SOP Title	**Cadaveric Sub-board for HSREB**
Number.Version	409.001
Effective Date	January 27, 2022

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		26 Jan 2022
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		27 Jan 2022

1. PURPOSE

This standard operating procedure (SOP) describes the required oversight and administrative processes for ethical research on cadaveric material.

2. GENERAL POLICY STATEMENT

The Tri-Council Policy Statement states that research involving the collection and use of human biological materials requires REB review. Consent of a deceased participant by means of a donation decision must be made prior to death, or by an authorized third party. This consent is documented through Form A of the Body Bequeathal program in which participants request their body be used for medical education and research purposes. A delegated review process for research involving cadaveric materials through the department of Anatomy and Cell Biology is to be documented through a structured review process. The Cadaveric Research Ethics Sub-Board (CREB) is responsible for the oversight and review of research using cadaveric material. The CREB operates under the oversight of the Health Science Research Ethics Board (HSREB) and is required to file an annual report stating the number of renewed studies, closed studies, and approved studies over the calendar year. All SOPs that direct the HSREB must also be followed by the CREB.

3. RESPONSIBILITY

This SOP applies to all HSREB and CREB members including the Chair(s) and Vice-Chair(s) and to all Office of Human Research Ethics (OHRE) staff.

The CREB Chair, or designee, is responsible for determining if research is eligible for delegated sub-board review. If the CREB Chair determines a study to be higher than minimal risk, they will contact an OHRE staff member and request that the researcher submit to the HSREB.

The CREB Chair and CREB members are responsible for conducting the Delegated review.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. **Determinations of Qualification for Delegated Review**

5.1.1. Full Board review by the convened HSREB is the default for research involving human participants, however, some research may be eligible for Delegated CREB review;

5.1.2. Where it is determined that the research is of minimal risk and includes only Cadaveric Materials, the CREB Chair or designee may authorize Delegated ethics review;

5.1.3. When a research project is submitted for review, the CREB Chair will perform an initial assessment of the research to confirm the project qualifies for Delegated CREB review;

5.1.4. Examples of research that may be eligible for Delegated CREB review are as follows:

- Research projects that involve no more than minimal risk;
- Minor and minimal risk changes to approved research;
- Continuing review of research that is more than minimal risk research;
- Continuing review of research that is more than minimal risk research when there has been little or no modifications of the research;
- The submission by the Investigator in response to the REB review as a condition of approval, as authorized by the Board;
- All others are at the discretion of the Chair .

5.1.5. The CREB Chair or designee may be authorized by the Full Board to use Delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

5.1.6. When determining if initial review of research or modifications to previously approved research are eligible for Delegated review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

5.2. **Authority of Delegated Reviewer(s)**

5.2.1. For research meeting the criteria for Delegated review, the review may be conducted by the CREB sub-board;

5.2.2. In reviewing the research under delegated procedures, the delegated reviewers may exercise all of the authorities of the REB, except that he/she may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;

5.2.3. The delegated reviewers who review the delegated project must not have any conflicts of interest for the research;

5.2.4. If expert consultation is needed (i.e., *ad hoc* advisor) on a delegated project, the delegated reviewers reviewing the project will contact the Chair or the EO to request this. The *ad hoc* advisor cannot participate in the final decision regarding the approval of the research;

5.2.5. Final approval must be signed off by the CREB Chair, Vice-Chair(s), or authorized signatory.

5.3. **Continuing Review: Proposed Revisions to the Approved Protocol and/or Letter of Information and Consent, Supporting Documentation, Renewals**

5.3.1. Research that was previously approved by the delegated review procedure may be reviewed at the time of continuing review using the same review procedures;

5.3.2. Research that was previously approved by the convened Full CREB may be reviewed at the time of continuing review using delegated review procedures when there are only minimal-risk changes or no changes to the previously approved research;

5.3.3. If the risk of the previously approved study is now more than minimal, the CREB Chair or designee should refer the study for full HSREB board review at a convened HSREB meeting;

5.4. **Notification of the REB**

5.4.1. The HSREB is informed annually of new research submissions or revisions that were approved using the delegated review procedures through attachments to the meeting package.

5.5. **Documentation**

5.5.1. The type of REB review conducted will be noted in the review and approval letters sent to the Investigator;

5.5.2. The CREB minutes and or attachments will include documentation (list) of research that was approved using delegated review procedures.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) Chapter 1 section C; Chapter 2 section B; Article 6.12;

6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;

6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.102, 46.110;

6.4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.102, 56.110;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
409.001	Original	01/27/2022