

CHEER



**Canadian Collaboration for Child Health: Efficiency
and Excellence in the Ethics Review of Research**

**Collaboration pancanadienne pour la santé des
enfants: Efficacité et excellence dans la révision
éthique de la recherche**

Community Members on REBs:
Their Role, Value, and Desired Education

A Poem for the Lay Member

I know that my time as Lay Member
Is one I'll ne'er fail to remember.
For 'good' research I vote,
Subject 'protection' I promote,
And I hope that I've kindled your ember.

<https://journals.sagepub.com/action/doSearch?filterOption=thisJournal&SeriesKey=reab&AllField=lay+member>

Community Members and TCPS2

- ▶ Article 6.4 of the TCPS2 requires:
 - ▶ “one community member has no affiliation with the institution.”
- ▶ “Their primary role is to reflect the perspective of the participant. This is particularly important when participants are vulnerable and/or risks to participants are high.”
- ▶ “The community member requirement is essential to help broaden the perspective and value base of the REB, and thus advances dialogue with, and accountability to, relevant communities.”

CHEER Patient and Family Advisory Committee

- ▶ CHEER PFAC is a network of REB Community Members from across Canada.
- ▶ Also includes a member from the NCI cIRB.
- ▶ Integration of the Patient and Caregiver voice in all aspects of CHEER.
- ▶ Patients and Caregivers as active decision makers and recognized contributors.
- ▶ Provide support, guidance, mentoring and education for community representatives of research ethics boards.

CHEER PFAC Members

- ▶ Daria Ilkina Toronto, Ontario. SickKids REB (Privacy).
- ▶ David Bell Ottawa, Ontario. CHEO.
- ▶ Donna Ludwinski USA. NCI Central Institutional Review Board (cIRB).
- ▶ Eva Sokol Montreal, Quebec. Montreal Children's REB.
- ▶ Gerard McDonald Newfoundland. Health Research Ethics Board (Clinical Trials Committee).
- ▶ Karen Haas Brampton, Ontario. Ontario Cancer Research Ethics Board.
- ▶ Kent Cadogan Loftsgard Vancouver, BC. BC Support Unit, Educator, Child-BRIGHT.
- ▶ Laura Zitron Vancouver, BC. BC Women and Children's REB.
- ▶ Lorne Gould Calgary, AB. University of Calgary Conjoint Health REB.
- ▶ Nancy Paoli St. Leonard, Quebec. St. Justine REB.
- ▶ Richard Carpentier CHEER PI, Hôpital Montfort REB.
- ▶ Samantha Drover CHEER Project Manager.
- ▶ Tania Selman Toronto, Ontario. SickKids REB.
- ▶ Antonia Palmer (Chair) Mississauga, Ontario. Ontario Cancer Research Ethics Board.

Community Member Needs Analysis

- ▶ 14 one-hour interviews conducted with Community Members of REBs who review pediatric research studies.
- ▶ Target number of interviews to complete: 20.
- ▶ Interviewees from across Canada. Most interviewees from Ontario at this time. One interviewee from the USA (NCI cIRB).
- ▶ Interview questions on the role of the Community Member, education provided for on-boarding and on-going training and desired educational needs.

Research Ethics Boards

- ▶ REBs typically meet monthly.
- ▶ Some meet every 2 weeks, one every 3 weeks.
- ▶ Meeting length varies from 2-6 hours.
- ▶ Studies reviewed varies from 3-12 per meeting. Average of 8 studies per meeting.
- ▶ Adult and pediatric studies reviewed. Or, only pediatric studies.

Community Members

- ▶ Most often, the role is called a “Community Member”. “Public Member” is also used.
- ▶ There are typically more than one Community Members on an REB.
- ▶ Community Members interviewed have been in the role from 1–10 years. An average of 5 years across interviewees.
- ▶ Usually review all studies. Reviews are not typically divided between the Community Members.

Community Members Continued

- ▶ Almost all are university educated, many with advanced degrees and professional designations.
- ▶ Most are female.
- ▶ Experience varies:
 - ▶ Some have ethics backgrounds
 - ▶ Some are retired health professionals
 - ▶ Most (all) are committed volunteers

Community Members Continued

- ▶ For almost all interviewed, only one experience on an REB.
- ▶ Community Members most often bring the caregiver or patient perspective.
- ▶ Few Community Members bring only the “public” perspective.
- ▶ Rarely act as a Primary Reviewer (low risk studies).
- ▶ Sometime act as a Secondary Reviewer.

Community Member Recruitment

- ▶ Few Community Members seek out the role on the REB.
- ▶ Most Community Members are directly asked / recruited.
 - ▶ If recruited, they often know (or are friends with) other REB members, most usually the Chair.
 - ▶ Different dynamic when you know the Chair.

Compensation

- ▶ Most Community Members are compensated but some are not.
- ▶ \$50-\$400/meeting (\$250/meeting average).
- ▶ Parking costs covered (pre-COVID).
- ▶ Sometimes travel costs covered and a meal provided (pre-COVID).
- ▶ Few receive an annual “thank you” with review of year’s activities.

Compensation: Volunteer Members

- ▶ One Community Member meets every 2 weeks for 3 hours, plus preparation time. (6+ hours/month)
- ▶ One Community Member meets every 3 weeks for 2.5 hours, plus preparation time. Also the only Community Member on the Board.
- ▶ Four Community Members meet monthly for 2.5-4 hours, plus preparation time.

Ethics Review During the Pandemic

- ▶ Transition to virtual meetings has gone fairly smoothly.
- ▶ Less discussion on studies in comparison to when REB meetings were conducted in person.
- ▶ Reduced ability to read informal and visual cues from people in the meeting as members often have their cameras off.
 - ▶ This is particularly important to Community Members.

Community Member Satisfaction

- ▶ Being a Community Member on an REB is a significant amount of work.
- ▶ There is an enjoyment to learning something new at every meeting.
- ▶ Great satisfaction in “giving back” and doing “important work” while being a part of the research process.

Community Member Satisfaction Continued

- ▶ All Community Members feel that their role is understood and valued.
- ▶ Feeling confident and competent in the role are two different things.
- ▶ Most Community Members stated that it took at least a year to feel some confidence in conducting ethics reviews.

An Environment of Trust

- ▶ Overall, Community Members feel that their voice is equally valued with those of the other members.
- ▶ There is always the concern about asking the “ignoble” (aka stupid) question.
 - ▶ Ignoble questions can lead to important conversations.
- ▶ Important role of the Chair and Vice-Chair for creating an environment of trust for open dialogue.

Onboarding Training

- ▶ Most Community Members completed TCPS2 Core online.
 - ▶ Many not satisfied with course, felt it was too high level, and often don't remember what was covered.
 - ▶ Few refer back to TCPS2 when conducting reviews.
- ▶ Some had no training at all!
 - ▶ One interviewee had no training and was thrown into their first meeting without even observing a meeting prior to conducting ethical reviews.
- ▶ No Community Members had any pediatric specific ethics training.

Onboarding Training Continued

- ▶ Types of Onboarding Training
 - ▶ Observing meetings
 - ▶ Ethics presentations from the REB chair or REB administration
 - ▶ TCPS2 Core online course
 - ▶ Open offer of being able to go the main REB office for one-on-one education
 - ▶ **Watching how other Community and REB Members review studies**
- ▶ Technical Training on the REB Review System
 - ▶ Some received technical training, some did not
 - ▶ Figure it out as you go

Onboarding Training Continued

- ▶ Almost all Community Members said that they would have felt more confident in their role sooner if that had received more comprehensive onboarding education.
- ▶ Would have liked more training on reviewing pediatric studies.

Ongoing Training

- ▶ Over half of the Community Members receive ongoing training.
- ▶ Types of ongoing training:
 - ▶ Evening, half-day or day long “retreats” with guest speakers
 - ▶ Access to articles and emerging ethics research
 - ▶ Emails clarifying issues (infrequent)
 - ▶ Small training sessions at the start of each meeting
 - ▶ Ability to attend ethics conferences/meetings (e.g., CAREB)

Desired Education Topics

The following slides outline the desired topics for education and training that were shared in the interviews with Community Members.

Suggested Education: Clinical Trials 101

- ▶ REB roles: descriptions and expectations
- ▶ Description of the different REB documents and forms
- ▶ The overall health research process (e.g., where is Health Canada involved?)
- ▶ Terminology

Suggested Education: Clinical Trial Design

- ▶ Different designs for clinical trials for health research
 - ▶ Controls, arms
 - ▶ Platform, umbrella, pick the winner
 - ▶ Different phases
 - ▶ Interventional, Behavioural, Observational, Registry
- ▶ Use of placebos in research design, rationale

Suggested Education: Consent and Assent

- ▶ Do parents and children understand research and the clinical trial they are enrolling on?
- ▶ Common vs ideal consent process
 - ▶ Difference in the consent process from low to high risk studies
- ▶ How do you ascertain the understanding of the child for assent?
- ▶ Consent form design
 - ▶ Does length matter?
 - ▶ Are visualizations in consent forms helpful?

Suggested Education: Pediatrics

- ▶ Pediatric clinical trial design and how it differs to adult clinical trials.
- ▶ Challenges in pediatric clinical trial design and how they are addressed.
- ▶ What burdens are families willing to accept when enrolling on a clinical trial?
 - ▶ Removing the emotion about including children in research.
- ▶ Genetic and genomic data.
 - ▶ Placement in medical records.
 - ▶ Return of all results (actionable and not actionable).

Recommendations for REBs

Onboarding Training:

- ▶ REB 101 training is important.
- ▶ Tailor training to the Community Member.
- ▶ For REBs reviewing pediatric studies, provide pediatric specific education.
- ▶ Establish a formal mentorship with an experienced REB member.
- ▶ Allow Community Members to observe 1-3 meetings before conducting ethics reviews of studies.
- ▶ Provide checklists of elements to consider when reviewing studies.

Recommendations for REBs Continued

Performance Based Feedback:

- ▶ Provide regular and ongoing performance-based feedback to Community Members.
 - ▶ Especially important if meetings are virtual.
 - ▶ Consider having an annual meeting with all Community Members of an REB to discuss ways to better support the role.
 - ▶ Meet with Community Members on a formal, semi-annual basis to gauge how they are feeling about their role.
 - ▶ Check-in with Community Members after meetings with challenging or critical decision points.

Recommendations for REBs Continued

Say THANK YOU!

- ▶ It is such a simple thing but an end-of-year thank you letter can mean so much.
- ▶ Make sure it is personalized.
- ▶ Include information recognizing the amount of work completed over the year – number of studies reviewed, number of meetings attended, and other information.

Recommendations for REBs Continued

On-Going Training:

- ▶ Carve out time before and during meetings to provide just-in-time training on pertinent topics.
- ▶ Provide ethics resources for Community Members on a regular basis (small / digestible).
- ▶ Offer ability to attend workshops or conferences (at the cost of the REB).
- ▶ When a new template, system, or policy is put in place, make sure all members are provided training.

Recommendations for REB Chairs

- ▶ Create an environment of trust where members feel they can openly contribute.
 - ▶ Handle the “ignoble” questions with grace.
- ▶ Ensure that all members can provide feedback when reviewing a study.
- ▶ Allow all members to provide feedback on REB processes and policies.
 - ▶ The importance of an efficiently run meeting.
- ▶ Provide an opportunity for members to anonymously share feedback on the REB Chair and Vice-Chair roles.

Recommendations for Community Members

- ▶ Learn about the role and expectations around the Community Member role before accepting the position.
- ▶ If you are unsure, don't be afraid to ask.
- ▶ If you need more education in a certain subject area, ask for help.
- ▶ When you are offered training, say yes as much as possible.
- ▶ It is a steep learning curve – don't beat yourself up if you are a year into your role and still feel like you are figuring things out!

Conclusions

- ▶ The Community Member is a critical role on a Research Ethics Board.
- ▶ The Community Member brings their own experience and professional background to the role but require specialized training.
- ▶ Providing training geared for the Community Member can benefit all members of the REB.