CREB Initial Application Form

Orange text indicates an upload or action feature
Red//bold indicates question/feature dependencies
Green text indicates a question that can be duplicated to provide multiple answers
Blue Text indicates the help text associated with the question
Questions with an asterisk (*) are mandatory and must be completed prior to signatures and submission

Cadaveric application: Section 1: General Information

1.1 *Please confirm that if this is the first time you are submitting this particular application form to the REB, select "Initial Application". If this application form has already been reviewed by the REB and they issued recommendations, select "Response to REB recommendations":

☐ Initial Application
☐ Response to REB recommendations

1.2 *ONLY research studies that have obtained the cadaveric material(s) through the Body Bequeathal program that is overseen by the Western's Department of Anatomy & Cell Biology should submit this application for review to the CREB. Cadaveric material obtained through all other means MUST submit their study using the HSREB initial application form.

☐ I confirm that the cadaveric material(s) obtained for this study was/will be obtained through the Body Bequeathal program

1.3 *As this study is taking place at Western, type in "Western Research Services" in the below Search User text box:
*Name:
*Email:

Once the PI is added to this form you MUST also add them into the ROLES tile (See ROLES tile in the actions items on the left hand side of your screen).

1.4 *Use the Search field to enter the Principal Investigator (PI) details from the WREM user directory: [search user directory]
Prefix:
*First Name:
*Last Name:
Telephone:
*Email:

*Complete the additional PI details: [drop down]
*Western Faculty/ Department:

*Hospital Department/ Division:

1.5 *Are there any additional study team members (from Western and/or it's affiliate institutions) who are working on this study**?**

☐ Yes there are additional study team members

☐ No other study team members involved

Once study team members are added to this form you MUST also add them into the ROLES tile (See ROLES tile in the action items on the left hand side of your screen).

If "Yes" is selected in 1.5, then the following appears

1.6 *Complete the following information for additional study team members (from Western and/or its affiliate institutions) who are working on this study. **Please use the "Add Another" button to add a new entry for each study team member.**

Prefix:
*First Name:
*Last Name:
*Address:
*Email:
*ROLE and RESPONSIBILITY in this study. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data.) **<Single-Line Text Box>**
<ADD ANOTHER>

1.7 *Enter the Complete Study Title: **<Multi-Line Text Box>**

*What is the acronym or nickname/short title for the study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and REB applications associated with this project.): **<Single-Line Text Box>**

1.8 *Is there a protocol/research plan for this study?

#HELP TEXT: A document (e.g., sponsor protocol, working group protocol) that describes the objectives, design, methodology, statistical considerations and organization of a research project.

☐ Yes ☐ No

If Yes: *Upload the protocol: **Upload Document (Document Name, Document Date, Version) – Document Type: Protocol**

If 'No': *What measures are in place to ensure this study will be implemented consistently? <Multi-Line Text Box>

1.9 *Is this an Investigator-initiated study?

#HELP TEXT: Investigator-initiated Study refers to a research effort in which the investigator designs and implements the study protocol and the investigator or the institution acts as the study sponsor.

☐ Yes ☐ No

1.10 *Who is the Study Sponsor?

HELP TEXT: An individual, corporate body, institution or organization that takes responsibility for the initiation and management of the study.

☐ Industry Sponsored

☐ External not-for-profit

☐ External PI (outside of Western)

☐ Local Team Member (Western-affiliated team member other than PI on this REB application)

☐ Local Principal Investigator (PI on this REB application)

If 'Industry Sponsored" in 1.10:

*Enter the Sponsor's Study ID Number: **<Single Line Text Box>**

If any checkbox other than 'Self" is selected in Question 1.10:

***Complete the Sponsor details:**

Title:

*First Name:

*Last Name:

***Organization:**

***Address:**

***City:**

***Province/State:**

***Postcode/Zip:**

***Telephone:**

***Email:**

1.11 ***Is this a student project?**

☐ No

☐ Yes-Resident/Fellow

☐ Yes-MD

☐ Yes-Post-doctoral Fellow

☐ Yes-PhD

☐ Yes-Masters

☐ Yes-Undergraduate

☐ Yes-Other

If Other: *Specify Other: <Multi-Line Text Box>

1.12 ***Is this study directly related to a previously approved study at this institution (e.g., is this study a sub-study, extension, rollover, subsequent to a pilot study)?**

☐ Yes ☐ No
If Yes: *Who was the PI for the previous study? **<Multi-Line Text Box>**
If Yes: *What is the REB number? **<Multi-Line Text Box>**
If Yes: *Indicate the study title of the previous study. Provide a brief summary of the study as it relates to this application (if applicable) **<Multi-Line Text Box>**

1.13 *Has the study undergone a formal scientific or peer review (i.e., internal peer review or external review (e.g., CIHR, NSERC, NIH, etc))?
☐ Yes ☐ No
If Yes: *Describe (e.g., names of committees or individuals involved in the review, whether review is in process or completed, etc.): **<Multi-Line Text Box>**
If Yes: Upload any relevant scientific review documents or correspondence (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Other Scientific Documents
<Add Another>

1.14 *Has the study been reviewed and approved by another REB in Canada?
☐ Yes ☐ No
If Yes: *Upload the approval letter(s) and/or relevant correspondence.
Upload Document (Document Name, Document Date, Version) – Document Type: Other REB approval letter

1.15 *Has the study been rejected by any other REB?
☐ Yes ☐ No
If Yes: *Describe: **<Multi-Line Text Box>**
If Yes: Upload any relevant documents (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Other REB rejection letter

1.16 *Is this research supported by the United States federal government (including a study funded by a US governmental agency)?
☐ Yes ☐ No

1.17 *Is this a multi-centre study?
☐ Yes ☐ No
If Yes: *Name the lead site and project leader for the study: **<Multi-Line Text Box>**

1.18 *Provide a brief lay/non-scientific summary of the study (max 250 words)
HELP TEXT: Lay or non-scientific refers to language that is simple and non-technical and is used in every-day conversations; terminology that an average non-professional can understand.
<Multi-Line Text Box>

Cadaveric application: Section 2: Study Information

2.1 *What is the rationale for this study (why is it being done)? *In your response ensure to include relevant background information from previous studies that have been done. Cite references where appropriate and add as a separate attachment (do not include within your response).* **<Multi-Line Text Box>**

Upload any references used above (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: References

2.2 *Provide a brief summary of the study design type and methodology being employed in this study. NOTE: Information about objectives, inclusion/exclusion criteria, study procedures, sample size calculations and data analysis should be described when prompted elsewhere in the application.**<Multi-Line Text Box>**

If you have a Flow Diagram please upload here:
Upload Document (Document Name, Document Date, Version) – Document Type: Flow Diagram

2.3 *Are there any associated sub-studies and/or companion studies?

☐ **Yes** ☐ **No**

If Yes: *Will your site be involved in the sub-studies and/or companion studies?

☐ Yes ☐ No

If Yes* Briefly describe the sub-studies and/or companion studies including the rationale for it.: **<Multi-Line Text Box>**

2.4 *Indicate the inclusion criteria for cadaveric specimen (Name specimen type required). **<Multi-Line Text Box>**

2.5 *Considering your inclusion criteria list in question 2.4, what is the basis to exclude a potential cadaveric specimen? **<Multi-Line Text Box>**

2.6 *How many cadaveric specimens will be required **<Number Box>**

2.7 *Define the nature of the cadaveric specimen(s) required (i.e., fresh/frozen, soft/floppy embalmed, fixed (embalmed)): **<Multi-Line Text Box>**

HELP TEXT: Fresh/Frozen cadaveric material indicates tissue that has never been fixed with any type of embalming fluid. It may have undergone previous freeze/thaw cycles. Soft/Floppy embalmed specimens have been arterially injected with embalming fluid free of formalin. Fixed specimens have been arterially injected with a traditional formalin based embalming fluid.

2.8 *Are cadaveric specimens being acquired from a third party?

☐ Yes ☐ No

*Indicate the supplier **<Multi-Line Text Box>**

If Yes in question 2.7 then the following appears

2.9 *Do the cadaveric specimens sourced from a third party require cremation at study end with the assistance of the Anatomy and Cell Biology department (NOTE: extra fees will apply):

☐ Yes ☐ No

2.10 Which of the following Standard Operating Procedures (SOPs) are required for the proposed study? (Select all that apply)

HELP TEXT: URL to SOPS is Anatomy Lab SOPS 2023 - OneDrive (sharepoint.com)

☐ SOP 1.1 – 1.4 – Waste Management, CL1 PPE, Safe Handling of Brachytherapy Implants, Responsibilities of Stewardship (ALL USERS)
☐ SOP 2.1 – CL2 PPE for Unembalmed Fresh/Frozen Cadaveric Material
☐ SOP 2.2 – Transportation & Storage of Cadaveric Tissue on Campus
☐ SOP 2.3 – Post Exposure Protocol for Unembalmed Cadaveric Material
☐ Other :

If Other is selected in 2.10:
Please Specify: **<Multi-Line text box>**
Upload other SOP: **<Document Upload> (Add Another)**

2.11 *Describe the method(s) for data analysis: <Multi-Line Text Box>

Cadaveric application: Section 3: Risks and Benefits

3.1 *What is the overall anticipated public and/or scientific benefits of the study? **<Multi-Line Text Box>**

3.2 *List and describe the known risks/harms of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only: **<Multi-Line Text Box>**

Cadaveric application: Section 4: Informed Consent

4.1 *I acknowledge that consent by cadaveric donor for research is indicated by the executor/ next of kin statement on the Department of Anatomy and Cell Biology's Form B for Body Bequeathal.

☐ confirmed

Cadaveric application: Section 5: Confidentiality and Data Security

5.1 *I acknowledge that the demographic information about each cadaveric specimen provided to me will include the Sex, Age and Medical Cause of Death of each individual specimen. No other demographic information is provided

☐ confirmed

*Will any other Personal Identifiers be collected/ accessed during this study (other than Sex, Age and Cause of Death)?
☐ Yes
☐ No

If 'Yes': *Specify: **<Multi-Line Text Box>**
HELP TEXT: This would include Date of Birth, Name, Initials, Address, etc.

5.2 ***Where will information acquired as part of this study be stored (applies to both paper copy and electronic copy)? (select all that apply)
☐ University or Hospital network drive
☐ University or Hospital local hard-drive
☐ Laptop
☐ Memory Stick
☐ Cloud Storage
☐ Off-site
☐ Other
If 'University or Hospital network drive': *Specify the university or hospital network drive: <Multi-Line Text Box>
If 'Laptop": *Specify who owns the laptop: <Multi-Line Text Box>
If 'Laptop": *Where will the laptop be stored for the duration of this study: <Multi-Line Text Box>
If 'Laptop": *Who will have access to the laptop? <Multi-Line Text Box>
If 'Memory Stick":*Who will have access to the memory stick? <Multi-Line TextBox>
If 'Cloud Storage": *Specify which Cloud Storage platform will be used:<Multi-Line Text Box>
If 'Cloud Storage":*What are the security details of the Cloud Storage? <Multi-Line Text Box>
If 'Off-site":*Specify where off-site the data will be stored: <Multi-Line Text Box>
If 'Off-site":*Who will have access to the data that is stored off-site? <Multi-Line Text Box>
If 'Other':*Specify Other: <Multi-Line Text Box>

5.3 ***Indicate the measures in place to protect the confidentiality and security of any study data including Personal Information (PI) or Personal Health Information (PHI) that is acquired, collected and used (select all that apply):
☐ Access to study data will be limited to authorized personnel
☐ Access to electronic data will be password protected and encrypted
☐ Electronic data will be stored on a Western, hospital or other institutional server with firewalls and other security and back-up measures in place

☐ Study data stored on external hard drive, laptop(s) and/or mobile device(s) will be encrypted

☐ Paper copies of study data will be stored in locked filing cabinets in a secure location

☐ Other

If 'Other': ***Specify Other: **<Multi-Line Text Box>

If box 3-5 in Q5.3is selected then Q5.4 appears

5.4 ***Describe where the electronic and/or paper copies for all study data collected for this study will be kept (hard copy data, electronic databases, etc.) **<Multi-Line Text Box>**

HELP TEXT: Data spreadsheet, data collection form, etc.

HELP TEXT: the local hospital C: Drive is not an acceptable storage location, even behind a corporate firewall, unless encryption is used to protect data. Only an network drive, S: F:, G:…Z: is considered acceptable if not encrypted.

5.5 ***If someone other than the local PI is the study data custodian (who is responsible for maintaining the study data) explain below (otherwise just indicate local PI):**<Multi-Line Text Box>**

5.6 *Will you be sending/sharing data off-site for this study?

☐ Yes ☐ No

If 'Yes' to question 5.6, then question 5.7-5.9 appears

5.7 *What data is being sent off-site: **<Multi-Line Text Box>**

5.8 ***Describe where/to whom the data will go: **<Multi-Line Text Box>**

5.9 *How will the data be sent?

☐ Secured Fax
☐ Electronic (online) data collection
☐ Secure file transfer
☐ Encrypted email
☐ Private courier delivery
☐ Canada Post registered mail (NB: Regular mail may not be used)
☐ Other

If 'Other': ***Specify Other: **<Multi-Line Text Box>

5.10 *Will you link the locally collected data with any other datasets, databases or registries (e.g., health registries, Statistics Canada)?

☐ Yes ☐ No

If 'Yes' in 5.10, questions 5.11-5.15 appear:

5.11 ***Identify the dataset, databases or registries to which it will be linked: **<Multi-Line Text Box>**

5.12 *Explain the purpose for the linking: **<Multi-Line Text Box>**

5.13 *Explain how the linkage will be done: **<Multi-Line Text Box>**

5.14 *Describe the likelihood that identifiable data will be created through the linkage: **<Multi-Line Text Box>**

5.15 *Describe the security measures that will be in place to protect the confidentiality of the study data: **<Multi-Line Text Box>**

5.16 *Is the purpose of this study to establish a registry/database?

☐ Yes ☐ No

If 'Yes' in 5.16, question 5.17 will appear:

5.17 *Will Personal Identifiers (PI) be stored in the registry/database?

☐ Yes ☐ No

If 'Yes': *Who maintains the registry/database? **<Multi-Line Text Box>**

If 'Yes': *Where is the registry/database located? **<Multi-Line Text Box>**

5.18 *How long will you retain identifiable data?

- 7 years as per UWO policy
- 15 years as per Lawson policy
- Other

If 'Other': *Specify Other: **<Multi-Line Text Box>**

5.19 **If 'Yes' in 5.17:** How will you destroy the identifiable data after this period? (If applicable) **<Multi-Line Text Box>**

5.20 If you will be taking Photographs or Video of the Cadaveric Specimens please complete and upload the Request for Photography/Videography form.

Upload Document (Document Name, Document Date, Version) – Document Type: CREB Request for Photo form

Cadaveric REB application: Section 6 - Conflict of Interest (actual, apparent, perceived, or potential)

6.1 *Will the PI or Co-Investigator(s) or anyone connected to them though their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal financial benefit in connection with this study?

☐ Yes ☐ No

If 'Yes': *State how much money (in Canadian dollars) is paid by the funder and to whom it is being paid, over and above the direct cost of conducting this study (e.g., recruitment incentives consulting fees, advisor fees): **<Multi-Line Text Box>**
If 'Yes': *Explain what this amount covers with respect to the direct costs associated with doing this research: **<Multi-Line Text Box>**
If 'Yes': *In the last three years, how much money (in Canadian dollars) or other benefits has the investigator or sub-investigator or anyone connected to them through their interpersonal relationship including their family members, friends, or their former or current professional associates (or any company owned or managed by the investigator or sub investigator or anyone connected to them through their interpersonal relationships) received from the sponsor and/or funder? **<Multi-Line Text Box>**
If 'Yes': *For what purpose did they receive these funds? **<Multi-Line Text Box>**
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>**

6.2 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) receive any personal (financial or otherwise) benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?
☐ Yes ☐ No

If 'Yes': *Please describe the benefits: **<Multi-Line Text Box>**
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>**

6.3 *Is the PI or Co-Investigator(s) aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?
☐ Yes ☐ No

If 'Yes': *Describe the relationships, interests or incentives: **<Multi-Line Text Box>**
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>**

6.4 *Is the PI to Co-Investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?
☐ Yes ☐ No

If 'Yes': *Describe the institutional conflicts of interest: **<Multi-Line Text Box>**

If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: <Multi-Line Text Box>

6.5 ***Does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?

☐ Yes ☐ No

If 'Yes': *Describe the interest: <Multi-Line Text Box>
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: <Multi-Line Text Box>

6.6 ***Will or does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)

☐ Yes ☐ No

If 'Yes': *Describe the association or connection: <Multi-Line Text Box>
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: <Multi-Line Text Box>

If 'Yes' is selected in question 1.9, then 6.7 appears

6.7 ***Are you or your institution the sponsor of this investigator-initiated/sponsored study?

☐ Yes ☐ No

If 'Yes': *Describe any real, potential, or perceived conflict of interest: <Multi-Line Text Box>
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: <Multi-Line Text Box>

6.8 ***Are there any other real, potential or perceived conflict of interest to declare to the REB?

☐ Yes ☐ No

If 'Yes': *Specify: <Multi-Line Text Box>
If 'Yes': *Describe the proposed management plan to mitigate the conflict of interest: <Multi-Line Text Box>

6.9 *Does the PI or the Study Team Members know of anyone that has donated their body to the Anatomy and Cell Biology Bequeathal Program at Western University?

☐ Yes ☐ No

Cadaveric application: Section 7 – Resubmission Information

This section appears only if 'Response to REB recommendations' is selected in 1.1.

7.1 *Upload the Response Letter, listing all REB recommendations/questions/comments and an explicit response to each:
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: REB RESPONSE LETTER

7.2 If changes have been made to a previously submitted study instruments/stimuli (e.g., data collection form) at the request of the REB, upload the track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES DOCUMENT

7.3 Please provide any additional comments for the REB to consider (if applicable):
<Multi-Line Text Box>

Cadaveric application: Section 8-Confirmation of Responsibility

If "Initial Application" is selected in Question 1.1, then question 8.1 appears:
8.1 *Principal Investigator Signature:

- As the PI, I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- As the PI, I assume full responsibility for the scientific and ethical conduct of the study at this institution;
- As the PI, I agree to conduct this study in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND, if applicable, with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND, with all other applicable laws, regulations or guidelines (e.g., if applicable, Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
- As the PI, I certify that all Co-investigator(s), researchers and other personnel (research team) involved in this project at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this project;
- As the PI, I acknowledge that I am responsible for promptly reporting to the REB, through the electronic application system, any proposed specific:
    - modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), etc.;
    - all local reportable events that meet the REB reporting criteria, including but not limited to privacy breaches, protocol deviations and any new information that may adversely affect the conduct of the trial;

    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - study completion or termination.
- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol as approved by the REB unless to eliminate an immediate safety hazard and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, as the PI, I am aware of my obligations in maintaining the importance of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information;
- As the PI, I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the personal health information is maintained in accordancewith the Personal Health Information Protection Act (PHIPA) and/or the Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.

If "Response to REB recommendations" is selected in Question 1.1, then question 8.2 appears:

8.2 ***Principal Investigator OR Delegate Signature:**

The Principal Investigator may choose to sign off electronically on all **re-submissions** (i.e., response to REB recommendations) or he/she may delegate this task to another qualified individual. **NOTE:** The PI is still fully responsibility for the scientific and ethical conduct of the study at this institution.

- I attest that this application as submitted is in compliance with the TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND, if applicable, with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND, with all other applicable laws, regulations or guidelines (e.g., if applicable, Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice).
- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that this application contains the current and complete protocol, including, if applicable, any sub-studies;
- I acknowledge that I am responsible for promptly reporting any of the following to the REB:
    - modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), etc.;

    - all local reportable events that meet the REB reporting criteria, including but not limited to privacy breaches, protocol deviations and any new information that may adversely affect the conduct of the study;
    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - study completion or termination;
- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol as approved by the REB unless to eliminate an immediate safety hazards to the cadaveric material(s) and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information (PHI)/Personal Information (PI) and the privacy of individuals with respect to that information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the PHI/PI is maintained in accordance with the Personal Health Information Protection Act (PHIPA) and/or Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.