

## FAQs About the Health Research Ethics Authority

### **How can I see a copy of the Health Research Ethics Authority Act?**

This act is available online by going to Statutes of Newfoundland and Labrador (SNL) Chapter H-1.2; An Act to Establish A Health Research Ethics Authority For the Province (Assented to December 12, 2006)

<http://www.assembly.nl.ca/legislation/sr/statutes/h01.2.htm>. The regulation requiring all clinical trials and genetics research to be directed to the HREB can be found at <http://www.assembly.nl.ca/legislation/sr/regulations/rc110057.htm>

### **Does the HREA have paid positions?**

The HREA is a voluntary not-for-profit agency. As directed in the HREA Act, members of the Board of the Authority, the Health Research Ethics Board (HREB), the Appeals Panel and the Advisory Committee shall serve without remuneration but may be reimbursed for their travel and other expenses incurred as members. This reimbursement is based on the usual government rates.

The chairpersons of the Board of the Authority, the HREB and the Appeals Panel are compensated based on the usual government rates for carrying out their duties. The Authority does have salaried staff to maintain the usual operations and functions of the Ethics Office and to provide support to the HREB and to the Board of the Authority.

### **Is there a fee for ethics review?**

All industry sponsored contract research projects submitted to the HREA are subject to a review fee. The invoice for this fee is sent directly to the sponsor/CRO after the first review by the committee. Payment is due upon review by the committee for services rendered and is not contingent upon securing approval by the HREB or executing a contract with the PI and/or institution. The current review fee is \$2500. There is a further fee of \$1000 for each additional site in a study where there are multiple sites within NL. This is a single one-time fee inclusive of amendments and annual renewals and management of safety reports.

### **How does proclamation of the Act affect ongoing studies?**

- ***Current ongoing studies*** remain under the jurisdiction of the board which had granted approval; that board will remain the REB of record for that study. All future reports and correspondence related to the study will continue to go to the board that had granted approval.

Studies that had been approved by HIC are grandfathered over to the HREA under the Authority.

- ***A new project not yet submitted*** to any ethics board before the date of proclamation (July 1 2011) must go to an HREA-approved ethics board. At present, the HREB, ICEHR and are the only HREA-approved research ethics boards.
- ***A project submitted but not yet approved*** would remain with the board where it was submitted until it is approved or not approved. If the project is approved, the board of approval will remain the board of record.
- ***Industry-sponsored clinical trials adding new sites for a project already approved by another ethics board*** would continue with the approving board serving as the board of record for that study. That is, no new application would need to be made to HREB for these existing approved studies. However, if the original application did not include NL sites and it is intended to add new sites in NL, full application must be made to the HREB.
- ***Multi-site studies (other than industry sponsored clinical trials) adding a new site within the province for a project already approved by another ethics board*** must apply to the HREB or any HREA-approved research ethics body.

**What about ethics review for an industry-sponsored clinical trial that has been approved through a central ethics board but plans to establish new sites in NL as of the date of proclamation?**

Adding new sites to an approved project would continue with the approving board serving as the board of record. That is, no new application would need to be made to the HREB for these existing approved studies.

**What about a multi-site study that is not an industry-sponsored clinical trial and intends to add a new site within the province?**

The principal investigator would apply to the HREB or any HREA-approved research ethics body for approval to add a new site.

**What does a timely and efficient review really mean?**

The HREA Act provides timelines for the HREB in stipulating that notice or receipt of an application must occur within 2 business days and review and response to an application must occur within 30 days. The HREB review process is designed to meet these requirements.

### **Does the HREB have a role in contract negotiations?**

Contract negotiations remain the responsibility of the institution/investigator as per current processes

### **Can sponsors still use commercial REBs if studies are not done in an institutional setting?**

No. As a not-for-profit independent corporation, the HREA is responsible for the review and approve all industry-sponsored clinical trials to be conducted in both institutional and private settings in the province.

### **If an investigator has approval from the HREB does he/she have to get approval from other authorities?**

Under the mandate of the HREA, all human health research to be conducted in NL is required to be reviewed and approved by the HREB or an HREA-approved REB to ensure that health research involving human participants is conducted in an ethical manner. This review focuses on both ethical and scientific issues and centres on protecting research participants.

This approval does not give researchers permission to access the premises or resources of any institution, organization or aboriginal community nor does it require institutions, organizations or aboriginal communities to participate in research that may not fit within the values of the group or compromise their resources. Researchers are responsible for contacting participating institutions, organizations and aboriginal communities to seek appropriate approvals. It is left to the discretion of the individual institution, organization, aboriginal community to define what this approval process will entail.

### **Is the HREB responsible for only multisite clinical trials or single site ones as well?**

All health research involving human subjects being conducted within the province of NL is be required to be approved by the HREB or another approved health research ethics body under the HREA. Only the HREB is responsible for the review of clinical trials and genetics research projects taking place in NLI..

### **What is the application process for industry-sponsored, multi-centred studies?**

The HREB follows a process similar to that of central REB in that the sponsor, their representative or designate can make application for the project and each site is required to submit a brief site form.

**What are the other approved research boards under HREA?**

ICEHR

Western Health