

**National Council on Ethics
in Human Research**

*Report on NCEHR
Site Visits
1998 to 2004*

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O'Hara Consulting



**Report Prepared by:
Dr. Paddi O'Hara
Dr. Catherine Schuppli
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EXECUTIVE SUMMARY

The National Council on Ethics in Human Research (NCEHR) plays a major role in supporting the activities of Research Ethics Boards (REBs) in Canada by offering site visits to institutions in order to advance the protection and well-being of human participants in research, and foster high ethical standards for the conduct of research involving humans. The process begins with the completion of pre-visit questionnaires by institution staff and continues when the surveyors meet with key institutional stakeholders including the President or designate, senior administrative staff responsible for overseeing ethics processes in human research, REB Chairs and members, researchers, students, participants in research projects, and partnership stakeholders. The site visit process culminates in a confidential report that is sent back to the institution.

Recently, a database containing the results of 55 site visits (40 universities and 15 hospital/health settings) conducted between September 1998 and June 2004 was created. All visits took place after the *Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans* (MRC, NSERC & SSHRC, 1998) was issued. The TCPS is considered by many to be the national standard for the ethical conduct of research with humans in Canada.

Description of REBs visited:

- Almost half the sample reviewed more than 100 protocols per year.
- The most time consuming activity for REBs was the review of the informed consent form/process.
- A majority of submitted protocols were approved immediately or with requests for minor revisions.
- Most REBs had good supporting documents and forms.

Issues identified:

- Clarity was needed in TCPS definitions of research and minimal risk.
- Some research requiring review was not seen by REBs.
- Some REBs did not have the time or resources to conduct a thorough review of protocols.
- REBs required more administrative support.
- Workload for REB members was often too heavy.
- More guidance was needed regarding multi-centre trials and expedited review, as well as new areas such as Internet-based research.
- There was interest expressed in the idea of consent templates or consent standards.
- There was often insufficient independence of the REB from research and institutional interests.
- Despite positive comments of research participants, there was concern regarding pressure to take part in studies, the overuse of some populations and the way in which data would be used (including concerns regarding confidentiality).
- More monitoring was needed during the course of research.
- Greater communication was needed between REBs and investigators (who are often unaware of many aspects of the ethics review process: for example, the existence of an appeal mechanism).
- Greater communication was needed between REBs and institution administration (who may not be well informed about the lack of financial and other support that REBs need).
- More education was needed for all individuals involved in research with humans, including REB members, investigators, students, participants and administration.

The picture that emerges from these data suggests that there are many hard working, over-burdened REBs struggling with similar problems and often working on innovative and viable solutions. Investigators are often frustrated by a review system that is not sufficiently transparent and too bureaucratic, although it would appear that most protocols are approved immediately or with only a request for minor revisions. As the complexity of the ethics oversight system increases and Canada moves toward a system of accreditation for human research protection programs, there will be an increasing need for all parties involved in research with humans to communicate with each other and have adequate and appropriate support, understandable and comprehensive guidelines, and access to education in research ethics.

1. INTRODUCTION

1.1 Background

The responsibility for the protection of humans in research is shared among the entire research team, sponsors/funders and the institutions where the research takes place (Sugarman, 2000). In Canada, Research Ethics Boards (REBs) are established to help ensure that ethical principles are applied to research involving humans. The National Council on Ethics in Human Research (NCEHR) plays a major role in supporting REB activities by offering assistance in:

- interpreting and implementing guidelines for the ethics of research involving humans;
- establishing and implementing procedures for evaluating and monitoring the performance of research involving humans;
- assessing the function of REBs; and
- ensuring that human research ethics guidelines or pronouncements meet the needs of research involving human subjects in Canada.

One of the key ways in which NCEHR fulfills this part of its mandate is through voluntary site visits to Canadian universities, hospitals and other research institutions. These visits are considered educational in nature and are designed to assist institutions review the strengths and weaknesses of their current system of ethics review and offer ways to improve the review process. The site visit process culminates in a confidential report that is sent back to the institution.

1.2 Purpose of Report

In this report site visit data were analysed in order to: (1) provide a description of REB practices in Canada and (2) identify challenges that REBs and institutions face in the ethics review process. Although not part of the original site visit program (and, therefore, not included in the site visit database), some information concerning “good practices” identified by site visit surveyors has also been included. Where appropriate, findings are presented in connection with introductory information from the *Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans* (MRC, NSERC & SSHRC, 1998).

As we move towards a system of accreditation for human research protection programs (see the NCEHR Options Paper, April 2005), the insights derived from past educational site visits will provide a valuable source of information about the ways in which ethical oversight has both succeeded and failed in this country.

2. DESCRIPTION OF DATABASE

Recently, a database containing the results of 55 site visits conducted between September 1998 and June 2004 was created. This report is a synthesis of the information held in that database, which is composed of:

1. pre-site visit questionnaires that are completed by institution staff; and
2. site visit reports that are the result of the interaction between NCEHR surveyors and the people connected to the institution who participated in the visit (i.e. REB members,

administrators, members of the research community, department chairpersons and research participants).

The text database was created with askSam® software (Seaside Software Inc.) and some variables were translated into a quantitative database for analysis with SPSS, Version 12 (SPSS Inc.). In addition to descriptive statistics presented in this report, continuous variables were analysed by t-test and categorical variables were subjected to chi-square tests where possible (significance set at $p < 0.05$).

Prior to the creation of this database, NCEHR had issued reports summarizing earlier years of site visits (e.g., *Communiqué, 1995 Volume 6, Number 1*) but this paper is significant in that all visits took place after the TCPS was issued. The TCPS describes the policies of the Medical Research Council (MRC is now the Canadian Institutes of Health Research: CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). It is considered by many to be the national standard for the ethical conduct of research with humans in Canada.

3. FINDINGS

It is clear from the site visits that the majority of institutions had REB members, investigators, department heads and administrative staff who were highly committed to the process of ethics review and who were concerned about ethical issues regarding research with humans. There were, however, a number of areas where REBs required clarification of issues, questions answered, improved policies and procedures, additional support and education.

3.1 Universities Versus Hospital/Health Settings

Between June 1998 and the end of the fiscal year 2004/05, NCEHR surveyors visited 42 universities and 20 hospitals or organizations with ties to health research (hereinafter known as hospital/health settings) for a total of 62 visits (see Figure 1).¹ The site visit database currently holds information for a portion of those visits, that is, the 55 institutions (40 universities and 15 hospital/health settings) visited between September 1998 and June 2004. There are missing data for one institution seen during that period and it has not, therefore, been included in the database.

REBs from universities and hospital/health settings did not differ in terms of average number of protocols reviewed every year (see Table 1) but hospital/health REBs met significantly more often than university REBs (see Table 2). In fact, 59% of university REBs met at least once a month compared to 93.3% for hospital/health REBs. Hospital/health REBs tended to spend more hours per year in full board meetings than university REBs (39 hours versus 28 hours), and hospital/health REBs also took significantly longer to issue a decision (5 weeks versus 4 weeks).

¹ The division between university and hospital/health settings should not be interpreted as indicating a clear separation between social science and humanities research versus health or biomedical research. It is probable that all institutions reviewed a range of protocols, including social science, humanities and biomedical research.

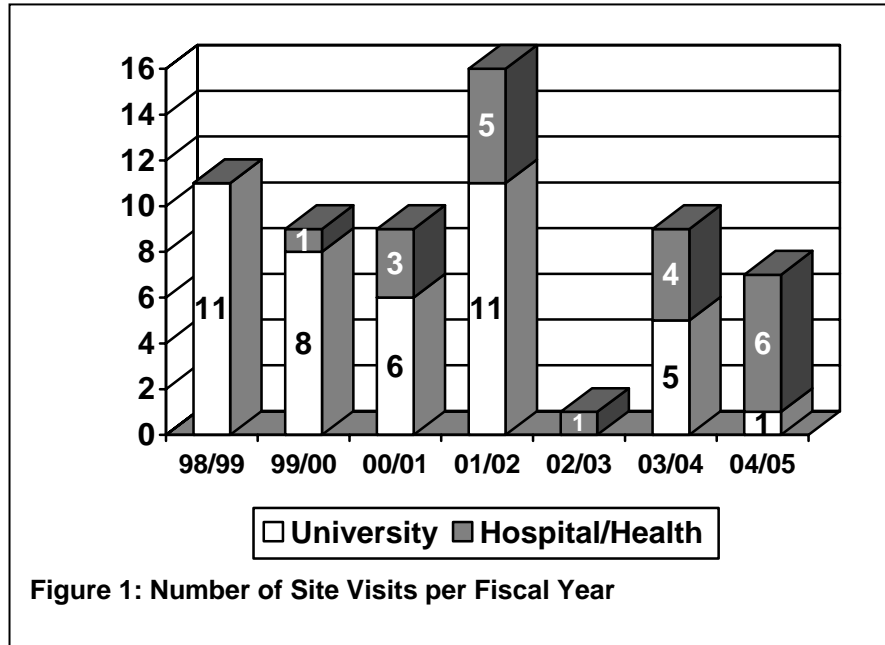


Table 1: Number of Protocols Reviewed Per Year

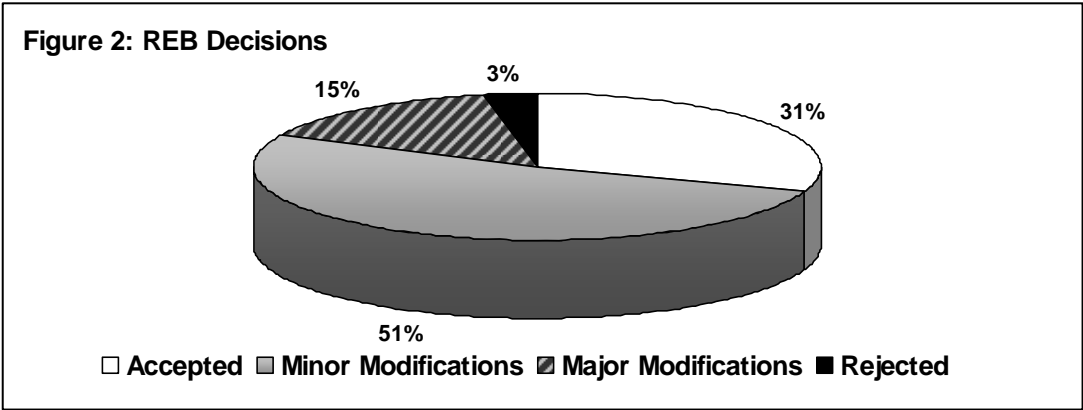
Number of Protocols	University	Hospital/Health	TOTAL
0-10	5 (13.9%)	1 (9.1%)	6 (12.8%)
10-25	1 (2.8%)	0	1 (2.1%)
25-50	9 (25.0%)	4 (36.4)	13 (27.7%)
50-100	4 (11.1%)	1 (9.1%)	5 (10.6%)
> 100	17 (47.2%)	5 (45.4%)	22 (46.8%)
TOTAL	36 (100%)	11 (100%)	47 (100%)

Table 2: Frequency of REB Meetings

	University	Hospital/Health	TOTAL
< Once per month	16 (41.0%)	1 (6.7%)	17 (31.5%)
Once per month	18 (46.2%)	10 (66.7%)	28 (51.9%)
> Once per month	5 (12.8%)	4 (26.7%)	9 (16.7%)
Total	39 (100%)	15 (100%)	54 (100%)

3.2 REB Decisions

According to the TCPS (Article 1.2), it is the mandate of the REB to “approve, reject, propose modifications to, or terminate any proposed or ongoing research” involving humans. With respect to REB decisions reported by this sample, 82% of protocols were approved immediately or with requests for only minor revisions (see Figure 2). The majority of REBs tried to reach a decision through consensus first (78%) rather than majority rule (22%).

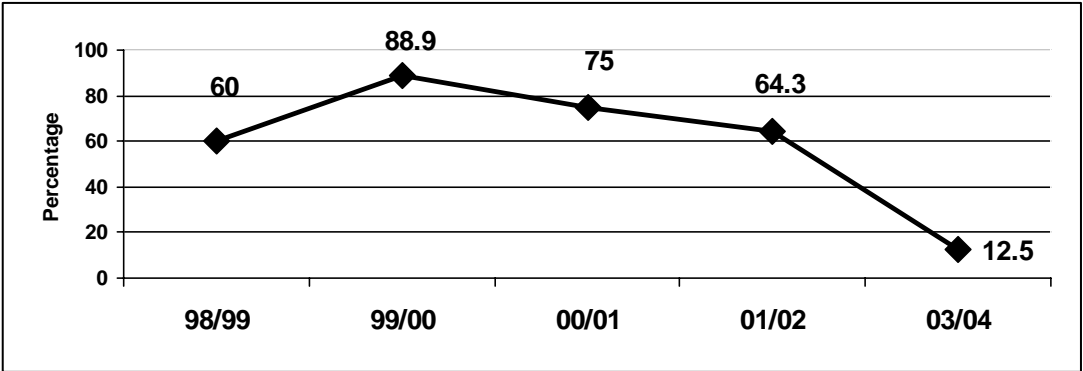


3.3 Difficulties Faced by REBs

When asked about the most time-consuming activities REBs face, the majority (90%) named the informed consent form and/or procedures. Specific types of consent, such as that for non-competent participants (44%) and groups (40%), were also identified. Recruitment procedures as well as risk-benefit analyses were mentioned by 58% of the sample. Other time consuming activities included attention to risk reduction (52%), legal issues (37%), scientific evaluation (33%), and deception (31%).

Respondents were asked whether or not their REB had sufficient administrative support (see Figure 3). It appeared that there was a trend of less support for REBs over time although the sample size is too low to make any generalizations. Snapshot depictions of fiscal years having at least eight site visits show that the percentage of visited REBs having adequate support reached a high in 1999/2000 (8/9) and a low in 2003/2004 (1/8).

Figure 3: Percentage of Visited REBs that Reported Sufficient Administrative Support



When asked about specific problems that REBs face, 68% of those responding reported that their workload was a major concern. More than one third of the sample (38%) had difficulties because submitted protocols were incomplete (this was reported by more hospital/health REBs

than universities but the difference was not significant), and 26% were concerned that their board lacked expertise (ethical, legal etc.) to review proposals. At least 12% of REBs did not have a community member, as directed by the TCPS.

3.4 Sources of Research Funding

When asked to estimate the sources of funding for protocols reviewed, hospital/health REBs reported reviewing significantly more proposals funded by research contracts (50%) than university REBs (16%). See Table 3 for details.²

Table 3: Percentage of Research Funding From Various Sources

Type of Research Funding	University (n=25)	Hospital/Health (n=13)
External Grants, Peer Review	30%	15%
External Grants, No Peer Review	10%	10%
Internal Funding	16%	15%
Research Contracts	16%	50%

3.5 Issues with the TCPS and/or Principles of Ethics

According to the TCPS [Article 1.1(d)], REBs exist in order to help ensure that ethical principles are applied to research involving humans. REBs are directed to take a proportionate approach to this task meaning that the more invasive or risky the research, the greater should be their care in conducting an assessment. Site visit participants were sometimes unclear, however, about the definitions of both research and risk.

1. **What is research?** Simply put, the TCPS defines research as a “systematic investigation to establish facts, principles or generalizable knowledge” [Article 1.1(d)] and the focus of such research can be humans or human tissue. This raised many questions related to research in the humanities and social sciences where, for example, the degree of oversight required for student or classroom research was unclear.³ There was also uncertainty regarding certain types of investigations such as naturalistic observation, and the need for oversight for activities of disciplines not normally linked to research, such as fine arts or journalism. Although the TCPS stipulates that quality assurance studies are not normally subject to REB review, respondents were not always sure where to set the boundary between this type of activity and “research.” This was particularly of concern in hospital/health settings.
2. **What is minimal risk?** If the care taken by an REB in conducting an assessment is tied to the magnitude of potential harm to participants, then it is essential to be able to define the parameters of that risk. Concern was expressed that minimal risk is a difficult concept to

² Note that totals do not add up to 100% because REBs were providing estimates for predetermined categories in the pre-site visit questionnaire which did not necessarily include all types of research funding.

³ The Interagency Panel on Research Ethics (PRE) created a Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC) in November 2002. Its mandate is to provide advice and recommendations to PRE on (a) priorities, and (b) methods and strategies for coherently addressing priority ethical issues in social sciences and humanities research involving human participants.

operationalize and many respondents pointed out the need for case studies that could be used as examples. This was particularly confusing for research in the social sciences as the type of risk encountered may be different from that found in biomedical and health settings.

Some respondents pointed out that the TCPS lacks guidance in certain key areas: for example, appropriate lines of reporting within an institution, and Internet-based research. Concern was also expressed that the TCPS is not always compatible with other guidelines, such as those from the U.S. National Institutes of Health (NIH, 2003) and the International Conference on Harmonization Good Clinical Practice Guidelines (ICH GCP, 1997).

Respect for privacy and confidentiality is a major principle of the TCPS, and site visit participants had a number of concerns regarding access, control and dissemination of personal information. For example, questions were raised regarding the protection of people in the public eye, or those who might be put in a position of revealing sensitive information. There were other concerns around the collection of archival data, especially from private sources such as diaries. Confidentiality was also seen as an issue that goes beyond the individual and can implicate communities (e.g., genetic data). The notion of what constitutes a personal identifier was raised; for example, does the use of initials as part of an identification code for blood samples have the potential to breach a patient's confidentiality?

3.6 Practical Issues in Research Ethics Review

In addition to the broad concerns regarding principles of ethics that were raised during site visits, a number of practical issues were identified:

Conflict of Interest: Some REBs had ties to research and institutional interests which may create (or have the appearance of creating) a conflict with their primary responsibility of protecting research participants. This happened when the REB reported to the Office of Research or a similar authority, when the REB Chair was also Director of Research or other senior administrator, or when administration had the power to overrule REB decisions. Other potential sources of conflict of interest occurred when an REB member was also a primary investigator of a protocol being reviewed, or researchers were being paid by industry. Surveyors recommended that policies and procedures must be in place to prevent these problems, or at least provide guidance for disclosing information relevant to REBs as well as participants.

Ethics Application Process: Surveyors were often pleased to find good supporting documents and forms. In some cases there was helpful pre-screening of applications by departmental committees, a full-time protocol officer, or by administration. A small number of REBs needed to work on providing standardized forms and adequate guidance for investigators.

No Ethics Review: When asked if any research took place that was not reviewed by an REB, 44% of universities and 13% of hospital/health settings said that this happened. The type of research not necessarily reviewed included minimum risk, chart reviews, research that was funded by the investigator, longstanding projects that existed before the implementation of ethics review, undergraduate student class projects (the role of departmental committees, as well as student supervisors, was often unclear) and community-based research where it was not apparent where responsibility lay for oversight. The reasons for this omission were varied, including ignorance of requirements on the part of investigators. It was even suggested that some research was not submitted because of the expected difficulties in getting a positive review.

Insufficient Ethics Review: The ethics review process was not always considered sufficient due to a number of factors, including too few face-to-face meetings of the REB, too little time spent discussing each protocol during meetings, limited number of reviewers seeing any given protocol and too many protocols sent to expedited review.

Expedited Review for Minimal Risk Research: Where two associate REB Chairs shared the process of expedited review, the process was accomplished more quickly. On the other hand, several REBs did not have a policy for this type of review and it ended up being the responsibility of only one REB member (usually the Chair) and not always for research designated as minimal risk. The entire REB did not always ratify decisions resulting from expedited reviews.

Multi-Centre Research: Studies occurring at multiple sites could require multiple reviews, which raised questions about the redundancy of the review process. While some REBs have adopted or are moving towards a system of central review, there were concerns about the responsibilities of local sites. Others were concerned about “REB shopping” and the problem of inconsistent reviews between REBs.

Consistency and Communication Between REBs: When an institution had more than one REB, there were sometimes problems with inconsistency of reviews as well as lack of communication between boards. In some cases it was indicated that departmental REBs did not report to a central REB, resulting in multiple and possibly inappropriate ethics review procedures.

Review of Scholarly Merit: Although the TCPS (Article 1.5) describes the need for scholarly review as part of the overall ethics review, this has long been a contentious issue for investigators who are concerned that this may require the REB to go beyond its arena of expertise (SSHWG, 2004). It was reported that scholarly or scientific merit was, however, evaluated by 72% of REBs (either directly by the board or by separate committees organized for that purpose). When scholarly or scientific merit was not evaluated, REB members often felt discomfort with this aspect of the review process and/or institutional policies were lacking in this regard.

Informed Consent: A number of problems with informed consent were identified, including lack of detail regarding contact information, risks and other important information that should be disclosed, for example, conflict of interest (policies regarding appropriate disclosure were sometimes absent). On the other hand, some consent forms were criticized for having too much detail. Small font was also blamed for the reluctance of participants to read the document. Many respondents had specific questions about informed consent: for example, requirements for obtaining oral consent, ethnic and cultural factors that affect consent, appropriate consent procedures for Aboriginal participants (and the possibility of including community consent), consent for children or others with diminished capacity and continuing consent in longitudinal studies. There was interest expressed in the idea of consent templates, or at least some means of ensuring consistency in consent standards across the country.

Coercion of Research Participants: It was pointed out that researchers and REBs need to pay more attention to the possibility that there could be implicit or explicit pressure on potential research participants to participate or stay enrolled in studies. This can occur in settings where there is an imbalance in the power relationship between investigators and participants, or where participants are dependent on investigators for some reason: for example, students are sometimes offered course credit for enrolling in experiments. A related concern is the overuse of some participant populations in multiple research studies.

Monitoring: According to the TCPS (Article 1.13), continuing ethics review should be in place for research that is ongoing and the rigour of the review or monitoring should correspond to the level of risk associated with the research. At minimum, investigators are expected to submit an annual status report, as well as notification of the end of the project, to the REB. There are, however, growing concerns about the need to make sure that studies are conducted, recorded and reported in accordance with the REB approved protocol, institutional policies and procedures and all regulatory authority and relevant law. This suggests the need for a more involved monitoring and/or audit process. This study showed that more hospital/health REBs demanded annual reports than university REBs (93% vs. 63%), and a significantly greater proportion of hospital/health REBs required end-of-protocol reports (93% vs. 47%). Of course these differences may be due to the types of protocols reviewed by hospital/health REBs which would tend to review more ongoing clinical trials. This is further demonstrated by the significant difference in requirements for reports of adverse events (hospital/health REBs: 93%, university REBs: 51%). It would appear that few REBs know what happens to a research project after giving initial approval, apart from perfunctory annual reports.

Appeals Process: When investigators and REBs cannot reach agreement through discussion and reconsideration, the TCPS (Article 1.11) suggests that institutions should permit review of an REB decision by an appeal board. Ninety percent of university REBs reported that they had appeal procedures in place compared to 80% of hospital/health REBs. For those institutions that had mechanisms for appealing REB decisions, 50% of university REBs reported that they had been used compared to 21% of hospital/health REBs. Of the 11 incidents where data were available on outcome of appeals, 64% of decisions were upheld and 36% of decisions were overturned. It was observed that several REBs had appeal procedures that were unclear, lacking or *ad hoc* (specifically not permitted by the TCPS). Concern was also expressed that some appeal boards lacked independence or credibility because of limited expertise. Some appeals were limited to procedural problems and not substantive issues.

Research Ethics Education: Surveyors felt that more institutions need to recognize that education is a priority and should provide the resources to ensure that REB members, investigators and students receive adequate training in ethical issues, ethics review procedures and guidelines such as the TCPS. Where good education in research ethics exists, it is often included in undergraduate and graduate courses. All too often, however, REB members are expected to simply learn “on the job.”

3.7 Perspectives

REB Members: Many REB members (sample size not recorded) pointed to a large and growing workload without access to sufficient support or resources as being a significant burden for what is, essentially, a volunteer position. Some REBs were concerned about a lack of ethics and/or scientific expertise. Several difficulties with researchers were identified, including inadequate or incomplete applications for ethics review and problems with lack of accountability of investigators (this was particularly troublesome where no formal relationship existed between hospital and non-affiliated researchers in a health authority).

Researchers: At least 54 researchers from 11 hospital/health settings and 30 universities were interviewed during site visits to discuss their experiences. Many found the ethics review to be very useful and valued the work done by REBs. In some cases, however, it was felt that there was insufficient communication (or lack of clarity in communication) between REBs and investigators, leading to frustration in the research community. Some investigators were unaware that they could have access to their REB and that an appeal process existed. The general feeling was that the review process was not sufficiently transparent and much too

bureaucratic. All of this contributed to some investigators feeling that REBs inhibit, rather than encourage, research (particularly in the area of social sciences). As a result, some investigators focused on the research they felt would be approved by the REB, rather than on “good” research. Certain REBs found that difficulties with investigators were lessened when they were given the opportunity to appear at meetings.

Research Participants: At least 28 research participants from four hospital/health settings and six universities were interviewed during site visits to discuss their experiences. The majority of student participants were satisfied with the way they were recruited, informed and treated in studies. Many found that participation in research was very interesting and at least three people commented on receiving financial compensation or credit. While many students had confidence about the way in which their data would be used, some were concerned about confidentiality, particularly after their involvement in the study was over.

The majority of non-student participants (94%) expressed satisfaction with their involvement in research. In general, they found the consent process to be respectful and thorough and the investigators were willing to discuss issues raised in the consent form. Even when the consent form was long and complex, patient participants found it understandable, or at least well explained by the investigators. They often said that they were pleased to be part of a study and they supported research endeavours. Many expressed an interest in receiving information about the results of the research. There were some complaints, however; one individual said that participants are under the assumption that REBs monitor trials and this activity should, therefore, be mandatory. This person also wanted a “debriefing session” after finishing the study.

Administration: At least 32 administrators from 11 hospital/health settings and 31 universities were interviewed during site visits to discuss their view of REBs. Many indicated their commitment to the ethics review process as well as interest in updating the TCPS, and the provision of education in research ethics. Some were aware of insufficient support for REBs and were willing to increase funding for infrastructure. Others thought that the contributions of REB members should be recognized through promotions and release time.

3.8 Research Ethics Good Practices

As NCEHR continues to refine and improve the methodology for site visits, new and interesting possibilities for data collection are incorporated into the process. A recent example of this evolution of the site visit process has to do with information about “good practices.” Where the site visit surveyors have been sufficiently impressed by some aspect of the human research protection program in place at an institution that they have suggested it be identified as a “good practice,” this is now being noted. This list is far from comprehensive and is provided in Table 4 (with the permission of the institutions identified) as a means of sharing information that could be helpful to other REBs.

Table 4: Examples of Good Practices Noted in Site Visits

DATE	INSTITUTION	GOOD PRACTICE
June 2003	St. Michael's Hospital Research Ethics Board Research Administration Room 4052 Queen Wing 30 Bond Street Toronto, Ontario M5B 1W8	The monitoring process (a full-time research ethics monitor position has been created).
June 2004	University of Ottawa Heart Institute 40 Ruskin St. Ottawa, Ontario K1Y 4W7	Policy on Conflict of Interest & Professional Ethics
June 2004	University of Ottawa Heart Institute 40 Ruskin St. Ottawa, Ontario K1Y 4W7	Policy on Consent for Chart Reviews for Research Eligibility, ensures that specific populations of potential research participants are not over-researched.
February 2005	Trent University 1600 West Bank Drive Peterborough, Ontario K9J 7B8	Conducting research with aboriginal peoples.

4. DISCUSSION

Many Canadian institutions where human research is conducted have taken advantage of the opportunity to have a site visit by the NCEHR team in order to advance the protection and well-being of human participants in research, and to foster high ethical standards for the conduct of research involving humans.

The impact of site visits by NCEHR was illustrated by a report posted on the University of Saskatchewan web site (2004). It pointed out that the Ethics Office is already acting on the recommendation from the NCEHR site visit report that a protocol pre-screening procedure be implemented to reduce the workload on board members. They were also pleased to mention that the Bio-REB was praised for its "model" consent form for research involving genetic testing and tissue banking. In their online newsletter, Wilfred Laurier University (July 2001) reported that all recommendations of the NCEHR site visit team had been implemented. These are just two examples of institutions using the NCEHR site visit program to improve their systems of protection for humans in research.

The construction of a database with the results of some of these visits is an important first step in creating an understanding of the way in which REBs operate in Canada. There are, however, limitations in the scope of this report as the richness of much of the qualitative data collected has not yet been explored. There is also potential for additional quantitative analysis. It should also be kept in mind that these data are from institutions that volunteered to take part in the site visit program. This type of self-selection undoubtedly creates a somewhat biased sample and, therefore, any generalizations to all REBs in Canada should be made with caution.

It is clear that university REBs were structured differently, and had some dissimilar concerns, from REBs found in hospital and health settings in this sample. For example, university REBs were more likely to find that TCPS definitions of research and minimal risk lacked specificity or relevance to their setting. Despite these distinctions, all REBs shared many features in common

such as lack of administrative support and the need for more guidance regarding multiple aspects of the ethics review process. Although this can appear to manifest itself as confusion over the TCPS it may simply reflect an evolution in the thinking of institutions that need to refine policies based on this guidance document. The TCPS is not, of course, meant to provide answers to all of the procedural queries faced by REBs but is a statement of principles that can inform the ethics review process.

Although REBs from universities and hospital/health settings did not differ in terms of average number of protocols reviewed every year, hospital/health REBs met significantly more often, spent more hours per year in full board meetings, and took significantly longer to issue a decision than university REBs. More than 80 percent of proposals were accepted immediately or with only a request for minor revisions. This seems to contradict the feeling expressed by some investigators that REBs inhibit, rather than encourage, research. It should also be mentioned that most REBs were found to have good supporting documents and forms.

Some of the issues identified in the site visits include:

- Clarity was needed in TCPS definitions of research and minimal risk.
- Some research requiring review was not seen by REBs.
- Some REBs did not have the time or resources to conduct a thorough review of protocols.
- REBs required more administrative support.
- Workload for REB members was often too heavy.
- More guidance was needed regarding multi-centre trials and expedited review, as well as new areas such as Internet-based research.
- There was interest expressed in the idea of consent templates or consent standards.
- There was often insufficient independence of the REB from research and institutional interests. According to McDonald (2000), the vulnerability of Canadian REBs makes it crucial that REBs not “report to or be appointed by offices of research.”
- Despite positive comments of research participants, there was concern regarding pressure to take part in studies, the overuse of some populations and the way in which data would be used (including concerns regarding confidentiality).
- More monitoring was needed during the course of research.
- Greater communication was needed between REBs and investigators (who are often unaware of many aspects of the ethics review process: for example, the existence of an appeal mechanism).
- Greater communication was needed between REBs and institution administration (who may not be well informed about the lack of financial and other support that REBs need).
- More education was needed for all individuals involved in research with humans, including REB members, investigators, students, participants and administration.

The picture that emerges from these data suggests that there are many hard working, overburdened REBs struggling with similar problems and often working on innovative and viable solutions. Investigators are too often frustrated by a review system that is not sufficiently transparent and too bureaucratic, although it would appear that most protocols are approved immediately or with only a request for minor revisions. As the complexity of the ethics oversight system increases and Canada moves toward a system of accreditation for human research protection programs, there will be an increasing need for all parties involved in research with humans to communicate with each other and have adequate and appropriate support, understandable and comprehensive guidelines, and access to education in research ethics.

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