

## **Guide to the use of Biological Material and Live Animals at the CLS.**

The following presents an outline to aid researchers who wish to use Biological Materials at the CLS.

Researchers working with biological materials must identify the biological samples they wish to work with at the CLS, identify the risks of these materials and provide the CLS with a written plan for control of these risks in their proposal. Experiments using biological materials require review and approval by the CLS Biological Safety Coordinator or designate.

The CLSI Biosafety guidelines (Document No. 11.1.55.2) define biological materials as any material that includes (but is not limited to):

1. Microorganisms
2. Recombinant DNA (rDNA)
3. Cell lines
4. Animals (live or tissues and biological fluids)
5. Plants
6. Human tissue or biological fluids
7. Microbial Toxins

For users wishing to use biological materials at the CLS here are some points to consider when preparing a proposal.

### **Risk Group Levels:**

The CLS is designed to accommodate Risk Group Level (RGL) 1 and 2 materials only.

#### **Risk Group Level 1 (RGL1)**

RGL1 is defined as any biological agent or material that is unlikely to cause disease in healthy workers or animals.

Any animals or tissues and biological fluids obtained from animals that are deemed healthy (show no signs of disease and come from a reputable source) are considered RGL1.

#### **Risk Group Level 2 (RGL2)**

RGL2 is defined as any biological agent or material that can cause human disease but is unlikely under normal circumstances to be a serious hazard to laboratory workers, the community, livestock or the environment.

Any unfixed human materials (blood, body fluids, tissues, etc.) are designated RGL2 due to the potential for blood-borne pathogens. All human neurological tissues, fixed or unfixed, are designated as RGL2 due to the potential for unconventional pathogens (prions).

Any animal that has been challenged with a RGL2 organism or is diseased is designated at a minimum RGL2.

### **Containment levels:**

The CLS has containment level 2 labs for use by users. All manipulations of RGL2 materials must be performed in these designated areas.

RGL2 materials must be contained in sealed sample holders when in use at the Beamlines.

Transport to, from and within the CLS must follow the procedures outlined in the CLSI *Sample and Material Transport Procedures* (Document No. 11.7.1.1). These procedures require the use of appropriate primary and secondary containers and labelling of samples according to WHMIS regulations. All surfaces of the containers must be free from any contamination of infectious materials. Users are responsible for providing the appropriate primary and secondary containers.

### **Risk Assessment:**

The Public Health Agency of Canada's Laboratory Biosafety Guidelines state:

“a risk assessment is a critical step in the selection of an appropriate containment level for the microbiological work to be carried out....In addition to the Risk Group classifications, which are based on the risk factors inherent to the organism, the following factors associated with the laboratory operation should also be examined:

- Potential for aerosol generation
- Quantity
- Concentration
- Agent stability in the environment
- Type of work proposed
- Use of recombinant organisms”

A risk assessment of any experiment performed at the CLS facility is mandatory. The CLS Health, Safety and Environment Department (HSE) will review and approve the risk assessment based on the information submitted in the proposal and assign the appropriate controls.

For an efficient review the following information is requested by the CLS HSE. Failure to provide this information may result in delayed review and approval.

### **Sample information:**

A detailed sample description is required. This includes the type of sample, the number of samples and any treatment the samples may have received prior to arrival at the CLS (are the samples frozen, fixed, etc.).

Example: 5 cubes of formalin-fixed and frozen human liver tissue, infected with hepatitis B. Each tissue cube is 1 mm x 3 mm and is sealed in a Lucite sample cell with a Mylar window.

Documentation to identify the sample, if available, should be attached to the proposal. This could include a technical sheet from the vendor or a Material Safety Data Sheet (MSDS). A MSDS is required for any biohazardous material. It is recommended that proposals using human or animal cell lines be submitted with supporting documentation to identify the source as some cell lines may require ethics review.

Any manipulations or preparations of the sample(s) performed at the CLS should be described including which research team member(s) will be performing the procedures and any equipment required for the procedures (e.g. Biosafety cabinet). This should include any additional materials that will be used and any anticipated waste generated. Waste may be required to be transported to the User's home institution for proper disposal or arrangements made with the CLS for disposal.

Any change to the samples or materials requires a permit amendment to be submitted, reviewed and approved. Please allow ***four weeks*** for reviews of Permit Amendments prior to the scheduled experiment. While every effort will be made to approve amendments in a timely manner, amendments submitted after the four weeks are not guaranteed to be processed and the last valid permit will be used for the experiment. Currently amendments can only be approved during working hours (M-F 8:00 – 16:30)

## **Training**

Completion of some training will be required on your first visit to the CLS before you begin your experiment. The training is valid for 2 years so will not be required to be repeated on each return trip. Additional training may be assigned based on the proposal.

All individuals who will be handling biohazardous material at the CLS require appropriate biosafety training. Confirmation of Biosafety training from your home institution should be supplied (i.e. copy of training certificate). Additional CLS site specific Biosafety training will be required. Individuals without adequate Biosafety training will be restricted from accessing certain labs and handling biohazardous materials.

All individuals who will be handling live animals must have completed the University of Saskatchewan's web based animal care course or equivalent from their home institution. Proof of animal care training will be required for ethics approval. Additional site specific training may be assigned by the CLS and will be available online.

## **Documentation**

The use of many biological materials requires supporting documents. These documents should be included with the proposal to assist with the review. Proposals will not be approved until all the documentation is received and reviewed. Copies of the official signed documents should be included when available.

## Biological Materials

- Technical sheet from vendor, if applicable (such as ATCC)
- MSDS sheet, if applicable. (MSDS sheet required for RGL2)  
MSDS for human pathogens can be found at <http://www.phac-aspc.gc.ca/msds-ftss/index-eng.php> and animal pathogens at <http://www.inspection.gc.ca/english/sci/bio/anima/disemala/disemalae.shtml>
- Exposure Control Plan is required for any RGL2 work. A template is available from the CLS, if required.

## Additional Documentation Required for:

### Tissues or biological fluids from animals

- All research performed at the Canadian Light Source facility involving tissues or biological fluids from animals requires approved ethics.
- If you do not have approved ethics and your research at the CLS meets the criteria for a Category A experiment described below you may submit a [University of Saskatchewan \(UofS\) Animal Use Protocol \(AUP\) Category A Short Form](#). If you have approved ethics you may submit a Category A Short Form in lieu of submitting your ethics protocol application.
- CCAC Category A experiments involve the use of animal tissues, but do not involve any work on live vertebrates. Examples include: use of tissue culture; use of tissues obtained at necropsy, from a slaughterhouse, or from another research scientist; or the use of eggs.
- Studies using most invertebrates (except cephalopods and some other higher invertebrates) or on live isolates, such as protozoa or other single-celled organisms do not need to be submitted for ethics approval.

### Live Animals

- All research performed at the Canadian Light Source facility involving live animals (use of cephalopods and non-human vertebrates) requires review and protocol approval by the user's home institution and/or appropriate animal care committee and the University of Saskatchewan's Animal Research Ethics Board.
- Attach a copy of your valid Certificate of Protocol approval and a copy of the signed supporting protocol application. *Please note your protocol application must reference the planned use of the CLS facility.*
- Standard Operating Procedures (SOPs)
  - May be requested by CLSI HSE or the University of Saskatchewan Animal Ethics Review Board. SOPs may be required for holding, handling and manipulations (including anaesthesia and monitoring) of live animals. It is impossible for the CLS to develop SOPs for all possible experimental variations involving all species of laboratory animals.

Therefore, it is the responsibility of the user to provide the required SOPs to HSE for review.

### **Human subjects/human tissue or biological fluids subjects living or not**

- All research performed at the Canadian Light Source facility that involves human subjects or the use of human tissue or biological fluids from subjects, living or not, requires review and approval by a University of Saskatchewan Research Ethics Board.
- Attach your University of Saskatchewan Certificate of Ethics Approval.
- If you are not affiliated with the University of Saskatchewan (UofS) please attach an equivalent Certificate of Ethics Approval and copy of the signed supporting protocol application.
- A University of Saskatchewan Researcher's Summary Form may be submitted for de-identified human tissues in lieu of the supporting protocol application.
- *Please note your protocol application must reference the planned use of the CLS facility. All non UofS affiliated users will have their CLS proposal and supporting ethics documents forwarded to the appropriate UofS Research Ethics Board (REB) for review. If additional information is required, the UofS REB will correspond directly with you.*

**Review of ethics documents may take several weeks and ethics approval for experiments involving live animals may take several months so please plan accordingly.**

### **Import Permits**

If biological materials are to be imported from outside of Canada, import permits may be required. Contact the CLS Biological Safety Coordinator or see the following websites for additional information:

Importing Human Pathogens -Public Health Agency of Canada

<http://www.phac-aspc.gc.ca/ols-bsl/pathogen/index-eng.php>

Importing Animal Pathogens -Canadian Food Inspection Agency

<http://www.inspection.gc.ca/english/sci/bio/anima/animaie.shtml>

Importing Plant and Plant Products -Canadian Food Inspection Agency

<http://www.inspection.gc.ca/english/plaveg/internat/importe.shtml>

### **Additional Resources**

1. Public Health Agency of Canada Laboratory Biosafety Guidelines:  
<http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index.html>

2. Public Health Agency of Canada MSDS:  
<http://www.phac-aspc.gc.ca/msds-ftss/index.html>
3. Canadian Food Inspection Agency Containment Standards for Veterinary Facilities (CSVF):  
<http://www.inspection.gc.ca/english/sci/lab/convet/convete.shtml>
4. Canadian Food Inspection Agency webpage regarding animal pathogens:  
<http://www.inspection.gc.ca/english/sci/bio/bioe.shtml>
5. Canadian Food Inspection Agency Plant Biosafety Webpage:  
<http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml>
6. General information on aspects of the New Substance Program.  
[http://www.ec.gc.ca/substances/nsb/eng/home\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/home_e.shtml)
7. New Substances Notification Regulations ([Chemicals and Polymers](#))
8. New Substances Notification Regulations ([Organisms](#))
9. CLSI Documents
  1. Biosafety Guidelines 11.1.5.2
  2. Laboratory Safety Guidelines 11.1.55.1
  3. Animal Care and Use Guidelines 11.1.55.3
  4. CLSI Ethics Guidelines: when animals are involved 22.1.1.4
  5. CLSI Ethics Guidelines: involving humans 22.1.1.3
  6. Sample and Material Transport Procedures 11.7.1.1
  7. Hazardous Materials Management Plan 11.12.56.1