

## **Context**

In January 2013, the *Ministry of Health and Social Services* (MSSS) began, in conjunction with the *Research Fund of Quebec - Health* (FRQ-S) and four *integrated university health networks* (RUIS), a process to favor the recognition of ethical evaluations within the *public institutions of the Health and Social Services Network* (RSSS). Ultimately, the objective of this process is for any research project done in more than one public site within the RSSS to get a single ethical review which would be recognized by other institutions involved.

## **The adopted design**

Thus, at the end of this process, a consensus emerged and a harmonized working proposition for the entire Province of Quebec imposed itself, along with a timeline for implementation. Consequently, the preferred option consists on a single ethical review whenever a research project is to take place in more than one public institution of RSSS.

## **Implementation of the new process**

These new modalities, which will be implemented on December 1<sup>st</sup>, 2014, will replace those dictated by the 2008 "Mechanism supervising the ethical review and ongoing monitoring of multicenter projects".

The basic principle of the chosen process is one of straightaway recognition. As such, any ethical evaluation performed by a competent Research Ethics Board (REB) in a public institution of the RSSS will be recognized right away by all institutions involved in this research project, whether or not they have their own REB. **The general rules are as follows:**

- The evaluating REB must first be competent, meaning must have met the normative requirements and have the expertise and a recognize experience with research projects. The criteria for choosing the evaluating REB will be, in order of priority:
  - 1) The affiliation of the principal investigator and;
  - 2) The main location for recruitment of participants (as soon as the REB proficiency is recognized). This criterion will become the dominant one in cases for any investigator not affiliated with an institution of the RSSS.
- The Minister of Health and Social Services Central Research Ethics Board may act as an evaluating REB just like any REB from a public institution of the RSSS;
- Existing agreements between institutions will be maintained;
- The evaluating REB will be the only one to decide on the project and request changes, if necessary;
- A feasibility reviews will continue to be performed by each institution where the research project will take place. It can be performed during or after ethical review;
- Passive monitoring of the project will be the responsibility of the evaluating REB, while the active monitoring will be under the responsibility of the authority formally appointed by each of the public institutions taking part in the research project.

### **A transitional period**

Currently, the amounts the institutions charge for the services rendered by their REB cover a portion of the REBs operating costs. Moving towards a single ethics review by a single evaluating REB must not lead to the underfunding of the non-evaluating REBs and, consequently, to the loss of skills and expertise in place. Thus, considering these various issues and challenges which the REBs will have to face when a single ethical review will be conducted for the multicenter research projects, there will be a transition period during which the following will be provided:

- The billing will be maintained by the institutions REBs for ethics review and ongoing monitoring of multicenter projects, whether or not the REB acts as the evaluating REB. The institutions will continue to levy, for services rendered by their REB for a multicenter project or not, amounts at least equal to those which are currently in place.
- Monitoring of the REB activities resulting in cash inflows for the establishment in connection with the ethical review of multicentre research projects.
- Creation of a working group to determine how the best financial support methods for the REBs.

The transition period will run from 1 December 2014 until 31 March 2016.

Throughout this process, constant communication will be maintained with all those involved. Briefings, discussions and training will also take place in the fall. Daily assistance may be obtained by writing to this address: [deq@msss.gouv.qc.ca](mailto:deq@msss.gouv.qc.ca) and telephone support will be provided.

All information regarding the actual process and the implementation stages and will be available on the website of the Directorate of Ethics and Quality of the MSSS ([www.ethique.msss.qc.ca](http://www.ethique.msss.qc.ca)).