

Nov 6, 2019

## **RE: Human Research Ethics Updates**

Dear Colleagues,

Over the coming months, we will be introducing several changes to our services and processes, which I'd like to outline here. More information about each can be found below.

### **SUMMARY**

- In January 2020, we will introduce a new Cadaveric Research Ethics Sub-Board.
- In January 2020, we will introduce a new multi-jurisdictional research application form, a new pedagogical projects application form and a new QA/QI/PE application form.
- Effective May 1, 2020, we will increase industry-sponsored research study fees to \$3,500.

#### **1. CADAVERIC RESEARCH ETHICS SUB-BOARD**

The Tri-Council Policy Statement requires Research Ethics Board (REB) review for all research involving the collection and use of human biological materials. 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 through Western's Department of Anatomy & Cell Biology. To ensure compliance, the Clinical Anatomy Executive Committee (CAEC), which is responsible for the Bequeathal program, and our office, have established a Cadaveric Research Ethics Sub-Board (CREB), which will operate under the oversight of the Health Sciences Research Ethics Board (HSREB).

**Beginning in January 2020, all application forms previously submitted to the CAEC will be submitted through WREM, using CREB-designated application forms.**

If you have any questions, please contact [Erika Basile](#) or [Haley Linklater](#).

#### **2. REMINDER OF NEW FORMS**

This is a reminder of previous communications related to new REB application forms (currently in .PDF format), which will be available in WREM, effective January 2020:

- **Multi-jurisdictional Research application form:** Used to help researchers determine if oversight by Western's REB is required. See [Multi-Jurisdictional guidance document](#) for more information.
- **Pedagogical Projects application form:** All pedagogical projects considered to fall within Category 2, as per the Student Research and [Pedagogical Activities guidance document](#), will be required to submit a pedagogical application form.

- **QA/QI/PE application form:** If you are seeking clarification of your project being considered Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (PE), and therefore not requiring REB oversight, you will be required to fill out the QA/QI/PE application form. See [QA/QI/PE guidance document](#) for more information.

In addition, all initial HSREB applications (delegated level 1 & 2 and full board) will be required to include a protocol/research plan. **NOTE:** this policy is not applicable to applications submitted to the Non-Medical REB. For help on how to develop a protocol/research plan, please see the relevant [guidance document](#) on our website.

### 3. INDUSTRY-SPONSORED RESEARCH FEES

Effective May 1, 2020, we will increase initial REB fees for all industry-sponsored research studies from \$3,000 to \$3,500 to cover increases in operating costs. There will be no increase in REB fees for amendments and renewals. This process is in effect only for studies initially reviewed on, or after, May 1, 2020. Please see the following for a synopsis of our fees and processes:

**Initial Review Fee:** An initial REB review fee of \$3,500 (effective May 1, 2020) is required for each new application funded by a for-profit entity (e.g., pharmaceutical/medical device company). This fee is charged regardless of the review's outcome.

**Major Amendments:** A \$500 fee will be charged for all major amendments, which include those that alter the risk-benefit assessment of the research. The REB may also classify an amendment as major based on the level of review required to approve the amendment. This fee will be charged at the time of each amendment review. This fee is charged regardless of the review's outcome.

**Annual Renewal Fee:** A \$500 fee is charged for continuing ethics review only for those submissions submitted on or after July 1, 2015. This review fee will be charged at the time of each annual renewal/continuing review. The sponsor is expected to pay the REB fee within 30 days of receipt of the invoice.

**We also ask that when investigators negotiate contracts with industry partners, they ensure the budget specifies that all REB fees are to be paid directly to Western University's Office of Research Ethics. The REB retains the right to withhold an approval notice until the REB fee is paid.**

Finally, we have updated a number of guidance documents to support the research community and to ensure compliance with regulatory bodies. If you would like to review any previous memoranda or other communications, you can find them on our website, under [Communications and Memos](#). To review all guidance and template documents, please visit our [Guidance and Templates](#) page, or go to WREM (under HELP-Templates).

If you have any questions, please contact us at [ethics@uwo.ca](mailto:ethics@uwo.ca) or 519-661-3036. You are also welcome to contact me directly (519-661-2111, ext. 86764 or [ebasile@uwo.ca](mailto:ebasile@uwo.ca))

Sincerely,



Ms. Erika Basile, Director, Research Ethics and Compliance Office, Western University