

National Council on Ethics in Human Research
Report on Site Visits
October 1998 to December 2001

In the winter of 1995, the result of a series of site visits to Canadian Research Ethics Boards was published in Communiqué¹. From 1993 to 1995, 16 medical schools were visited to review the strengths and weaknesses of research ethics review. At that time, the MRC Guidelines were in effect for such review.

In August of 1998, the Tricouncil Policy Statement of Ethical Conduct for Research Involving Humans (TCPS) was published. The three funding Councils wished “to promote research that is conducted according to the highest ethical standards”² and required those institutions receiving Council funding to adhere to the TCPS as a minimum standard. In late 1998, the National Council on Ethics in Human Research (NCEHR) began a second series of invited visits, with the emphasis on institutions reviewing behavioural or qualitative types of research. The objectives of the visits were to discuss the process of review with Research Ethics Boards (REBs), to identify issues of concern in the policy area, to identify administrative issues related to research review, to discuss issues related to the implementation of TCPS, and to discuss means of enhancing both the quality of the review and the enhancement of participant protection. Between October of 1998 and December of 2001, 37 visits were completed.

Unlike the first series of site visits, the more recent have included universities of varying sizes as well as both teaching and community-based hospitals. The site visits describe a snapshot of institutions either handling the introduction of the TCPS to already existing research ethics committees or the formation of an REB.

Prior to the visits, invitations were sent to institutions known to have REBs. As well, requests were received for visits in some cases. Each centre was sent a standardized pre-survey questionnaire (copy appended) and asked to return this prior to the visits. A team of surveyors comprised of NCEHR Council members, trained volunteers from other REBs, and a staff member conducted each site visit. The surveyors asked to meet with all groups involved in the research process at the institutions: administration, the REB chair(s), REB members, department heads, researchers, students, and research participants. The groups were asked to share the local experiences with the review of research ethics involving humans. The process was an interactive one, with both the local site and the surveyors identifying issues, proposing solutions, and sharing information.

Following the visit, a draft report was prepared and sent back to the site for comments. The final report reflected the local input. The individual reports themselves were confidential between NCEHR and the site. In this report, cumulative findings are reviewed.

A. The review process

REBs reported that defining what constituted research was a problem; while most had a definition of research similar to that used in TCPS (“a systematic investigation to establish facts, principles or generalizable knowledge”, Article 1.1, TCPS¹), several problems were identified. Some goals of some types of qualitative research were not to fit the definition. Many institutions were grappling with clarifying differences between quality assurance and research or innovative therapy and research. Professional programmes (e.g. nursing or social work) had issues with defining training generally governed by the particular profession’s code of ethics and research. A few sites had no available definition or criteria for students and researchers.

As the reports cover a period just after the promulgation of the TCPS, a few sites were grappling with the first organization of a central committee. The most successful with the process had invested significant time communicating with individual departments, faculty, and students. Similarly, the preparation of educational tools enhanced the communication.

Student research was an area of special concern. Issues included clarifying whether the policy was meant to cover all student research or only that done as part of a thesis or other major project. Most sites had a system (usually departmental) to deal with course-based research, and had all other applications come to the formal REB. The departmental process could involve a formal committee or review by one individual. Some REBs reported little knowledge of the extent of undergraduate research at their institutions; rarely, a few doubted whether any review existed. Whether the REB reviewed student-based research most often depended on the level of the student (i.e. undergraduate vs. graduate) or whether the research was course-based rather than on potential harms to participants. Most sites identified either defining the research or the risks to be a difficult issue.

Two institutions separated research review according to whether it was funded or not. This was seen to be a problem by the surveyors, as the potential existed for inequities and a lack of a standard approach or diligence in the review of all protocols. As well, separating out unfunded research in one case allowed some number of projects to escape any review.

B. Research Ethics Boards

Although the REBs generally were appropriately constituted, with appropriate lines of authority, potential conflicts were identified. These centered on an actual or perceived lack of independence from the activities promoting research. Most REBs reported to the President or equivalent; one reported only to Senate. It was suggested that the lines of reporting be clear, and that REB activities were summarized regularly for the responsible body.

Membership varied enormously. Some had excellent numbers and coverage of membership criteria with representation from researchers, ethics and legal expertise, as well as community members. Such success was at least in part related to the institution's interest and method of recruitment of REB members. Some required that every faculty or department provide a member, one had nominations and elections, and one asked faculty members to list which committees were of interest and filled needed positions from this. It was clear that a pro-research ethics attitude lead to success in recruitment. Generally, membership on the REB was seen as time consuming, and interfering with a new faculty member's teaching and research responsibilities. This was particularly true as the commitment of committee members were rarely recognized in any meaningful way. REB members themselves suggested options: teaching relief, stipend, consideration during tenure and advancement deliberations, educational opportunities.

Other institutions had insufficient numbers or lacked the appropriate membership. Most often, expertise was needed to cover ethics and law (the latter necessary for those REBs dealing with biomedical research). Using the institution's legal counsel as an REB member was generally recognized to create a conflict, but two committees had not yet solved this issue. Similarly, having a member of administration as a chair could create a potential conflict of interest.

Several had difficulty filling the community/non-institutional member slot. Others had done an excellent job not only in having one or more community members, but also in having the background of those individuals reflect the research done at the institution (for example, an aboriginal member for an REB dealing with many such protocols). Methods identified to engage such members included community meetings, advertisements, word-of-mouth, recruiting retired professionals (judge, principal, teacher), or asking for members from patient advocate groups. No REB reported a lay member having a "single issue"; indeed all were praised for their devotion to the process.

C. Number of REBs

In the first visits of this cycle, almost all sites had or were moving to a central REB, with one to many departmental research committees. Some were still in the process of changing to a formal REB, and a repeat visit would be of interest (or a follow up questionnaire). The sample changed as more medical school-containing institutions were re-visited. The creation of health care regions and the amalgamation of hospitals and higher educational institutions was observed to be changing the role of some REBs to reviewing many more community-based protocols.

D. Assessment of risk

Concern was expressed regarding the definition of minimal risk. The majority of REBs had a system in place for proportionate review, with the default being full review. However, the two extremes also existed: one REB which considered everything at full

committee (and was managing only because of a relatively light load) and some REBs which either handled everything as expedited, or had very few protocols come to full committee. Part of this might have been related to whether the committee had regular face-to-face meetings. Several met irregularly or only four times per year. Business was accomplished by e-mail. In both cases, the opportunity for members to learn from each other and from the case discussions was lost. It was suggested that at least a proportion of the meetings should be actual.

Expedited review, when utilized in this way, had a number of potential concerns: quality of review, education of committee members, consistency of review, evaluation of risk. One committee had most of the review done by staff, with the chair and a small committee reviewing only protocols passed to them.

E. Scholarly review

Few committees had a formal mechanism to evaluate whether the research had received such a review, or were able to accomplish this themselves. Some REBs dealt with graduate student research as their sole business, and felt the supervisory committee could accomplish this. For others, unfunded projects particularly might not receive an adequate review. As most of these REBs were not biomedical in nature, scholarly review had not been a norm. As well, researchers themselves felt REBs did not have the expertise to evaluate the various qualitative methodologies, and at times were felt to impede such research. Suggestions given included the use of a separate scholarly merit committee, the use of either internal or external reviewers, education of all committee members regarding the characteristics of the types of qualitative research, and encouraging appropriate research expertise on the committee. Departmental scientific review had been set up in some areas, having an advantage of local expertise, as well as clarifying the REB role.

F. Meetings

The reviews reflected a time of change within many institutions, with half the REBs still not meeting face-to-face on a regular basis. Institutions frequently reported either experiencing or encouraging an increase in research protocols; leading to surveyors' concerns regarding workload, adequacy of review, and education of the REB.

Twice monthly meetings on the part of many REBs fostered more rapid turn-around times, and lessened the number of reviews for any one meeting. However, REB members generally found it increasingly difficult to devote the time preparing for and attending the meetings without some form of release time.

G. Conflicts of interest

Several potential conflicts were raised: administrators as chairs or members, memberships of committees biased toward a particular field of research in a small institutions, committees closely linked to research services (with the mandate to increase

funding for research), or lines of reporting of REBs such that independence could be compromised. Several committees described a potential conflict with roles of committee members and gave examples of either the ethicist or a member with particular research expertise having difficulty separating their own research interests from an unbiased review of protocols. REB members, not those submitting protocols for review, voiced these types of concerns.

H. Process issues

REB review was enhanced with a clear and descriptive application process and form. One particularly innovative one had a document outlining a sample consent form that the researcher could cut and paste. Most REBs asked that all documentation be sent in (full protocols, questionnaires, etc). A few had only the application and no access to the full protocol. Two had no formalized process as yet, and understandably had problems with documentation sent in. The surveyors saw examples of clear and concise manuals available to the research community, or the equivalent posted on a Web site. The advantage of the latter was to allow rapid communication of changes to researchers.

Most, but not all, had a good system for keeping minutes (one with poor funding had REB members keeping the minutes). Most kept minutes, protocols, etc. either for many years or indefinitely. One kept only one year – very difficult even for monitoring.

I. Monitoring

No REB had a full system of monitoring; some asked for yearly or every several year reports. Adverse event reporting was difficult to quantitate as most site visits were with non-biomedical REBs. A point can be made that all REBs should have a mechanism for adverse events. Clarification was sought as to what constituted the minimum requirements (and who should be taking the responsibility for the monitoring). Good examples of monitoring practices included protocol audits with communication back to researchers, subcommittees of the REBs to handle aspects of monitoring, and database designs that facilitated timely requests for yearly and summary reports. At this time, the surveyors are unaware of any monitoring which includes the experience of research participants.

J. Education

Two REBs had formal training of new REB members: one of these had videotapes and readings. Most REB members were found to be knowledgeable, and interested in the area. Some institutions had excellent mechanisms in place for overall research ethics education: a workshop or orientation regarding research ethics for new faculty, regular reporting of research ethics topics in the campus paper, yearly workshops, curricula for graduate students. Others requested help in initiating such a process. The casebook should be of help. Common concerns include the provision of research ethics education to undergraduate students; education of new REB members; and commitment of administration to provide educational opportunities.

Summary

Thirty-seven site reviews of REBs have been accomplished to date. All had a clear mandate to comply with TCPS standards; success in achieving this varied. Institutions reported concerns with the financial implications of assuring support for adequate initial review and any increase in present monitoring activities. REB chairs and members were universally found to be committed, conscientious, but overworked and concerned regarding how the demands for review could be met. Common problem areas included: the need for a broader definition of research, further discussion and direction in the assessment of minimal risk, scientific review, monitoring, and the need for research ethics education at all levels.

The Tri-council Policy Statement was seen to be a reasonable starting document, but in need of revision to reflect the concerns. Areas suggested for development or major revision were: discussion and direction regarding qualitative research methodologies, research with communities, secondary use of data, web-based research, and a broader discussion of research vs. quality assurance or innovative therapy.

References

1. NCBHR. "Protecting and promoting the human research subject: a review of the function of research ethics boards in Canadian faculties of medicine." NCBHR Communique CNBRH 1995, 6(1): 3-32.
2. Tri-Council Policy Statement "Ethical Conduct for Research Involving Human Subjects", August 1998.