

Streamlined Ethics Review of Multi-centre Studies: Process Overview

November 24, 2009

Step 1: Application

- PI* submits application to PI-REB.
- CIs** notify CI-REBs of their participation in the multi-centre research project, and streamlined process.
- Upon request from PI-REB, Facilitation Team posts application on secure website, provides access information to participating REBs, and provides list of potential scientific reviewers.

Step 2: Review

- All participating REB Chairs/delegates involved with the study review application package and share comments on secure website.
- Lead REB conducts expedited or full board review; participating REB Chairs/delegates have the option of participating during Lead REB review via teleconference.

Step 3: Response

- CI-REBs may***
 - 1) accept that the level of participatory review is satisfactory, and concur with the Lead REB's decision;
 - 2) require own expedited review; or
 - 3) require own full board review.
- CI-REBs conduct ongoing monitoring in own institutions and provide information about protocol changes.

*PI=Principal Investigator

**CI=Co-investigator

***REBs are responsible for ensuring that they comply with all applicable laws, regulations and guidelines, including Part C, Division 5 of the *Food and Drug Regulations* (Drugs for Clinical Trials involving Human Subjects), the *Tri-Council Policy Statement*, and Title 45 of the U.S. Code of Federal Regulations (the *Common Rule*).