

Navigating REBs

Hurrah for Dr Ross Upshur's accurate and sane remarks in his commentary piece,¹ which was his response to the research article by Kotecha et al,² about Canadian research ethics boards (REBs), notably their alleged sins of slowness or delay in approval of protocols and inconsistency in their application of sound principles of research ethics.

I am a retired academic family physician from the University of Toronto in Ontario, the University Health Network (UHN), and Toronto Western Hospital, but I write from the viewpoint of my 1986 to 1999 chairmanship of the UHN's REB. The UHN embraces arguably the largest and most complex hospital-based clinical research body in the nation. My unpaid, part-time administrative job was replaced in 1999 by a full-time, dedicated specialty researcher and a multitiered and more diversified REB structure.

Current REB issues and shortcomings are similar to those of the 1990s. In Upshur's words, the REB is seen as "the most unloved component of the research endeavour."¹ Kotecha et al describe REBs as bodies having difficulties in "recruiting and retaining appropriately qualified members," "securing adequate resources and staff," and "responding to investigators quickly."² How true!

Certainly, the problem of inadequate physician resources persists—busy doctors voluntarily serve on other committees, probably to absent themselves from approving their own projects. And as for peer review, just who on the REB that I chaired were closest to being my "peers"? An overworked but only somewhat ethics-aware and perhaps slightly bored surgeon? A hospital obstetrics nurse who knew her environment and maybe a little about obtaining consent but who was not fully attuned to the world of complex internal medicine research issues? A laboratory scientist with limited patient contact? An experienced family medicine social worker? The hospital chaplain? A clinical ethicist? A well-educated UHN patient serving as a "lay" rep on committee? Was I—a family physician within the vast specialty-dominated UHN—a peer of theirs?

Although I might intuitively state a preference for the latter 4 individuals, in truth, folks of all these stripes, and more, are needed. Interestingly, my most memorable REB member was a UHN psychiatrist who saw and adroitly handled not only a protocol's overt ethical issues, but also any vexing subtexts involving clinical or investigator politics, while being true to the subtlest nuances of the consent process. As a bonus, he knew a great deal beyond his own field about both specialty and primary care science. To my relief and joy, he made his oral and written protocol reviews at REB meetings with an all-too-rare wit, a scientific precision without excess wordiness, and a promptness that shone as an example to other members.

Dr Upshur adds the conclusion of Edwards et al that "researchers who have served on REBs report more positive experiences with REBs than researchers who do not."³ My own observations over 13 years support this perception.

Beyond Upshur's remarks citing delays in the granting and manuscript domains of research, the structure and functions of REBs at all levels merit greater uniformity in order to facilitate a lower turnaround time from REB to investigator. As described, drivers of this necessity include increases in privacy legislation and in the amount of research performed by family physicians, especially given multisite studies and the collection of low-risk, collated, and de-identified data from past work (eg, Kotecha and colleagues' Canadian Primary Care Sentinel Surveillance Network²).

Regarding the process of obtaining patient consent for study participation, I harbour the perhaps naïve belief that voluminous, impenetrable, typewritten protocols exist mainly for the legal protection of participating institutions, whereas direct and unrushed face-to-face conversation with full explanation is the tool that serves a patient's best interest.⁴ Of course, this oral process must be followed by offering a written consent copy to a potential or actual subject.

I certainly hope that the processes of research ethics review, and the roles of REBs specifically, have not, as Dr Upshur says, "blunted the essence of many intellectual traditions."¹ Indeed, as per Dr Upshur's title, researchers should more often ask what we can do for our REBs, not only what they can do for us. Go and join such a committee! Even the "homework" is interesting and enlightening.

—Gordon D. Hardacre MD CCFP FCFP
Toronto, Ont

Competing interests

None declared

References

1. Upshur REG. Ask not what your REB can do for you; ask what you can do for your REB. *Can Fam Physician* 2011;57:1113-4 (Eng), 1115-7 (Fr).

The top 5 articles read online at cfp.ca

1. **Clinical Review:** Zopiclone. *Is it a pharmacologic agent for abuse?* (December 2007)
2. **RxFiles:** Behaviour management in dementia (December 2011)
3. **Clinical Review:** Canadian guideline for safe and effective use of opioids for chronic noncancer pain. *Clinical summary for family physicians. Part 1: general population* (November 2011)
4. **Clinical Review:** Treatment and prevention of herpes labialis (December 2008)
5. **Case Report:** Chronic vulvar irritation: could toilet paper be the culprit? (April 2010)

2. Kotecha JA, Manca D, Lambert-Lanning A, Keshavjee K, Drummond N, Godwin M, et al. Ethics and privacy issues of a practice-based surveillance system. Need for a national-level institutional research ethics board and consent standards. *Can Fam Physician* 2011;57:1165-73.
3. Edwards KL, Lemke AA, Trinidad SB, Lewis SM, Starks H, Quinn Griffin MT, et al. Attitudes toward genetic research review: results from a survey of human genetics researchers. *Public Health Genomics* 2011 April 11. Epub ahead of print.
4. Grady C. Do IRBs protect human research participants? *JAMA* 2010;304(10):1122-3.

Respect for the subject paramount

As a lawyer and long-time member of a research ethics board (REB) in Vancouver, BC, I read with interest the article by Kotecha et al¹ and Dr Upshur's well-thought-out response.² It might be helpful to researchers to at least know why proposals are questioned by REBs and why there can be delays before approval. This letter reflects my personal opinions and not necessarily those of my REB, and is based on Kotecha and colleagues' article rather than the original application and supporting material.

I sympathize with Kotecha et al¹ with regard to delays based on infrequent meetings of an REB. Hours are spent by the responsible board members in scrutinizing their assigned research proposals for reporting to the board. Then the board spends more time discussing the research

proposals. Research ethics boards are usually made up of volunteers, although sometimes a modest honorarium is paid, resulting in a rate per hour equivalent to minimum wage. As Dr Upshur points out, there is difficulty in getting experienced physicians involved in research to sit on REBs. If the expertise to review the proposed research cannot be found on the board, then the study is usually referred out to an expert, which adds to the delay.

A starting point in research, as in clinical medicine, is that there must be respect for the subject. Mason and Laurie said in talking about consent, "It must be remembered, however, that consent itself is a means to an end and that the real aim is to respect persons and their interests."³ The second edition of Canada's Tri-Council Policy Statement (TCPS2) describes "respect for human dignity" as the "underlying value" of the TCPS "since its inception."⁴ When the TCPS2 talks about "respect for persons" it includes those subjects whose data are "used in research."⁴ This requirement for respect is sometimes forgotten or is only paid lip service by researchers. The primary obligation of the REB in both law and ethics is to the subject. That obligation requires that the proposed research be vetted, from whether or not it is flawed in any way to whether it satisfies both the legal and ethical requirements of respect