



CLSI Ethics Guidelines: involving humans

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1.0 POLICY

All research performed at the Canadian Light Source facility (CLS) that involves human subjects or the use of human tissue from subjects, living or not, requires review and approval by the user's home institute and the appropriate University of Saskatchewan (UofS) Research Ethics Board (REB).

2.0 BACKGROUND

The CLS facility is licensed through the Canadian Nuclear Safety Commission (CNSC) and CLSI is required to comply with all applicable federal, provincial and municipal laws. CLSI is a wholly owned subsidiary of the UofS and follows the [UofS policies and procedures for Ethics in Human Research](#).

The UofS follows the national standards outlined by the Tri-Council Policy Statement: [Ethical Conduct for Research Involving Humans](#) and the [University Policy Research Involving Human Subjects](#). Additional guidance is also provided by the Tri-council MOU - [Schedule 2: Ethics Review of Research Involving Humans](#).¹

The Tri-Council Policy Statement expresses the commitment to the people of Canada to promote the ethical conduct of research involving human subjects.

CLSI's current operating license allows research to be performed on human tissue. Research is planned to be performed on living human subjects in the future. Research on human subjects will not be performed prior to obtaining all appropriate approvals (i.e. renewal of our CNSC operating license).

These guidelines are a living document and will be reviewed and amended accordingly.

3.0 RESEARCH REQUIRING ETHICS REVIEW

In accordance with Tri-Council Policy Article 1.1:

1. "All research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, before the research is started, except as stipulated below.
2. Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by the REB.
3. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to [Article 2.3](#) of this Policy.

¹ University of Saskatchewan http://www.usask.ca/research/ethics_review/human.php

4. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.²

4.0 PURPOSE

To provide guidelines and establish procedures in respect to ethical requirements for all research experiments involving human subjects or the use of human tissue from subjects, living or not, using the services of CLSI to conduct research at the CLS facility.

5.0 DEFINITIONS AND ABBREVIATIONS

CLS: Canadian Light Source Facility

CLSI: Canadian Light Source Inc.

CNSC: Canadian Nuclear Safety Commission

HSE: CLSI Health, Safety and Environment Department

Research involving Human living subject: Research involving living humans occurs when data is derived from: 1) information which is collected through intervention or interaction or observation of a living individual(s).

Research involving Human tissues: Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.

Research Ethics Board (REB): a Research Ethics Board which adheres to and is in compliance with, the standards and procedures of the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998 \(with 2000, 2002 updates\)](#) and with other standards and practices, as required.

Researcher's Summary: UofS Human Ethics application form.

Spokesperson: The Spokesperson (principal investigator, in the ethics applications) is responsible for all research team members associated with the proposal and is the primary point of contact for all communication with CLSI staff.

Status Report Form: UofS Human Ethics annual reapproval and closure form.

User: An individual who requires access to the CLS to perform their research and has registered and completed all requirements including HSE training to access the facility and participate in an experiment at the CLS facility.

UofS: University of Saskatchewan

UofS REB Reviews:

- **Delegated Review:** Applications assessed as minimal risk are forwarded to a subset of REB members. Comments from these reviews are returned to the REB Chair who on the REB's advice issues an approval certificate, solicits further information, or recommends changes to meet ethical requirements.
- **Expedited Review:** Reviews are done by the REB Chair only, under the condition that the research is minimal risk and has undergone prior review by another ethics board. Note that if, in the opinion of the Chair, the application fails to meet local standards on a sufficient number of dimensions, it will be subject to the normal review process.

² Tri-Council Policy Statement, Article 1.1

- **Full Board Review:** Applications assessed as above minimal risk are reviewed by the entire REB at its bi-monthly meeting. The REB may decide, based on its deliberations, to approve the research, disallow the research, request further information or clarification from the researcher, or request changes.

6.0 GUIDING PRINCIPLE

"At the University of Saskatchewan, the purpose of ethics review of research involving human subjects is a) protection of the research subjects, b) protection of the academic staff, support staff and students of the University of Saskatchewan, c) the education of those involved in research, and d) preservation of the confidence and privilege that the public bestows on the higher education community to conduct research involving human subjects. Where human subjects are used in the course of research or other comparable activities, it is the primary concern of the University that the rights of the subjects be respected and protected and that the procedures followed are ethically, medically, and legally correct."³

CLSI requires all users conducting an experiment(s) involving human subjects or tissues to have a valid Certificate of Ethics Approval from the UofS REB and if applicable from their home institute prior to the formal scheduling of beam time.

Experiments involving human subjects or tissue will be performed only after the necessary approvals are in place.

7.0 SCOPE

This guideline applies to all research involving human subjects or tissues requesting to use the services of CLSI to conduct research.

8.0 REVIEW PROCESS

In accordance with the Tri-Council Policy, Article 1.2 "The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within, or by members of, the institution, using the considerations set forth in the Tri-Council Policy as a the minimum standard."⁴

"Each institution is accountable for the research carried out in its own jurisdiction or under its auspices. An institution can authorize its REB(s) to accept the review of other REB's constituted under the Tri-Council Policy Statement if it so wishes."⁵

The UofS REB may perform an expedited or delegated review according to the following guidelines: "Proposals qualifying for an expedited or delegated review include those that: a) have changes to a previously reviewed protocol that do not require full-board approval; or b) involve a duplication of a previously approved protocol; or c) have been approved by a REB at another institution (must be minimal risk); or d) do not create risks greater than the minimum threshold; or e) involve unforeseen circumstances; or f) are course-based research projects where there is no Research Ethics Committee in place.

³ University of Saskatchewan Policies and Procedures for Ethics in Human Research

⁴ Tri-Council Policy Statement [Article 1.2]

⁵ Tri-Council Policy Statement [Article 1.2]

If the Chair is of the opinion that the protocol may go through the expedited or delegated review process, the Chair has the authority to: a) review and approve the protocol; b) approve the protocol with minor modifications; c) refer the protocol to at least one other member of the REB for review; and/or d) choose ad hoc reviewers that specialize in the area of research.”⁶

Therefore, all researchers requesting to use the CLS facility must provide CLSI with a valid copy of the UofS Certificate of Ethics Approval. If a request is received from a non UofS spokesperson, then the spokesperson must obtain both a) a Certificate of Ethics Approval from their home institution and b) a Certificate of Ethics Approval from the UofS in support of their proposal application.

All Certificates must reference the planned use of the CLS facility. If a certificate already exists without the mention of the use of the CLS, an amendment must be submitted.

8.1 ETHIC RENEWALS/COMPLETION

Applications for research at the CLSI may be active for up to two years. However, a Certificate of Ethics Approval is only valid for one year. Therefore, if a Certificate of Ethics Approval expires, the spokesperson is responsible to apply for reapproval of the ethics certification by submitting a Status Report Form to the Ethics Office at the University of Saskatchewan and providing a copy of this Status Report Form to the User Services Office in support of their application.

9.0 RESPONSIBILITIES

9.1 USER

Users involved with research experiments involving human subjects, living or not, will coordinate the appropriate reviews as required in collaboration with an appropriate REB.

The Spokesperson will:

1. identify at the time of beam time application whether their research involves human subjects or tissues; see Appendix A.
2. provide a valid Certificate of Ethics Approval to CLSI in support of their proposal application. If no such Certificate exists, then apply to the home institution and/or appropriate REB for review and final ethics approval.
 - a. UofS affiliate provides the UofS Certificate of Ethics Approval
 - b. non-UofS affiliate provides the Certificate of Ethics Approval and the Researcher's Summary Form or equivalent from their home institution and agrees to having these, plus their CLS proposal, forwarded to the appropriate UofS REB for review.
3. in the case of an application for reapproval of an expired Certificate of Ethics Approval, provide a completed copy of the Status Report Form to CLSI in support of the request for reapproval.
 - a. UofS affiliate provides the UofS Status Report Form
 - b. non-UofS affiliate provides the Status Report Form or equivalent from their home institution, and agrees to having it forwarded to the appropriate UofS REB for review.
4. provide any additional information as required to the UofS REB to complete their review.

⁶ University of Saskatchewan Policies and Procedures for Ethics in Human Research [7.13]

5. upon completion of the research project, the spokesperson shall inform the UofS REB that the project is completed by submitting the Status Report Form. In the case of a non-UofS affiliate, a copy of the Status Report Form or equivalent from their home institution will be forwarded to the UofS REB.
6. ensure all certificates are kept current.
7. be informed that:
 - a. All research performed at the CLS that involves human subjects or the use of human tissue from subjects, living or not, requires review and approval by the appropriate University of Saskatchewan (UofS) Research Ethics Board (REB), and if non-UofS affiliate, approval from their home institution in addition to UofS REB approval.
 - b. Beam time will not be formally scheduled prior to CLSI receiving a valid copy of the UofS REB Certificate of Ethics Approval and/or Status Report Form.
 - c. some reviews may take several weeks to complete, therefore, sufficient time for these reviews must be allowed.

9.2 CLSI

CLSI User Services Office will facilitate and track the appropriate Certificates of Ethics Approval for proposal submissions involving humans.

CLSI will:

1. request users to identify at the time of proposal application whether their research involves humans (see Appendix A).
2. inform users that:
 - a. All research performed at the CLS that involves human subjects or the use of human tissue from subjects, living or not, requires review and approval by the appropriate University of Saskatchewan (UofS) Research Ethics Board (REB), and if non-UofS affiliate, approval from their home institution in addition to UofS REB approval.
 - b. Beam time will not be formally scheduled prior to CLSI receiving a valid copy of the UofS REB Certificate of Ethics Approval and/or Status Report Form.
 - c. some reviews may take several weeks to complete, therefore, sufficient time for these reviews must be allowed.
 - d. User Services Office will assist non-UofS affiliates in facilitating the process to obtain the initial documentation for the UofS REBs. If additional documentation is required by the UofS REB to complete the initial ethics review, the UofS REB will correspond directly with the spokesperson to clarify any concerns or issues.
3. Upon receipt of proposals which involve humans, CLSI User Services Office will obtain:
 - a. if UofS affiliate, a copy of the Certificate of Ethics Approval
 - b. if non-UofS affiliate, a copy of the Certificate of Ethics Approval, Researcher's Summary Form (or equivalent) from their home institution. Upon receipt, User Services Office will forward a copy of the Certificate of Ethics Approval, Researcher's Summary Form (or equivalent) and a copy of the CLS Proposal to the appropriate UofS REB for review.
4. In the case of the need for application for reapproval of an expired Certificate of Ethics Approval, CLSI User Services Office will obtain:
 - a. if UofS affiliate, a valid copy of the Status Report Form.

- b. if non-UofS affiliate, a valid copy of their Status Report Form or equivalent from their home institution. Upon receipt, User Services Office will forward a copy of the Status Report Form to the appropriate UofS REB for review.
5. Upon receipt of the UofS approval, CLSI User Services Office will forward the Certificate of Approval and supporting documents to HSE for review.
6. Upon receipt of the final review from HSE (see Form 22.11.1.7), User Services Office will inform the spokesperson and beamline scientist of the results of the review.
 - a. If approved:
 - i. scheduling of the experiment may proceed
 - ii. CLS User Services Office will review the expiry date of the Experimental Permit and if required identify an alternate date (see Form 22.11.1.7). The expiration of the Experimental Permit will be the date whichever occurs first (expiry date of the Certificate of Approval, updated expiry date on the Status Report Form or proposal validation period (6, 12, 18 or 24 months).

9.3 UNIVERSITY OF SASKATCHEWAN ETHICS OFFICE

The UofS Ethics Office will:

- perform the required ethics review for research involving humans at the CLSI. The REB chair will perform an initial review to identify what type of review is required (full Board, expedited or delegated review), contact the spokesperson to address any concerns the REB may have in regard to the ethics review. Contact will be in the form of written notification.
- forward a signed original of the final Certificate of Approval to the spokesperson.
- forward an electronic copy of the Certificate of Approval or Status Report Form to the CLSI User Services Office in support of the researcher's CLSI proposal.
- Collaborate and assist the CLSI in relation to the human ethics review and approval process.

10.0 CONTACTS

Questions relating to the administration of the review process can be directed to CLSI Users Services Office, mail to clsuo@lightsource.ca or 306-657-3700.

Questions relating to the ethics review and approval process should be directed to the Ethics Office at 306-966-2975 or mail to ethics.office@usask.ca Forms and additional information are available at the ethics website: http://www.usask.ca/research/ethics_review

11.0 FORMS

- CLSI Form #22.11.1.7 CLS Internal Certification Tracking Form
- UofS Researcher's Summary Form <http://www.usask.ca/research/files/index.php>
- UofS Status Report Form <http://www.usask.ca/research/files/index.php>

12.0 REFERENCES

12.1 POLICY DOCUMENTS

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- University of Saskatchewan Policies and Procedures for Ethics in Human Research

12.2 WEBSITES

- Tri-Council Policy - <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
- UofS Policies and Procedures for Ethics in Human Research - http://www.usask.ca/research/ethics_review/human.php

13.0 APPENDIX A

Subset of Questions from Proposal Application Form

- Does this research involve human tissue human subjects* N/A
- *Note: This option will be made available when the appropriate approvals are in place to handle human subjects.
- When hovering over text, help text will read:
 - **Human tissue:** Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.
- If yes to human tissue, then the following is displayed on the proposal form “All research performed at the Canadian Light Source facility (CLSI) that involves human subjects or the use of human tissue from subjects, living or not, requires review and approval by a University of Saskatchewan Research Ethics Board. All human tissue requires a Biosafety Permit and Exposure Control Plan” See http://www.lightsource.ca/uso/involving_human.php
 - Certificate of Ethics Approval # _____ Expiry Date: _____
 - Biosafety Registration or Permit # _____ Expiry Date: _____
- If yes to human tissue, then upon submit of proposal the following is displayed on the proposal report. “You have indicated that human tissue is involved: All research performed at the Canadian Light Source facility (CLS) that involves human subjects or the use of human tissue from subjects, living or not, requires review and approval by a University of Saskatchewan (UofS) Research Ethics Board (REB). **Please forward to CLSI: a) UofS Certificate of Ethics Approval, if non UofS affiliation please forward the Certificate of Ethics Approval and Researcher’s Summary Form or equivalent from your home institute b) Biosafety Permit and c) Exposure Control Plan. Please note: non UofS affiliation – A copy of your CLSI proposal and supporting ethics documents will be forwarded to the appropriate UofS REB for review. If additional information is required, the UofS REB will correspond directly with you.**”