ No ☐ N/A *If YES, list virus:*

Genetic modifications:

Will cells be genetically modified to knock-out, knock-in, or mutate any genetic material in the cells, through plasmid transfection or viral transduction (select all that apply)?

☐ Yes, through plasmid transfection ☐ Yes, through viral transduction/infection * ☐ No, only parental cells used

* If genetic information will be delivered to cells via a virus or viral vector, you must submit a PDF copy of your approved BAPA,application along with this information form.

Is BAPA attached to submission? ☐ Yes

Any such genetic modifications must be listed on your laboratory's approved BAPA. Are these modifications listed?

☐ Yes ☐ No

If *NO*, please submit a BAPA modification form to the Biohazard subcommittee describing these modifications, and inform the LRGC when approved.

Will any proposed transformation or modification alter the containment level of the cells/cell line?

☐ Yes ☐ No

If *YES*, what containment level is now required:

Will the cells be producing infectious virus at the time they are brought into the facility for sorting?

☐ Yes ☐ No

If YES, please describe, including cell tropism:

Biosafety Identifier: ____

Do not fill shaded area. LRGC use only
v. 1 2019-10-25 JFR

☐ Approved ☐ Declined (reason below) ☐ Approved with the following conditions:

Due to the nature of the infectious agents present, these samples must be brought to the core facility:

☐ in capped sample tubes

☐ inside a leak-proof secondary container with a secure lid to prevent spills during transport

(For example, the Nalgene Bio-safe carrier, VWR catalogue number 56609-112)

Cell type:

Comments:

Approved by: Date (YYYY-MM-DD):