



Health Research Ethics Authority (HREA) Act Update: September 2007

On November 23, 2006 the legislation creating the HREA and the provincial Health Research Ethics Board (HREB) passed third reading in the House of Assembly. Since November, the HREA Transition Team has been working to ensure a seamless transition to a timely and efficient review process which promotes research in this province. Moreover, the Transition Team is developing processes, policies, and standard operating procedures to ensure efficient ethics review. The HREA Transition Team has representation from the partner institutions, the current Human Investigation Committee, and the private sector.

Members are:

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We will also be drawing on others who have kindly volunteered to support this committee .

When will the HREA act be implemented?

It is anticipated that the HREA act will be proclaimed within the next twelve months.

What does implementation mean?

The Act will require all health research in the province to be reviewed and approved by the provincial **Health Research Ethics Board (HREB)**, or an approved duly constituted health research ethics body, before the research can begin.

The HREB will review all clinical trials of drugs and devices and all genetics research. As per section 8 of the act, the HREA can also approve other *ethics review bodies*. Such approved bodies will be authorized to review and approve health research other than clinical trials of drugs and devices and genetics research.

What is the HREA?

How the HREA will function:

The HREA will be an independent, not-for-profit corporation reporting to the Minister of Health and Community Services. The Board of Directors of the HREA will be appointed by the Minister on the recommendation of the funding partners. The Directors will include one representative from each of the partner organizations (Department of Health and Community Services, Eastern Health and Memorial University) a person chosen to represent the public of the province. The chair of the HREB will sit as an *ex-officio* member. The HREA will be responsible for

- Appointing members of the HREB
- The approval of any other duly constituted health research ethics review body in the province
- Maintaining an inventory of all human health research conducted in this province

The HREA will be supported by Memorial University, Eastern Health, the Government of NL and through fees charged for the review of contract research.

The standards governing the HREA:

Research ethics review done by the HREB and other approved ethics bodies will be as specified by the Tri-Council Policy Statement. The HREB will also adhere to the principles and guidelines of ICH-GCP (E-6 Guidelines for Good Clinical Practice of the International Committee on Harmonization) and Division 5 of Health Canada and all applicable laws and regulations.

Public input:

An advisory committee of laypersons from across the province will be appointed to provide consultation and advice on local issues to the HREA and HREB.

Where is the process at this point?

- We anticipate the appointment of the Board of Directors of the HREA by fall 2007.
- Ms. Linda Purchase, formerly of the Patient Research Centre, Eastern Health, has been appointed as the Ethics Officer of the HREA/HREB.
- Meetings with regional health authorities and other groups to provide information and receive feedback have begun. The members of the Transition Team are keeping interested parties advised. Communication is viewed by the Transition Team as a significant responsibility during this transition period and beyond.
- As the research ethics board (REB) responsible for the review of the majority of clinical trials (drugs and devices) in the province the responsibilities of the Human Investigation Committee (HIC) will be taken on by the HREB.
- In preparation for the HREA, the office of the HIC of Memorial University will move to larger quarters outside the University.
- We are drafting policies, procedures, a budget and corporate documents for the approval of the HREA board.

For more information on the HREA, to follow our progress or to review the Act visit us at www.hrea.ca
We invite your questions and comments throughout the transition process. You can contact us by email at info@hrea.ca or call **709-777-8949**

Transition Team

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