“You are professionals and you know the issues. I ask – and life itself demands – that you take the time and energy to review each protocol as if you were going to enroll your own child.”

Mr. Paul Gelsinger, Keynote Speaker
Applied Research Ethics National Association
San Diego, CA
October 31, 2000
Cited in Amdur & Bankert (2002)

UNIVERSITY OF CALGARY

Ethical Review for Systematic Investigations Involving Human Subjects: Determining the Need for Research Ethics Board Review in Health and Human Service Organizations

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "Ethical Review for Systematic Investigations Involving Human Subjects: Determining the Need for Research Ethics Board Review in Health and Human Service Organizations" submitted by Helen Patricia Gardiner in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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ABSTRACT

Health and Human Service Organizations (HHSOs) involve human beings in many types of studies including quality assurance, program evaluation and research. All are necessary functions of responsible and accountable HHSOs. The methodology in each may vary from experimental to non-experimental qualitative inquiry. There is confusion regarding whether such work is research and, consequently, whether it requires Research Ethics Board (Henry & Wright) review.

REBs are intended to protect human participants and the risk to people may be greater in HHSOs than in academic settings; HHSOs have considerable control over and access to ill and needy individuals. HHSOs must carry out studies to ensure service quality and effectiveness, but research is not their primary purpose and they usually do not have access to research ethics expertise. Practical guidance, based on expert opinion but relevant to the HHSO environment, may help HHSOs make replicable, and appropriate decisions regarding when ethical review is required.

The current research developed a Research Ethics Decision Guide (REDG) for HHSOs. The REDG is based on data from 201 international experts in research ethics. The completed surveys indicate that there is consensus on ten variables that can be used to determine when ethics review is necessary. Two variables achieved more than 90% agreement among respondents. These were: (1) if the project involves testing a new drug, surgical technique or other invasive procedure; and (2) when the intended subjects are cognitively impaired or children. Eight other variables achieved agreement ratings of 80% - 90%.

The survey also identified variables where experts had moderate agreement (50% – 79%) and where there was a divergence of opinion.

The REDG may be of assistance to HHSOs, but it is important that it not be utilized in a reductionist manner. The REDG will help to screen those studies that require further review, but there is no substitute for the thoughtful discussion of each project by a group of individuals experienced in research ethics when human beings are participants.

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“The true civilization is where every man gives to every other, every
right that he claims for himself.” Robert Green Ingersoll, *The Post*, Washington,
D.C., November 14, 1880

CHAPTER ONE: INTRODUCTION

The primary purpose of this dissertation is to clarify when health and human service organizations (HHSOs) should seek the guidance of a research ethics board[1] (REB) or similar body when undertaking systematic studies involving human participants, regardless of whether the study is called research, program evaluation, quality assurance, or some other name such as accreditation. These areas overlap and attempting to differentiate each area by way of operationalized definitions is, “not a particularly fruitful exercise” (Goodyear, 2005[2]). However, it is often a road that HHSOs attempt to travel when first seeking guidance regarding whether the studies they carry out require REB review as indicated in various legislative or policy requirements (Ministry of Health and Wellness (Alberta), 2001; Manitoba Health, 2001; Canadian Institute for Health Research, 2000; Department of Health and Human Services, 2001; New Zealand Ministry of Health, 2002; World Health Organization, 2001; Bankowski, 1985; World Medical Association, 2004; Snider, 1999). The, “What is research?” question is tangential to the current work and speaks to a deep set of issues that involve power, control, trust, and personal risk, including the control of information, creation of new knowledge and the right to publish knowledge gained in reputable journals or at professional conferences (Appelbaum, 2000;

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[1] The term “research ethics board” has been used throughout this paper except when other terms are used in cited sources. REB is not a universal term. The more common term in the United States is Institutional Review Board (IRB). In the European Union, the term would be Research Ethics Committee (Correctional Service of Canada). The underlying responsibility remains the same: to ensure that research involving humans is conducted in an ethical manner and that human participants are protected from harm.

[2] This reference was taken from the NCEHR listserv. Consequently a page number is not available. However, the reference may be accessed via NCEHR for the March 10, 2005 postings.

Cobern & Loving, 2001; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004; Simon, Unutzer, Young, & Pincus, 2000). Although this dissertation does not directly deal with this question, Appendix A offers a summary of some of the main perspectives regarding this issue, including a sample of current definitions of research, program evaluation and quality assurance in use by widely recognized organizations.

This paper deals specifically with the needs of HHSOs that carry out systematic investigations involving human participants. HHSO is a general term used to refer to any organization that provides social or health services to human beings. For example, in Canada a Regional Health Authority (Overall & Gorham, 1988) would be considered an HHSO as would direct service agencies funded by the United Way and the Canadian Mental Health Association. Within the United States there is a Department of Health and Human Services (DHHS; United States Department of Health & Human Services, 2005). Under the mission statement of “Leading America to Better Health, Safety and Well-Being” the DHHS includes a wide range of governance areas such as “diseases and conditions, safety and wellness, drug and food information, disasters and emergencies, grants and funding, families and children, aging and specific populations” (United States Department of Health & Human Services, 2005). The American Public Human Services Association (APHSA), the first national group formed in the U.S. of those concerned with the delivery of government aid to the poor, states that its mission is “to develop, promote, and implement public human service policies and practices that improve the health and well-being of families, children and adults” (American Public Human Services Association, 2004). In Canada the governance structure is considerably different. HHSO governance is shared between federal and provincial responsibility in cases such as health, as well as between various other ministries (Federal Government of Canada, 2005). For example, at the Federal level, the Ministries of Human Resources and Skills Development, Health, Social Development, Infrastructure and Communities and Families and Caregivers all appear to address components of health and human services.

As can be seen from the above, the general terminology used to describe HHSOs leaves room for debate regarding some institutions and organizations. For example, many Non-Governmental Organizations (NGOs) are considered to be HHSOs even though they receive their funding from sources other than just the government. Also, an argument could be made that both the public school and university systems could be considered part of the HHSO network in Canada. However, in most countries, including Canada and the United States, education is handled by a separate ministry and is not considered a “service” that one can take or leave as desired. Rather, education is a mandatory requirement to a certain degree in both countries. Consequently, a university would likely not be considered an HHSO because, although they provide services, the main purpose of the organization is to educate and carry out research, not to provide health or social services directly.

The key characteristic all HHSOs have in common is that they provide health and/or social services directly to people in some capacity (Rossi, 1978).

The services provided form the social safety net within a particular jurisdiction. They are an increasingly regulated group of organizations, primarily due to the confidential nature of the information they collect and retain regarding their clients. HHSOs usually work with the sick and the disenfranchised, such as those who have suffered from domestic abuse, the elderly, minority groups that may face discrimination and other challenges in accessing services, and those who are in need of medical care. Many HHSOs are government-supported although there are a considerable number of NGOs and privately owned hospital facilities, particularly in the United States. Many of the more recently legislated requirements that apply to HHSOs have implications regarding the need for the ethical review of studies undertaken by HHSOs involving human participants, although this is usually dealt with as an issue related to the protection of privacy and information sharing (Canadian Institute for Health Research, 2000; Cavoukaian, 2000; Health and Wellness Alberta, 2001; Manitoba, 2001), rather than to the protection of human participants, as is the case in academic settings. This paper does not deal with organizations outside of HHSOs.

Also with regard to defining the landscape for the current dissertation, the term “experimental” has been used to denote studies that use classic scientific methodology, such as randomized clinical trials (RCTs) with random assignment to at least one control and one experimental group, and reliance on statistical techniques to determine significance of findings. “Non-experimental” has been used to refer to all other methodologies, including qualitative techniques. Certainly there will be disagreement with this dichotomous categorization of methodologies. However, the majority of legislation, policy and discussion regarding REB review is focused on experimental work, particularly medical experimentation, and this manner of reference is currently the most useful available.

REB review, and the related issue of personal privacy of information, has been a topic of increasing interest to policy makers, HHSOs, academic institutions and the public in recent years. It crosses many academic disciplines and organizational settings. Moreno (1998) states that, “the spring and summer of 1998 were seasons in the sun for IRB aficionados” (p.1). This statement can be attributed to a number of cases involving research gone wrong that became public knowledge via the popular press. For example, the Olivieri/Apotex case in Toronto was high profile (Baylis, 2004; Ferris, 2004), as was the death of Jesse Gelsinger (Gelsinger, 2000). When the U.S.A. Office for Human Research Protections (OHP) undertook a review of policies regarding research ethics (Henry & Wright, 2001), and then suspended research involving human participants at a number of U.S. university medical schools (D'Auria, 1999), the profile of REBs was again increased, leading to considerable debate regarding research ethics review and how research participants can be protected from harm.

The debate regarding the appropriate review process for academic and non-academic settings is not limited to the United States. For example, in Canada the Interagency Advisory Panel on Research Ethics (PRE) and the Social Science and Humanities Research Ethics Special Working Group

(SSHWC; Interagency Advisory Panel on Research Ethics, 2003; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004) have attempted to address concerns about research ethics review. Similar discussions are taking place in other Western countries, such as Australia and the United Kingdom (Israel, 2005; Jamrozik, 1992; 2000; Jamrozik & Kolybaba, 1999; Mawhood, 1997; Meslin, Rayner, Larcher, Hope, & Savulescu, 1996; van den Hoonaard, 2001). One key issue that continually arises is whether or not the current model of REB review, which was developed for RCTs and experimental work within academic settings, is appropriate for non-experimental studies that take place in the academy and in community settings such as HHSOs (American Association of University Professors Report, 2001; Hoffmaster, 1992; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004).

Edgar and Rothman (1995) refer to the current process in most western countries as the “one-size-fits-all” approach. This is likely due to the fact that the REB process utilized in most academic and research hospital settings has been designed around a natural science model of experimental research and RCTs that began with the post WWII Nuremberg Trials and continues today (Annas & Grodin, 1992; Edgar & Rothman, 1995; Fishman, 1991; Rosnow, Rotheram-Borus, Ceci, Blanck, & Koocher, 1993; Verdun-Jones & Weisstub, 1998). From one perspective, it makes sense to apply the experimental standard of science to gauge the merit of projects submitted to REB review. The natural sciences have been very successful in contributing to explanatory and predictive theory using this methodology because it allows causal attributions to be made. However, the issues addressed and the methods used in the natural sciences are often quite different from those addressed by investigators working in HHSOs, regardless of their academic affiliation or discipline.

To many, the experimental versus non-experimental debate is a historical one that has been settled in that both approaches are now considered valid in scholarly circles. This may be true with regard to the acceptability of a wide range of research methodologies within academic and applied settings. However, some issues are still outstanding such as how ethical reviews should be carried out and in what settings. For example, Flyvbjerg (2001) discusses the “war” that existed between the natural and social sciences over past decades from a number of perspectives, including financial (competition for grant dollars) and political (the ultimate authority to state “the truth”). Throughout his dissertation Flyvbjerg takes the perspective that the social science and humanities should not be judged by the same standards as natural sciences. In short, he argues that one size does *not* fit all and that a different REB review system is necessary for non-experimental research. He is not alone in this opinion (see American Association of University Professors report, 2001; Fairchild & Ronald, 2004; MacQueen & Buehler, 2004; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004; Williamson, Kent, Goodenough, & Ashcroft, 2002).

Flyvbjerg’s (2001) perspective may seem dated for those who have accepted the validity of experimental and non-experimental methodologies as legitimate modalities of research. However, such an enlightened perspective is not universally held in academia, government, or HHSOs. For instance, as recently as 2003 the U.S. Department of Education, an organization that arguably could be considered responsible for some HHSOs, clearly stated that the experimental model of research design was the gold standard for investigations within their purview, even when the study being undertaken was intended to be an evaluation. The Department stated that:

> evaluation methods using an experimental design are best for determining project effectiveness. Thus, the project should use an experimental design under which participants--e.g. students, teachers, classrooms, or schools--are randomly assigned to participate in the project activities being evaluated or to a control group that does not participate in the project activities being evaluated (U.S. Department of Education, 2003, p.62446).

One of the difficulties with this perspective is that HHSOs have a significantly different mandate than do universities and research organizations, and also operate under quite different circumstances. Most importantly, HHSOs usually deal with populations that would require additional attention from REBs if a study came before them for review. For example, if the public school system is considered to be a HHSO, then the individuals included in the study are likely to be children under the age of 18. End-of-life studies may take place in a variety of settings from research hospitals to private facilities, hospices, or via in-home interviews, and may be carried out by academic researchers, HHSO staff or some combination of the two. There is a considerable amount of confusion surrounding appropriate ethics review for situations such as these that take place outside of academia or teaching hospitals, but that deal with disadvantaged populations in circumstances that may significantly impact the lives of those who are studied. For example, with regard to end-of-life studies, Koenig et al. (2003) state that:

> on the one hand, there are instances when IRBs treat patients who are dying as vulnerable and in need of special protections from researchers who seek to study improved pain management techniques or best practices in communication. On the other hand, a patient's 'terminality' may be used to justify exposing that person to *greater* risks than would be allowed with a non-terminal patient. This is most common in the field on oncology drug trials. It is considered appropriate to ask 'terminal' cancer patients to consent to participation in research with no expected benefit (Koenig, Back, & Crawley, 2003, p.5).

End-of-life studies are not the only ones that create controversy. The same issues arise when academics or HHSO staff are working with children, the mentally ill, the infirm or elderly, and so on. The critical point to realize is that if such a study were developed within a university setting, it would necessarily go to REB review. If the identical study was developed within an HHSO, it is quite likely that it would receive no review at all. This is not due to any lack of diligence on the part of HHSOs. Rather it is more likely due to lack of resources, lack of knowledge that such a review might be of benefit to both client and organization, and the fact that there are currently no tools available in the public domain to assist HHSOs in making replicable, transparent and defensible decisions regarding when to seek out the advice of an REB or similar organization.

Without a clear process for reviewing the systematic projects involving human participants in HHSO settings, public trust in those organizations may be eroded. Systematic data collection projects rely on human participation. If the public loses faith in the process, then the creation of new knowledge will be slower as fewer people are likely to become involved in such endeavors. Of course, in HHSOs “participants” are less likely to be volunteers and consequently the work may go on regardless, but the willingness to share findings may be reduced. As such, HHSOs need to do more than just avoid scientific misconduct; they must avoid the *appearance* of scientific misconduct and actively balance the rights and responsibilities of the organizations with those of the individuals they serve.

The issue of appropriate REB review for disadvantaged populations may be attributed in part to the U.S.-based Belmont Report’s (1979) position on the need to balance individual autonomy with the need for protection of human beings (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). From a legislative perspective, it is impossible to anticipate the infinite number of combinations of study intentions, methodologies and populations in order to create concrete legislation or standards for working with vulnerable groups. However, since HHSOs serve disenfranchised groups, appropriate ethical review for systematic studies involving human participants within HHSOs is an important process for reassuring HHSOs that they are operating within the applicable legislation in their jurisdiction. More importantly, it is a critical process for ensuring the privacy and protection of HHSO clients. However, the current REB system is not structured to handle such reviews for HHSOs. Even within academia there is debate as to whether or not the ‘one-size-fits-all’ REB review works well for studies using non-experimental methodology (American Association of University Professors report, 2001; Fairchild & Ronald, 2004; MacQueen & Buehler, 2004; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004; Williamson et al., 2002). For example, one qualitative end-of-life study was required by their REB to include:

> language indicating that confidentiality *could not be guaranteed*, exactly as mandated for studies providing backup data for a new Food and Drug Administration (FDA) drug application. In fact, the researchers *could* guarantee a higher level of protection, since there was no need to preserve the real names of participants in case of an FDA audit (Koenig et al., 2003, p.6).

Koenig et al. (2003) make several recommendations that may help to direct practice, and to focus the conversation and resulting actions when working with potentially vulnerable populations, regardless of whether the study is being carried out by an academic researcher or HHSO staff, and regardless of the methodology employed. Although Koenig et al.’s (2003) recommendations were intended to apply to the U.S., they have considerable benefit for other western

REB processes. Recommendations extrapolated from Koenig et al. (2003) include:

1. Individuals should not be identified as “vulnerable” or in need of special protections based on assumptions alone. Research is needed to determine whether some groups (i.e. children, the mentally ill, individuals nearing the end of life) require special protections.
2. REB members should be educated so that they know how to evaluate the risks and benefits of all of the types of work they see. Alternatively, if comprehensive educational efforts are not possible, REBs can call on ad hoc members with expertise in the area under consideration, or ask for advice from members of the intended population when necessary.
3. Written consent should not be the panacea it has become. Consent forms should be flexible enough to include situations where it may be most appropriate to gain family, tribe or ongoing consent. Further, the project leader should not always have to go through the caregiver to access the potential participant based on assumptions of vulnerability. In effect, this process marginalizes some groups, such as the physically disabled, that may be perfectly capable of making their own decisions regarding participation in studies.
4. Qualitative researchers should be permitted to make changes in the narrative data to protect confidentiality.

5. There should be federal funding allocated specifically to studies of research ethics and the oversight process.
6. In the U.S., sensitive study areas should be added to the DHHS list of types of research that can be issued a “certificate of confidentiality”.[3] This would include such work as end-of-life or assisted suicide studies, where all records cannot be erased because the researchers cannot erase their memories and may therefore be subpoenaed.

Many of the above recommendations share common ground with recent Canadian reports (e.g., Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004). The recommendations add credence to the hypothesis that the current REB system does not serve academics who work in non-experimental modalities very well and that the current REB process needs significant modification to meet the needs of HHSOs, regardless of whether HHSO studies are reviewed by REBs or some other parallel process.

There is an increasing acknowledgement in the peer review literature that sensitivity to the needs of a wide variety of groups is not adequately provided by the REB system that currently exists in North America and throughout most of the West. For instance, a recent paper on the ethics of Aboriginal research (Castellano, 2004), “affirms that Aboriginal Peoples have a right to participate as principals or partners in research that generates knowledge affecting their

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[3] In the United States, some studies can be issued a “Certificate of Confidentiality”. “A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant”. (National Institutes of Health, 2002, p.1)

culture, identity and well-being" (p.98). Similarly, Roberts (2003) states that signed consent forms:

> …provide protection for researchers and ethics committees by providing documentation that ethical procedures have been followed, but poses problems for potential research participants, especially offenders (a unique population). There is a general reluctance amongst offenders to sign consent forms, creating a barrier to participating in research (p. 2).

Although traditionally these issues would be discussed in academic settings, which are the purview of REBs, HHSOs increasingly need the benefit of similar thought and consideration. For instance, it is not possible to randomly assign individuals to conditions such as homelessness, mental illness or incarceration. Nor would it be ethical to do so. Yet these variables are often the very conditions that define the populations served by HHSOs and that they seek to understand. Non-experimental studies carried out in HHSOs or in academia will not be able to determine the "cause" of homelessness, intention to commit suicide, or success in school or relationships, yet these are important social issues. These issues need to be studied in a systematic fashion in order to enable informed judgments on social policy and practice within government and HHSOs. In fact, unlike academic settings where the research agenda is set by the researcher, HHSOs are often required to review their programs and determine whether particular treatment approaches or overall system configuration is effective for the populations they serve. For example, in the province of Alberta, the Health Innovation Fund (HIF) stipulates that each HHSO that receives a grant must evaluate the effectiveness of the program that the grant funds (Howard Research and Instructional Systems Inc., 2001). HHSOs use a wide variety of non-experimental methods in order to provide “proof” of effectiveness in such situations. These systematic inquiries may be called research, program evaluation, quality assurance or some other name. Regardless of nomenclature, all such studies involve information collected from human subjects either directly or from use of secondary data.

The above is not meant to imply that HHSOs do not carry out experimental work. HHSOs can and often do carry out traditional experimental research such as RCTs, particularly in hospital settings. This research can speak to issues of causality. This is an important consideration because results from credible sources often set the agenda for government spending and policy. Such decisions have the potential for significant impact on the funding, data collection and reporting requirements placed on HHSOs. As Congressman John Dingell (1993) pointed out:

> scientific findings largely determine the agendas of government agencies with thousands of employees…the publication of a paper claiming that a food additive causes cancer or that a building material retards the mental development of infants can trigger a massive public outcry and demands for government action (as cited in Altman & Hernon, 1997, p.1610).

An increasing number of experiments are taking place outside traditional research settings, and are instead taking place within government or HHSOs (Ferris, 2004; University of Miami Ethics Programs, 2000). A somewhat extreme example of work considered by some to be research, that may not normally be viewed as such, can be demonstrated by a study carried out in 1993 by the Israeli Ministry of Transportation. The Ministry:

> initiated an ‘experiment’ to raise the interurban speed limit from 90 to 100 kph. The ‘experiment’ did not include a protocol and did not specify cut-off points for early termination in the case of adverse results. After the raise in the speed limit, the death toll on interurban roads rose as a result of a sudden increase in speeds and case fatality rates (Richter, Barach, Ben-Michael, & Weinberger, 1999, p.126).

The above example was clearly considered to be research by Richter et al. (1999), although they do not provide an explanation regarding the criteria used to make such a determination. From their paper it is also clear that human beings lost their lives as a direct result of the study, yet the study was not submitted for REB review because it was regarded to be government policy work rather than research.

Some other examples may be of assistance in understanding how experimental and non-experimental research methods are being applied outside of traditional research environments. For instance, curricula within school settings are changed with the intention of improving student performance and outcomes. Within mental health care systems treatment methodologies may be changed radically based on the background and preference of senior management. Such changes have the potential to significantly impact the lives of those individuals who “participate” in the revised approach to service delivery.

However, such work is rarely, if ever, subjected to REB review. This is perhaps based on a perception that such change is policy-based rather than research work. Consequently, much like stage 1 clinical trials, such work is rarely discussed within the context of REB review. Although the outcome is unknown, the “participants” are not volunteers, and the potential for harm to human beings may be quite large, even death, as in the case of the Israeli experiment, or as can be the case in health organizations. For example, if the Province of Ontario makes a health policy decision to discontinue the large number of Assertive Community Treatment (Research) teams that they currently have in operation to serve the severely and persistently mentally ill, there is the likelihood that implications such as decreases in quality of life, homelessness and even death might result. However, it is unlikely that such a change in practice would be reviewed by an ethics committee.

If any of the above studies took place within an academic setting, they would certainly go for REB review. This is not the case in most HHSOs. Clearly there is a double standard in the protections that are offered to study participants within academia but also between settings (i.e., academic and HHSOs) (Arboleda-Florez & Holley, 1997; Brent et al., 1993; Doyal, 2004; Lynn, 2004; J. I. Martin & Meezan, 2003; Motto & Bostrom, 2001; Nelson, 1987; Santiago-Rivera, Morse, Hunt, & Lickers, 1998).

Some universities may form partnerships with HHSOs in order to carry out field research involving human participants. For example, in the Calgary Health Region (CHR), it is common for the Information and Evaluation Unit to receive at least one request per month from academic researchers who wish to access mentally ill individuals being treated via CHR programs in order to carry out research. The methodologies employed by such researchers vary widely from RCTs to qualitative interviews and case studies (Arboleda-Florez & Holley, 1997). CHR staff suggest studies involving human participants or data collected on them for a variety of reasons. Some do so because they are adjunct university faculty looking for publishable material, some because they are working through university programs and others because they have a desire to better understand their clients, their treatment programs and how to improve outcomes for the people they serve.

The above is not meant to imply that HHSOs should or will begin applying en masse to university based REBs, only that there is confusion regarding what ethical standards need to be met for studies involving human participants carried out by HHSOs that are not affiliated with any academic institution. It is somewhat unlikely that HHSOs would want REB reviews in significant numbers, and even less likely that university based REBs would be able to accommodate them. The literature is thick with stories of multi-site studies, qualitative and quantitative, where REB approval was required from a series of REBs and where each REB tinkered with the methodology, causing long and costly delays for researchers (Jamrozik, 1992, 1997, 2000; Jamrozik & Kolybaba, 1999; Koenig et al., 2003). Calls for greater consistency in the REB process, particularly in North America, are frequent (Hyman, 2000). The American Association of University Professors concluded that:

> IRBs, in carrying out their responsibilities, too often mistakenly apply standards of clinical and biomedical research to social science research, to the detriment of the latter; its central recommendation is that IRBs can and should do more to take into account the pluralistic nature of academic research that is subject to their review (American Association of University Professors report, 2001, p.2).

HHSOs are likely to be aware of the challenges faced by REBs, and reluctant to invest time and resources into a process in which they might not need to participate. However, HHSOs still require some method for determining when a project includes variables that should serve as warnings that the study requires ethical scrutiny. Current legislation and policy lends little guidance for HHSOs that carry out systematic investigations involving human participants. For example, U.S.-based studies that are funded by federal dollars would look to the Title 45 regulations, which state that:

> research means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes (Department of Health and Human Services, 1997, p.6).

As mentioned, HHSO's may use experimental methodologies in some quality assurance and program evaluation work. Since generalizablity is based on methodology, Title 45 would seem to indicate that such work becomes research because of the methodology used. Consequently, if an HHSO is funded by any of the 17 federal agencies that fall under Title 45, it would have to determine whether an REB review was required. It would then face the additional challenge of gaining access to an REB.

Non-experimental work, particularly that which uses qualitative methodologies, often does not have generalizability as an intended study goal (Christians, 2000; Creswell, 1998; Koenig et al., 2003; Mays & Pope, 2000; Oral History Association, 1989; Salomon, 1991; Shadish, 1995). Consequently, if the letter of the law is adhered to, it would seem that a case could be made for not subjecting qualitative work to REB review. This is not current practice in the U.S. or elsewhere. Nor should it be; harm can certainly be done by interviewing the family members of individuals who died by suicide just as surely as harm can be done by RCTs. This example merely serves to demonstrate that current REB policies and practices in effect throughout North America and most Western countries do not adequately accommodate the myriad of possibilities that exist in systematic data collection projects involving human participants across disciplines and settings. This is true within academia but more particularly within HHSOs. As a result:

> many faculty who engage in institutional research are simply confused by the perceived inconsistent positions of IRBs at different institutions. Frequently we hear that local IRBs don’t review research involving data from program evaluation. In other cases, some hospitals exempt all educational studies. Michigan State University’s application of the federal

> regulations requires IRB review for even minimal-risk routine program and student evaluations if the data are disseminated as scholarship (e.g., generalizable knowledge) (Henry & Wright, 2001, p.875).

The confusion referred to by Henry and Wright reverberates through much of the literature on ethics across academic disciplines and study settings. Given the plethora of policies and regulations that currently address the need for REB review (e.g., Canadian Institute for Health Research, 2000; D. Casarett, Karlawish, & Sugarman, 2000; Department of Health and Human Services, 2001; Health and Wellness Alberta, 2001; Interagency Advisory Panel on Research Ethics, 2003; King, Henderson, & Stein, 1999; Lowman & Palys, 2002; Manitoba Health, 2001; Meslin et al., 1996; National Council on Ethics in Human Research, 2001; New Zealand Ministry of Health, 2002; Sieber, 1993; The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983; Van McCrary et al., 2000; Verdun-Jones & Weisstub, 1998), it appears that more piecemeal policy and legislation will not solve the problem of confusion and inconsistent interpretation of policies. Nor is it likely that additional bureaucracy will improve the protections afforded human participants of systematic investigations or ensure that the values of society at large are included in the decision-making process. Rather, HHSOs need a way to make replicable, transparent and defensible decisions regarding whether a study involving human participants requires further ethical review with the key intention of protecting the people they serve.

From the above it should be clear that HHSOs are carrying out studies that utilize experimental and non-experimental methodology involving human participants. Some organizations, such as the AMHB and the CHR, have internal processes to evaluate the administrative impact of such studies. However, administrative review is not equivalent to REB review. Although the literature review for the current dissertation was extensive, no information was found referring to REB review procedures within HHSOs, with the exception of teaching hospitals that conduct RCTs and experimental treatments or technologies (Griener & Storch, 1992; Meslin et al., 1996; Neff-Smith, Giles, Spencer, & Fletcher, 1997). There was relatively little information regarding formal or informal linkages between HHSOs and experienced REBs, such as the partnership between the CHR and the University of Calgary, where university-based REBs would potentially review systematic studies involving human participants to be carried out by the HHSO (Ferris, 2004). There is insufficient evidence to comment on whether or not other such partnerships exist.

Further, even if such partnerships do exist, the responsibility for reviewing community-based systematic studies involving human beings should not rest on the shoulders of the university REB system. Such studies are beyond their purview in all Western countries except New Zealand. Since HHSOs do not have the expertise, mandate or specifically allocated funds to establish and operate REBs (Health Systems Research Unit, 1997), much of the work that would be reviewed if it took place in a university setting receives no review at all when carried out by an HHSO.

Lack of an appropriate REB process for HHSOs has several serious implications. First, it lessens the likelihood that a thoughtful discussion of the ethical implications of a particular study will take place. The most commonly used North American REB process does not allow for public discussion outside of the REB, and the discussion of the REB or research program is usually carried out behind closed doors (Ashcroft & Pfeffer, 2001; Fischer, 2001; J. S. Jones, White, Pool, & Dougherty, 1996; Lock, 1995; J. B. Martin & Kasper, 2000; McCarthy, 1998; Schneider, 2001). Second, lack of an appropriate REB review is a value judgment regarding the importance of the undertaking in question, both in terms of potential harm to participants and with regard to the importance of study findings. Third, the HHSO may be caught in a "Catch 22" where access to information for the study requires ethical review, but ethical review is not available. This scenario is becoming increasingly likely as privacy legislation at the federal, provincial/state and regional/organization levels is created that may require REB clearance in order to access information (Ministry of Health and Wellness (Alberta), 2001; Manitoba, 2001). Fourth, it may perpetuate the belief that experimental work places participants at greater risk than non-experimental work. Fifth, there is a lingering belief that RCTs are the gold standard for research. This is clearly the case in some U.S. policy documents (U.S. Department of Education, 2003). Sixth, an increasing number of peer review journals and professional associations require submissions to have had ethical review to be considered for publication (Bordage, 2001). Although proof of REB approval is rarely required by journals unless the issue of ethics becomes a concern during the peer review process, this standard may be used to effectively shut the door on publications that result from studies that did not, or could not, seek REB approval. Consequently, access to a credible ethics review process can be equated with the ability to create and publish new knowledge.

This latter point creates a moral and ethical dilemma for HHSOs. Such organizations are primarily funded by public dollars and are, therefore, responsible to the public. They have greater access to, and responsibility for, individuals who need more protection due to illness or other health and social factors than do universities. The studies involving human participants carried out within HHSOs use the same methodologies as studies that emerge from academia and, therefore, may have the same ability to inform decisions and form the basis of what is regarded as credible knowledge. Further, as publicly funded organizations dealing directly with human beings, the moral obligation to publish and present the studies they carry out is at least as pressing as the requirement for university-based researchers to publish their findings. In essence, when studies are funded by public dollars, publication should always be a consideration.

Although HHSO studies are usually outside the purview of university- or research hospital-based REBs, it is important to acknowledge that the academic REB system is also the gatekeeper for resources that may be allocated to systematic data collection studies. For instance, in Canada there are many organizations that provide grants for research. The three primary national granting organizations are the Social Sciences and Humanities Research Council

(SSHRC), the Canadian Institute for Health Research (CIHR), and the National Science and Engineering Research Council (NSERC). Although there was never an actual “Tri Council”, these organizations, which were created by an act of the Canadian Parliament in 1977, together created the Tri-Council Policy Statement (TCPS), which has shaped much of the current Canadian context with regard to when REB review is necessary. Each organization has significant dollars to spend on research. The 2004-2005 budgets for SSHRC, CIHR and NSERC were $230, $662 and $760 million respectively (Canadian Institutes of Health Research, 2004; Canadian Institutes of Heath Research, 2004; Natural Sciences and Engineering Research Council of Canada, 2004; Social Sciences and Humanities Research Council of Canada, 2004).

Access to grant dollars is often prefaced by the explicit requirement to have REB approval for the study. Consequently, studies that do not have access to an REB, even if they are led by a Ph.D. trained individual who works in the community but is not affiliated with a university, cannot access available grant dollars. As a result, HHSOs often fund studies themselves out of operational dollars, as is the case in the CHR. This is not an optimal methodology if the goal is to ensure that studies carried out within HHSOs are of good quality and not influenced by political whims (Health Systems Research Unit, 1997). With an appropriate screening method to determine which systematic studies originating from HHSOs should be reviewed, university-based REBs may be more willing to form partnerships with HHSOs to review such studies. Such a screening instrument may also demonstrate the need, if such a need exists, to establish an REB system for HHSOs.

Primary Research Questions

In summary, HHSOs must “prove” that the programs and services they offer serve the intended population and generate positive results. They may call such work quality assurance, program evaluation, accreditation, research or some other name. The methods utilized range from experimental/RCT to non-experimental work, and the studies are carried out by individuals from a wide variety of disciplines. Most studies in HHSOs involve human participants or the data gathered from them. A system of REB review does not appear to exist in HHSOs as it does in academic settings. This causes confusion among HHSO staff, and establishes the potential for harm to individuals whose information may be used in such studies and to the professional reputations of those who carry out the work. Further, it also opens the door for HHSOs to misinterpret privacy legislation that applies to their organizations.

The current ethical review system impacts many groups and individuals, not just researchers and the organizations for whom they work. There is little doubt that the “one size fits all” approach to ethical review is not working well (Edgar & Rothman, 1995). There is also little doubt that, “medical or bio-ethics has in recent years been a growth industry” (Weisz, 1990) that is threatening to crush experimental and non-experimental studies under the weight of regulations, policies and practices, and which adds considerable burden to those involved in the practice but diminishing returns to those the legislation is intended to protect. There is also increased awareness that North American values and procedures around ethical review may be disrespectful of the perspective of the developing world and of cultural traditions of many groups (Bankowski & Bryant, 1985).

“Recently, work carried out by the National Bioethics Advisory Committee and regulatory agencies such as the Office of Human Research Protections documents a growing recognition that the entire system is in need of reform” (Koenig et al., 2003, p.4). Koenig et al. (2003) indicated that the path intended to be taken in order to address reform is identical to the process that brought the U.S. to its current state: more regulation. Both the National Science Foundation and the Institute of Medicine of the National Academy of Sciences have convened expert groups to make recommendations about whether revisions in the system are warranted, and a significant paper on the issue of system reform to possibly make adaptations for experimental versus non-experimental studies has recently been completed in Canada (Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004).

From the above it is clear that the REB system is in need of reform, and that HHSOs have a need for ethical review but are largely being left out of the discussion. As the debate continues, the most pressing need for HHSOs from an operational ethics perspective is the need for a method to make replicable, fair and defensible decisions regarding the level of scrutiny that must be given to studies carried out under their authority. Consequently, it should also be clear that the primary question for this dissertation is not “what is research”, but rather “how do we best protect human beings from potentially harmful studies, regardless of where in the world, country or community those studies take place”. It is the intention of this dissertation to determine if international experts from the areas of quality assurance, program evaluation, research across academic disciplines and settings, REB experts and those who must manage such endeavours agree on the variables they consistently use to determine whether a study requires REB review in a full or expedited fashion. If such consensus exists, the variables will be utilized to develop a Research Ethics Decision Guide (REDG). The purpose of the Guide would be to assist HHSOs, and/or the organizations that fund HHSOs, in their efforts to separate those studies that require some form of ethical review from those that do not.

This is a small but necessary first step in determining whether HHSOs require REB or similar review for systematic studies involving human beings and/or the data gathered from them. If development of a REDG is possible, it will help HHSOs to make good decisions regarding whether such studies require ethical review, and will help to generate discussion regarding ethical considerations even if REB review is not available. Further, the REDG may be used over time to determine whether an REB process should be established for HHSOs.

CHAPTER TWO: METHOD

In order to develop the REDG for the use of HHSOs regarding when to seek ethical advice for systematic studies involving human participants, several approaches to data collection were undertaken. The research methods utilized were both qualitative and quantitative. The qualitative component involved an initial literature review to identify key domains and variables. A domain is a “field or scope of knowledge or activity”. A variable is “any member of a class of entities” (Collins Concise Dictionary Plus, 1989). Throughout this dissertation ‘domains’ are considered to be distinct areas of knowledge with regard to research ethics, such as risk of harm. ‘Variables’ are a subset of domains and are the more specific features which comprise, and, hopefully, fully describe and capture the meaning of the domain.

In addition to the initial literature review, the process also included (a) preliminary interviews with the Alberta Mental Health Board Scientific and Administrative Review Committee (SARC) and the Alberta Heritage Foundation for Medical Research (AHFMR) Consensus Initiative Working Group, an investigative team examining this issue (Pachnowski, 2003); (b) survey and semi-structured follow-up interviews with subject matter experts (SMEs) in research ethics; (c) semi-structured interviews with research participants; and (d) consultation with University of Calgary librarians in order to distill data gathered from the above process and use it to optimally expand the academic and grey literature review for a second round. The quantitative aspect of the work primarily took the form of an international survey of experts in the areas of research ethics boards, research, program evaluation, quality assurance and administrative responsibilities for these areas, and the analysis of the survey results.

Much of this dissertation is focused on identifying domains and variables used by experts to make decisions regarding the need for REB review. Consequently, before proceeding further, it may be useful to explain that REB review is an administrative procedure, usually supported by policy and/or legislation. "The mission of an IRB is to protect the rights and welfare of human research participants" (Amdur & Bankert, 2002). It most often take the form of a board or committee, usually staffed by volunteers from the organization, although most boards also attempt to have a layperson on the board as well as a lawyer or someone knowledgeable in legal issues related to research (Amdur & Bankers, 2002; Interagency Advisory Panel on Research Ethics, 2003; New Zealand Ministry of Health, 2002). Individuals who participate on the boards must make decisions about the risk of harm to potential participants. 'Risk of harm" is mentioned in nearly every key document reviewed as part of the method employed in this dissertation. It is a "domain" because it covers a wide field of knowledge. There are many potential variables that experts might consider when deciding how high risk a study is. For example, they might discuss the qualifications of the project leader, whether the proposed procedure is invasive and, if so, to what degree and whether any adverse effects might result from the study. If a domain can be considered a diamond, the variables are the various facets of the diamond which must be examined in detail to determine the worth, or, in this case, the meaning, of the whole. The majority of the methodology in this dissertation was undertaken in order to determine the key domains used by experts to make decisions and the variables contained within each domain.

Many of the data collection steps were undertaken simultaneously. For example, an exhaustive literature review was continually taking place at the same time as experts were being interviewed and surveyed. This approach made the most sense since many of the topics requiring examination of the academic and grey literature were identified via the interviews with experts. However, for the sake of clarity, a rough time sequence of the methodology follows:

1. A review and summation of the academic and grey literature.
2. Preliminary interviews with knowledgeable individuals (AMHB and AHFMR) to sharpen the research question and to seek advice regarding methodology and individuals to include on an international advisory committee for the study.
3. Survey and semi-structured interviews with subject matter experts who agreed to be members of the international advisory committee.
4. Semi-structured interviews with people who had participated in a systematic data collection project (research, program evaluation or quality assurance).
5. Clarification of policies and procedures regarding proof of REB approval prior to publication for several peer review journals in the areas of medical research, program evaluation and quality assurance.

6. Using the points of consensus and divergence gathered from steps 1 – 5 above, a secondary review of the academic and grey literature. This additional examination of the literature was carried out with the specific intention of ensuring that all recommendations from the SMEs had been included in the literature review and would therefore be included in the development of the international web-based survey.
7. Development and administration of a web-based, English language survey of individuals who were identified as highly knowledgeable or expert in at least one of five topic areas including research, program evaluation, quality assurance, research ethics boards or REB policy and practice.

Each of these methods will be described in turn.

Literature Review

An extensive literature review was necessary to conduct this research in a meaningful manner, as the dissertation topic crosses many academic disciplines and organizational settings. In order to determine all of the variables experts might consider in deciding whether a systematic study required a full or expedited REB review, a thorough review of the academic and grey literature was necessary. The literature review was conducted with the assistance of the University of Calgary library staff in order to ensure that all potential sources of variables were included. This required investigation into the fields of medicine, psychology, social work, philosophy of science, sociology, epidemiology, quality assurance, program evaluation, and law.

A significant amount of information came from the “grey” literature. Grey literature included reputable authorities, often websites of governmental and quasi-governmental organizations, such as the Aurora Research Institute (Northwest Territories) the National Council on Ethics in Human Research (NCEHR) listserv,[4] the three main granting bodies in Canada (SSHRC, NSERC and CIHR), and so forth. The variables identified via the literature review were combined with the variables identified via interviews and the review of publication standards. The purpose of this comprehensive review was to identify those variables used to make the decision to review a study for ethical issues. In keeping with APA standards (Cone & Foster, 1993), the results section was the most appropriate location within this dissertation document to place the data collection from the literature review.

Although these variables almost exclusively applied to academic settings because that is the primary setting for REB review, the variables should serve as a reliable indicator of societal values regarding which projects should be reviewed, regardless of setting, if the primary goal is to protect human beings from being harmed by studies. In order to make the lessons learned from the literature review more coherent for readers, the review has been split into several parts. The first part has been used to build a case in the introduction for why the research was undertaken in the first place. The second part is presented in the results section, since the results provided the data necessary to select the

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[4] The NCEHR listserv is an unmoderated web-based discussion group primarily made up of individuals who work in the area of research ethics. One must apply to participate in the list and the forum provides an excellent method for those who are responsible for REBs or related activities to discuss the rapidly changing landscape of this field.

appropriate domains and variables for the international survey. The third part of the literature review has been incorporated into several of the Appendices. Appendix A includes a discussion of the “what is research” question. This question is closely related to the current work and is often where HHSOs and researchers in the area become bogged down in theoretical questions that are unlikely to be of assistance on a practical level. Appendix F provides information regarding the populist approach to REB review in use in New Zealand.

The New Zealand system is quite different from those used in other Western countries and, although an indepth examination of the New Zealand system is beyond the scope of this paper, the system does offer some lessons that may be beneficial to other Western countries as they attempt to deal with the issues of protecting human participants in systematic studies, regardless of the setting. Furthermore, the New Zealand system may provide some useful guidelines for HHSOs or the organizations that fund them if it is determined in the future that HHSOs require an arms-length ethical review process to meet their needs. Consequently, basic information and some references are included in Appendix F for those who want to know more about the New Zealand system.

Preliminary Interviews

The dissertation data collection process began with interviews that took place as part of the author’s responsibilities as Provincial Program Evaluation Manager for the Alberta Mental Health Board (AMHB). This position included responsibility for oversight of program evaluation projects within the AMHB and, in some cases, the 17 health regions in the province. It quickly became clear that project leaders were encountering difficulty in conducting their studies, most of which were intended to evaluate HHSO programs in order to improve performance.

Virtually all studies involved human participant (client) involvement via inclusion in new treatment techniques, or by collecting unique and time-limited data to evaluate the program, or involved a review of the client's case file data. The team leaders were receiving many questions related to ethical review and access to client data from program managers and front line staff in the programs they were evaluating. Project leaders were often asked whether or not a given project had been approved by an REB. Some staff members were adamant that all clients or patients involved in the study sign an informed consent form, even though the work being carried out was not intended to be academic research and was, in fact, intended to improve program or service delivery, which is the moral obligation of HHSOs. Others felt that they could not provide information on the clients they served, or the outcomes achieved with their clients, because their professional ethics prohibited such actions. This was also true of other HHSO organizations that were partners in the work, such as the Canadian Mental Health Association or the Calgary Police Service. This reluctance to share individually identifiable information did not appear to be due to any reluctance to improve services for clients. Rather, there was a great deal of confusion regarding the need for REB review and whether REB review was required for all systematic investigations involving human subjects given the recently introduced Health Information Act in Alberta (Health and Wellness Alberta, 2001).

HHSO organizations attempted to address this uncertainty in interesting ways. Some, for example, decided that if the intention of the project leader was to publish the work then it required REB review, although not necessarily informed consent.[5] Others requested informed consent from participants without going through an REB process or ensuring that the informed consent form met acceptable standards. Still others determined that they would adhere to the standards of their professional associations (which often meant that they would not provide any individually identifiable information on their clients).

The responsibilities of the AMHB Provincial Program Evaluation Manager also included participation as an ad hoc member of the Scientific and Administrative Review Committee (SARC). One of the intentions of SARC was to review study proposals that were to be carried out in AMHB settings or with AMHB clients. SARC is composed of academic researchers who were knowledgeable in many specialties related to mental health research.

The lack of clarity regarding which projects required ethics review quickly became apparent because it was commonplace for quality assurance or program evaluation studies to be submitted for review along with research proposals. This situation amplified the need for clarity on a pragmatic level regarding how to differentiate those projects that needed review from those that did not. Without such guidance, quality assurance and program evaluation work would quickly grind to a halt and the SARC would be overwhelmed with requests for reviews,

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[5] This reasoning was why the current study was expanded to include a brief review of some of the better known journals in each field to determine if the journals actually required proof of REB approval prior to publication.

much as an academic REB might be should they agree to review studies from HHSOs. Several conversations took place between members of the SARC in order to solidify the research question and methodology for the current study.

In order for the reader to gain some sense of the expertise of the individuals on the SARC, the most recent membership list available is included below. The AMHB divested all of the service delivery components of its work to the Regional Health Authorities in April of 2003, and as a result the SARC no longer exists. Scientific and administrative review of systematic projects involving human participants is now the responsibility of each region individually within the province of Alberta. Membership in the SARC is a matter of public record.

Table 1

AMHB Scientific and Administrative Review Committee Membership 08/13/01

SCIENTIFIC AND ADMINISTRATIVE REVIEW COMMITTEE (SARC)

MEMBERSHIP LIST – August 13, 2001

MEMBER
Dr. Carol E. Adair (chair) Director, Research Program Alberta Mental Health Board
Dr. Hugh Colohan Clinical Director, Claresholm/ Raymond Care Centres Alberta Mental Health Board
Ms. Helen Gardiner (ad hoc member) Manager, Evaluation Services Research Program Alberta Mental Health Board
Dr. Anthony Joyce Department of Psychiatry University of Alberta
Dr. Bonnie Kaplan Behavioural Research Unit Alberta Children’s Hospital
Dr. John C. Lind Quantitative Psychologist Clinical Diagnostics and Research Centre Alberta Hospital Edmonton
Dr. Stephen Newman Department of Psychiatry University of Alberta
Dr. Scott Patten Associate Professor University of Calgary Department of Community Health Sciences

MEMBER
Dr. Bruce Perry Medical Director Children’s Mental Health Initiative
Dr. Scot E. Purdon Clinical Neuropsychologist Alberta Hospital Edmonton
Ms. Karen Omelchuk Manager, Development and Administration Research Program Alberta Mental Health Board

Note. The above indicates the composition of the SARC at the time the Principal Investigator began preliminary interviews.

In addition, several focus groups were held with people who were not experts in REB procedures but who had participated in at least one systematic study. The majority of these individuals had experienced mental illness and had come into contact with studies via their mental illness. Responses from this group regarding what studies should be reviewed or whether reviews should be conducted at all were quite different compared to the information gathered from other sources.

The information collected through conversations with those who submitted work for SARC review, the members of the Committee, academic researchers at the University of Calgary and the University of Edmonton, as well as community stakeholders, was compiled and organized together with the literature review. This information formed the basis for a structured interview and survey intended for a small number of experts in field of REBs. The purpose of the structured interview was to gain additional clarity and understanding regarding the key domains and the variables that made up each domain as used by experts to distinguish those studies which required no REB review, expedited review or full review.

Subject Matter Expert (SME) and Semi-Structured Interviews

As described above, experience has shown that there has been confusion in applied HHSO settings such as the AMHB regarding when to apply for REB review among clinicians, managers, researchers, program evaluators and other stakeholders in HHSOs. Also, individuals who had been participants in systematic studies indicated that ethics review was not important to them and was not influential in their decision to participate in a study. Consequently, it was desired that SMEs from the areas of program evaluation, research, quality assurance, REBs and those who were responsible for the oversight of such endeavours would be able to provide more insight into the domains and variables that differentiate those projects that should go to REB review from those that should not. SMEs were identified and asked to participate on an advisory board, and Tables 2 and 3 present the list of those individuals who agreed to participate. Each individual provided verbal consent to include their name in the current document.

Table 2

National and international members of the Dissertation Advisory Committee

Name	Affiliation
Brunt, Dr. J. Howard	Associate Vice President, Research University of Victoria Chair, Interagency Advisory Panel on Research Ethics (PRE) Dr. Brunt was appointed chair of PRE in 2002.
Casarett, Dr. David. MD, MA	University of Pennsylvania Author of several highly cited articles on the subject of when quality assurance and program evaluation should be subject to REB review.
Idänpään-Heikkilä, Dr. Juhana E. MD, PhD	Secretary-General Council for International Organization of Medical Sciences (CIOMS) CIOMS is an international NGO, NP, organization established by WHO and UNESCO in 1949. Knowledge in research in third world countries.
Palys, Dr. Ted S.	Associate Professor Simon Fraser University School of Criminology Written extensively on the topic including comparison of U.S. and Canadian systems. Widely cited. Active participant on NCEHR.
Stacey, Dr. Terry	Director, Central Office for Research Ethics Committees London, England W2 3QR COREC works on behalf of the Department of Health. They coordinate RECs, provides training and advice on policy and operational matters to RECs.
Storch, Janet L. RN, PhD	School of Nursing University of Victoria Past President, NCEHR Facilitated the development of the Case-Based Learning for Canadian REBs (2000) book.

Table 3

Alberta members of the Dissertation Advisory Committee

Name	**Affiliation**
Bowker, Neil	Chair of the Community Research Ethics Board of Alberta (CREBA)
Desai, Dr. Sunil	Chair, Alberta Cancer Board Research Ethics Committee
Doig, Dr. Chip	Chair, Conjoint Faculties Research Ethics Board University of Calgary Assistant Professor Departments of Medicine and Community Health Sciences
Douglas-England, Dr. Kathleen	Calgary Health Region, Program Evaluation Manager, Children's Mental Health Calgary Health Region Children's Hospital
Enzle, Dr. Michael E.	Chair, U of A REB Office of the V.P. (Research and External Affairs)
Falkenberg, Dr. Loren	Chair, Research Ethics Policy Committee Faculty of Management, University of Calgary
Godlovitch, Dr. Glenys	Associate Professor, Community Health Sciences, University of Calgary Expert in New Zealand REB procedures
Mitchell, Dr. Ian	Director, Office of Medical Bioethics University of Calgary
Mueller, Dr. John	Division of Applied Psychology University of Calgary
O'Beirne, Dr. Maeve	Department of Community Health Sciences Faculty of Medicine University of Calgary
Venner, Dr. Peter MD FRCPC	Senior Medical Oncologist Cross Cancer Institute Professor of Oncology Division of Medical Oncology University of Alberta Chair, College of Physicians and Surgeons

Name	Affiliation
	Research Ethics Review Committee (CPSAREB)
Warren, Dr. Sharon	Chair, Health Panel B: Health Research Panel Health Research Ethics Board University of Alberta
Windwick, Brent F. BA Hons, LLB, LLM, Cantab.	Executive Director The Health Law Institute Law Centre University of Alberta
Work, Frank	Privacy Commissioner Office of the Information and Privacy Commissioner

A package was sent to each Advisory Board member and is included in Appendix B. The responsibilities of the board members were significant as the following list indicates. Each member was asked to:

#1. Read and analyze a package of six vignettes and decide whether each one should be submitted for REB review. A short explanation was requested for each decision. The vignettes were based on carefully selected factual instances[6] where considerable disagreement surrounded the decision of whether or not to submit it for REB review, and where the final decision was known. Consequently, it was possible to compare the decisions of the SME Advisory Board members to the decisions made by the REBs that reviewed the vignette cases.

#2. Review and comment on survey components consisting of items that could then potentially be organized into domains and variables. At this point the Principal Investigator had already organized the items into

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[6] Please note that although factual instances had been utilized to develop the vignettes, all identifying details had been removed or altered sufficiently to disguise the origin of the projects.

domains and variables. However, in order to avoid biasing respondents, the information sent to Advisory Board participants simply listed all variables as “items”. Board members were asked to indicate whether they considered each item when thinking about the whether a study required review and what level of review (none, expedited or full REB) might be best. The purpose of this undertaking was to determine whether all variables that might possibly influence a decision regarding the need to have full or expedited REB review would be considered, and whether the variables had been grouped appropriately. This was necessary to ensure the comprehensiveness of the planned international survey. It was also necessary to ensure that the resulting REDG could apply across academic disciplines and organizational settings, as well as to prepare for the possibility of a confirmatory factor analysis in the event that a sufficient number of responses were obtained in the international survey of experts.

#3. Once each Advisory Board member had responded to the vignettes, completed the survey component and returned the information to the Principal Investigator, they were asked to participate in a semi-structured interview to review their feedback. This offered Advisory Board members the opportunity to expand their answers, to raise any questions they might have regarding the process and, in general, to ensure that the Principal Investigator had considered all the important issues and that the intended process would result in worthwhile information.

#4. If sufficient international web-based surveys were collected and consensus existed on some of the variables on this survey, an REDG would be developed. The Advisory Board members were asked if they would be willing to validate the REDG by reviewing a new package of vignettes using the draft REDG. This was designed to establish the utility of the REDG for decision making and to determine inter-rater reliability. In addition, Board members were invited to provide feedback on the process.

#5. Review the final version of the validated REDG and provide comments.

#6. If panel members were sufficiently interested, they were also provided with a copy of the final research paper for comment.

It is important to note that the Principal Investigator knew in advance that all of these individuals are exceptionally busy people and that the vignettes, survey and interview required a significant commitment of their time. Consequently, although it was hoped that each person would be able to respond, a fairly low response rate was not outside the range of possibility. Given the time pressure experienced by most of these individuals, and the fact that this dissertation was under time constraints as well, the Principal Investigator is grateful to those individuals who took the time to participate.

Peer Reviewed Journal Publication Standards

Many individuals, including SMEs, indicated that one key variable that distinguished studies that must go for ethics review from those that did not was the intention to publish in peer review journals. This makes some sense in that protection of human research participants and their confidential information/privacy is the reason most often given for requiring REB review. Although “protection” can be construed in many ways, it is often espoused to be a valuing of privacy and of a life that is free from the unethical conduct of researchers. Publication of research findings is the logical conclusion to undertakings that expand knowledge in a significant way. The Council of Biology Editors Inc. states that, “writing is not extrinsic to research: it is inevitably a part of it, since research is not complete until it is published.” (Woodford, 1986, p.6). Consequently, peer reviewed journals are a logical lens through which research ethics practice can be viewed. The policy of relevant journals regarding the need for REB review in studies involving human participants demonstrates in part the actual value placed on REB review by the academic press as opposed to the espoused values.

In order to investigate this perspective, journals were selected from the research, program evaluation and quality assurance fields. In addition, respected medical journals were included for review since research, program evaluation and quality assurance work involving human participants often overlaps with medical practice. Medical settings are also where some of the most contentious debates occur regarding the need for REB review. A total of sixteen journals were contacted.

The journals were selected on two criteria only: that they employed a peer review process and that they represented journals that regularly publish empirical articles from researchers, program evaluators or quality assurance professionals. No attempt was made to identify the “best” in any of the areas of interest.

The “Instructions to Authors” material was obtained from each journal. In each case the Information for Authors was reviewed along with associated reference documents cited including, for example, the CONSORT guidelines (Moher, Schulz, & Altman, 2001) and the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors, 2004). When specific policy regarding proof of REB approval was not mentioned in the instructions to authors, the journals were contacted in order to clarify their policies around proof of REB review.

International Electronic Survey

The culmination of the research was the development, piloting and web publication of an international electronic survey that included questions based on the domains and variables developed during the process described above.

A decision had to be made regarding how to conduct the survey. Essentially there were two choices. The first was to continue with utilization of the vignettes and corresponding questions, which had been carefully developed to represent “real world” situations that might be faced by HHSOs and REBs. It was clear that experienced individuals rarely made decisions regarding whether a project requires review based on a single variable. Therefore, the advantage of the vignette approach was that it allowed for richer responses from survey participants. However, the experience with Advisory Board SMEs to this point indicated that such an approach was likely too time consuming and potentially complex for an international survey that could not be followed up by interviews.

The second approach, and the one ultimately taken, was to simplify the process as much as possible. This meant developing survey items based on the variables that comprised each domain and dealing with each domain in isolation, as though each item was the only issue under consideration across all studies submitted for review. This was likely to boost the response rate but also to somewhat aggravate experts who would view such an approach as simplistic. However, without data no progress in this area would be possible and consequently the decision was made to go with the more simplistic variable-by-variable approach in the hopes of obtaining a higher number of responses. With a higher number of responses, a confirmatory factor analysis could be carried out, which would address the issue of decision making based on multiple factors and determine whether the variables actually grouped according to the identified domains.

Consequently, the web-based survey was developed and piloted according to the second option. Leading organizations for researchers, including biomedical researchers, applied researchers, program evaluators, quality assurance professionals, managers of such operations and policy experts were approached and asked to complete the survey. The full survey is included in Appendix C.

Members from four different organizations were specifically invited to respond to the survey. The organizations included the American Evaluators

Association, the Canadian Society for Epidemiology and Biostatistics, the Canadian Evaluation Society and the International Society for Quality in Health Care. In each case the organization was approached with a request to sample a randomly selected group of 285 from their organization.[7] Although it would have been beneficial to adhere to a set protocol for each organization, this was not possible as the Principal Investigator had to work within the constraints of each organization and each had a somewhat different response to the request.

The American Evaluators Association provided the Principal Investigator with the full AEA membership list with the caveat that the list could only be used in conjunction with the randomizing function in SPSS to select 285 AEA members. These were the only members who could be contacted and no additional members could be selected. These individuals received the full Dillman method (see below).

The Canadian Evaluation Society could only offer to post the survey invitation and link to the survey on their website. Reminder notices following the Dillman method were similarly posted to the main website rather than being sent to individuals.

The Canadian Society for Epidemiology and Biostatistics allowed the author to use the complete Dillman method with their entire membership, rather than randomly selecting 285 members. The CSEB is a very specialized group

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[7] Based on the Dillman literature (see below) and other sources, a 30% response rate was considered conservative for a web-based survey following the Dillman technique. If a 30% response rate had been achieved across organizations, the total number of responses would have been 342. This would be sufficient to carry out a confirmatory factor analysis while at the same time conserving resources.

and consequently has a small membership. At the time of this study the membership was close to 400 people.

The International Society for Quality in Healthcare is a large society with 4,000 non-member associates and 1,000 members spread throughout most countries around the world. This presented potential problems in a number of respects. First, the survey was only available in English. Second, the respondents had to be able to receive the invitation to participate by email, even if they then chose to respond via hard copy. The ISQ executive group recommended that they hand-pick a group of 200 individuals from the membership list who were known to have an interest in this topic and who had the ability to respond to the survey electronically and in English. This was accepted as the best method to reach this highly diverse and important group.

In addition, the several hundred attendees at the *National Human Research Protections Workshop* held in the Georgia Centre for Continuing Education at the University of Georgia from July 28 to 30, 2003, all received invitations to complete the survey online as part of their information packages.

Dillman Checklist for Web-Based Surveys

The Dillman method of survey design and execution is widely recognized as the gold standard for survey methods. A full description of the Dillman method is included in Appendix D. The following is the checklist of activities that was reviewed and undertaken when approaching each of the organizations whose members were asked to participate in the electronic web-based survey. It was adhered to as closely as possible, given the unique requirements of each organization.

Ways of providing rewards

1. Show positive regard.
2. Say thank you.
3. Ask for advice.
4. Support group values.
5. Give tangible rewards.
6. Make the questionnaire interesting.
7. Give social validation.
8. Inform respondents that opportunities to respond are scarce.

Ways of reducing social costs

1. Avoid subordinating language.
2. Avoid embarrassment.
3. Avoid inconvenience.
4. Make questionnaires appear short and easy.
5. Minimize requests to obtain personal information.
6. Keep requests similar to other requests to which a person has already responded.

Ways of establishing trust

1. Provide a token of appreciate in advance.
2. Sponsorship by legitimate authority.
3. Make the task appear important.
4. Invoke other exchange relationships.

Using the Dillman method, it was anticipated that the response rate would fall in the 20% – 30% range, which is often achieved in web-based general/consumer surveys (Surveylab, 2003). The goal was to obtain at least 300 completed survey responses in order carry out a confirmatory factor analysis on the data. Although it is possible to carry out a confirmatory factor analysis with fewer than 300 responses, the results can be unstable and therefore misleading, and therefore the decision was made in advance that such analysis would not be carried out if there were insufficient responses.

Ethical Considerations for the Current Study

The current study involved data collection from many human participants. Although the research proposal was submitted to the University of Calgary REB (see Appendix F), a request to the committee was made, and granted, to modify the informed consent process. This was due to the fact that all of the intended participants were very well educated individuals and were familiar with REB procedures. Also the Principal Investigator had no influence over the potential participants and consequently the participants were free to refuse to participate without any restrictions; refusal simply meant not completing the survey. Further, the data collected were specific to individual opinions about a topic that was not likely to give rise to any personal consequences in terms of psychological harm. The REB agreed with the request and as a result formal informed consent was not used. Individuals did not participate if they did not want to.

It should also be noted that the Principal Investigator has committed to providing the results of the current study to all participants who asked for them to be sent. A list of such requests, which currently includes more than 50 individuals, has been kept. Furthermore, each of the participating organizations will receive a summary of the work, including the Research Ethics Decision Guide and a full copy of the dissertation document if they so desire. The researcher has also agreed to speak at each of the annual conferences of the participating organizations, if they are interested in more personal feedback. The ISQua has already made this request and the author intends to participate in their next annual conference as a result. Dissemination of information to the participants is, from the Principal Investigator’s perspective, a critical component of treating participants ethically. Consequently, it is a significant concern for this study as is the issue of peer review publication.

Summary of Methodology

As can be surmised from the above, the research process used in the current study has been an iterative one, beginning with general questions regarding the current standards and procedures of REB review, the possibility of defining research, program evaluation and quality assurance and then proceeding toward increasingly specific information regarding how decisions are made in reviewing projects and protecting participants. The research began with casual discussions with individuals who were knowledgeable in the areas of research and program evaluation. This in turn led to a more formal attempt to gather data systematically from individuals identified as being subject-matter experts in the field of REBs. The feedback from SMEs led to the addition of a brief review of peer review publication standards with regards to proof of REB clearance. The culmination of the casual conversations, literature review, SME feedback and review of publication standards was the development and process used for the international electronic survey. At each step along the way the process was piloted tested by the Principal Investigator and then reviewed by a core group of individuals who had considerable experience in conducting research in applied and academic settings. These individuals were most helpful in ensuring the final data collection process and instruments used were as well done as possible.

CHAPTER THREE: RESULTS

Interviews

Interviews with individuals who were not laypeople and who had participated in systematic studies indicated that the decision to participate in any study is primarily dependent on two characteristics: (a) whether there is potentially something beneficial for the participant in the study; and (b) whether they liked the researcher or whomever approached them about participating. Few laypeople indicated that informed consent made them feel more safe or secure. Several stated that they believed signing the informed consent document made them responsible for any harm that might occur to them during the process and removed responsibility from the researcher. This was an interesting finding and one that is worthy of further investigation. It became clear during the focus groups that many of the nuances of REB review were not known to laypersons, nor were the details important to the groups that were interviewed. However, novel criteria raised by the layperson focus groups were included in the international survey variables.

Discussions with the layperson groups as well as the more formal survey and follow-up debriefing with the Advisory Committee resulted in several recommendations regarding the names of domains and the variables that comprised each domain as they had originally been organized by the Principal Investigator. The feedback from both groups also yielded additional guidance regarding how questions should be worded for each variable.

Additional guidance from SMEs and the Advisory Committee regarding the development of the REDG indicated that the domains, as originally conceived, should be made more concrete if possible. It was recommended that the survey move from the Likert-type scale format used with SMEs to a more clear-cut approach for the web-based survey. The most consistent of the recommendations received was to narrow the options from degrees of importance to forced choice answers for the sake of clarity in the results. It was suggested that the web-based survey include only the following with regard to each variable when considered in isolation from all other variables and independent of the jurisdictional parameters, such as local laws, which might otherwise influence the web-based survey respondents: (a) clearly requires some level of ethical review; (b) may require ethical review; (c) does not require ethical review and (d) not clear/undecided.

It was also recommended that some of the survey questions might benefit from examples, to ensure all respondents were working from a similar frame of reference, even if they came from different academic disciplines. In addition, both the SARC and the Advisory Committee recommended additional sources of information that would support the inclusion of each question on the survey. It was further recommended that a section be added to the web-based survey that would allow respondents some small measure of qualitative responding. SARC members and the Advisory Committee warned against making the survey too long or philosophical. They urged the Principal Investigator to stay focused on developing an instrument that could be widely and easily used by HHSOs in order to make replicable and clear decisions regarding whether a study required ethical review. The emphasis was clearly on determining which projects required review rather than those that did not since the greater potential risk to participants lies in projects that should receive review but did not get it rather than in those projects that did not require review.

During the SME interviews, survey, and follow-up debriefing, there was quite a lot of discussion regarding terminology. For example, one issue concerned whether a systematic investigation should be called a “study”, a “project” or some other term such as program evaluation, research or quality assurance. In the end it was decided that “study” or “project” was sufficiently innocuous that respondents would not immediately divide questions into research versus non-research and would instead focus on the variables. In addition, there was a great deal of debate regarding how to refer to those individuals leading such projects. In research such individuals are traditionally referred to as “Principal Investigators”. Again, this would lead potential respondents to the international survey to move into a research mindset and away from the particular variable under consideration. In the end “project leader” was determined to be the best choice, although it is certainly a decision that will not satisfy all readers in this contentious area.

As the SME and layperson interviews and focus groups progressed, it became clear that for the purpose of this dissertation the emphasis would need to be placed on information gathered from key reference documents regarding research ethics and on information gathered from individuals who had expertise in research, research ethics, research ethics boards, quality assurance and/or program evaluation rather than from laypeople. Although laypeople had a keen interest in the subject, they could only base their answers on their own experiences and opinions, and their experiences were often limited to a handful of studies. Conversely, professionals had a considerable amount of knowledge and experience regarding the finer points of REB review and what variables might indicate that a project could pose harm to potential participants.

Several changes to the process were made as a result of comments from the professionals. First, a determination was made to revisit the key documents in the literature in order to develop the final international survey as recommended by the Advisory Board and SMEs. Second, a further decision was made to invite the members of professional associations to complete the survey rather than to further pursue the layperson perspective. The layperson perspective is valid and important in decision making with regard to REB review; however this line of investigation will be pursued in a separate study. An additional consideration when making this decision was the fact that most REB systems, including the higher levels of the New Zealand populist approach to review, depend on expert opinion.

Literature Review: Identification of Key Domains and Variables

The first part of the literature review was presented in the introduction in order to explain the importance of the research question and why this particular dissertation was undertaken. This section of the literature review is more appropriately placed in the results section since it is a critical part of the data collection process (Cone & Foster, 1993). In order to develop a web-based survey designed for an international audience of experts from a variety of academic disciplines and across many settings, it was necessary to examine key historical documents as well as current references for REBs within the academic and grey literature.

The purpose of this component of the review is to bring to light all possible variables that experts might use to make decisions regarding whether a study requires ethics review. The review was also used to group variables into domains, such as potential harm to participants, which were mentioned in virtually all key documents. Wherever possible in the pages that follow, key variables have been set in bold or placed in italics after a relevant descriptive phrase in order for the reader to more easily identify each variable included in the web-based survey.

A Brief History of REB Review, Including Important Domains and Variables

REBs are a response to the scientific community's realization that general ethical principles are not sufficient to fully guide the conduct of modern scientific research (Annas & Grodin, 1992; Augsburg University, 2001). Much of the developmental work of putting ethical principles into policy and legislation began in earnest after World War II. The revelations of the Nuremberg Doctors' Trial and related cases spurred a flurry of research, legislation and policy documents directed towards ethical standards for research involving human participants (Smith, 1999; Annas, 1992). The first post WWII document that can be considered a policy statement and the touchstone for all that followed is the Nuremberg Code.

The Code itself is quite simple, particularly when compared to the complex legislation and policies that exist today. However, it was not originally intended to be a code. Rather, it was part of the judgment handed down by the Tribunal for the Doctors' Trial on August 20, 1947. What is now known as the Nuremberg Code was included in counts 2 and 3 of the guilty verdict for war crimes and crimes against humanity:

> The human experimentation carried out by the Nazi physicians included both ware-related and non-ware-related activities. The judgment contains the documented proof of crimes and proceeds to the question of the permissibility of medical experimentation. The judgment concludes with enumeration of a 10-point code of human experimentation ethics that is now known as the Nuremberg Code." (Annas & Grodin, 1992, p.4).

The ten points that must be included in any study are:

1. *Voluntary consent* that is *informed* and obtained *without duress*.
2. The likelihood of *fruitful results* for the good of society *(distributive justice)*.
3. *Results that justify the means (risk of harm vs. benefit)*.
4. A design that *avoids all possible harms (risk of harm)*.
5. No chance of death or disabling injury, except when the experimental physicians are the subjects *(risk of harm)*.
6. A *balance between risk and benefit (risk of harm vs. benefits)*.
7. Research facilities that *protect against harm (methodology)*.
8. The study must be undertaken by *qualified individuals (risk of harm – qualifications of project leader)*.

9. Participants should be able to *end the study early (methodology – clinical equipoise).*
10. The scientist in charge must also be willing to *stop the study early (risk of harm – clinical equipoise)* (Annas & Grodin, 1992).

The United Nations General Assembly (UN) quickly followed suit by proclaiming its *Universal Declaration of Human Rights* on December 10, 1948 (http://www.un.org/Overview/rights.html). The World Medical Association (WMA) followed along almost two decades later by declaring its *Ethical Principles for Medical Research Involving Human Subjects* at the 18th WMA General Assembly in Helsinki, Finland in June 1964 (http://www.wma.net/e/policy/17-c_e.html), usually referred to as the Declaration of Helsinki. Each of these proclamations has been reaffirmed and updated on a regular basis.

The United Nations *Universal Declaration of Human Rights* necessarily speaks in general terms. However, it makes reference to domains that are important when considering whether a study undertaken by an HHSO may require ethical review. For example, Article 2 states that, “everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion and so forth”. This clearly relates to *distributive justice* that is included in the *risk of harm* domain. *Risk of harm* in studies is also relevant to Article 5 which states that, “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.” The Declaration also speaks to issues of *confidentiality and privacy* in Article 12 which states that, “No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation" (United Nations General Assembly, 1948).

The World Medical Association policy statement has been revised several times, most recently during the Toyko General Assembly in 2004 (World Medical Association, 2004). The policy speaks to the issue of *risk of harm* in several sections including A.1 where it states that, "it is the duty of the physician to promote and *safeguard the health* of the people", A5 where it states that, "in medical research on human subjects, considerations related to the *well-being of the human subject should take precedence* over the interests of science and society" and acknowledges that all research involves "*risks and burdens*" (A.7 and B.16). The policy also speaks to the issue of *informed consent* (A.8 and B.20), particularly among populations that are *vulnerable and need special protection* and to protection of *privacy* (B.10 and B.21). The policy addresses the issues of *undue influence* (B.13, B23), *adverse effects* (B.13), *methodology* (B.13), the requirement for REB review (B.13), *qualifications of the investigator* or project lead (B.15), *clinical equipoise* (B.17), *conflict of interest* (B.22), *ability to consent* (B.24), *intention to publish* (B.27), and *medical research combined with clinical care* (B28) (World Medical Association, 2004). The Council for International Organizations of Medical Sciences (CIOMS) offers similar guidelines and was updated as recently as August, 2002 (Council for International Organizations of Medical Sciences (CIOMS), 2002).

Internationally the above documents are perhaps the most frequently cited with regard to ethical review of studies involving human participants. Their language and intent can be seen in the legislative and policy work that has taken shape in countries such as Canada, the United States and New Zealand, among others.

Now, nearly 60 years after the Nuremberg Code was enacted, virtually all western universities have at least one REB, as do teaching hospitals.[8] There may be more than one at each facility. For instance, there may be one REB for biomedical research and another for non-biomedical work. This is the case in New Zealand where there are specialized boards for health and disability support services, and assisted human reproduction (New Zealand Ministry of Health, 2002). The authority of any REB is limited to the jurisdiction of the organization within which it functions (Medical Research Council of Canada, National Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 2003).

It is expected that REBs will establish a process that meets procedural justice requirements, including having, “fair methods, standards and procedures for reviewing research protocols and that the process be effectively independent” (Medical Research Council of Canada et al., 2003). The range of projects reviewed by REBs varies depending on jurisdiction and philosophy. For instance, in New Zealand any individual who wishes to obtain a considered opinion on the ethics of any study may approach any local REB (New Zealand Ministry of Health, 2002). In the U.S. and Canada the range of projects

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[8] Although such boards have historically consisted of volunteers, usually from the academic community, there are a growing number of research ethics review boards which are being set up for profit and where the members are paid either a stipend or a salary.

considered appropriate for review is considerably more restricted. For instance, a university REB may review all studies that involve human participants from medicine, natural sciences, social sciences and perhaps humanities faculties, even those non-experimental studies that are only accessing databases of information previously collected from human participants, such as Statistics Canada Census data. However it is unusual to find such boards open to similar projects brought forward by non-academic members of the community or HHSOs. If such partnerships do exist, they are not well documented in the literature. This is true even if the community-based projects are virtually identical to projects reviewed within the university setting.

There is clearly a lack of consistency in practice between academic and non-academic (i.e. HHSO) settings regarding whether systematic studies involving human participants are subjected to ethics review. For example, in Alberta there is only one board recognized by the HIA and specifically designed to review projects from the community that do not fit the mandate of any other HIA designated board (Health and Wellness Alberta, 2001; Provincial Health Ethics Network, 2001). Generally speaking, there are few formal agreements in place for university or research organizations such as the Alberta Cancer Board to review projects from HHSOs that are outside of their membership, based on interviews with subject matter experts.

There is little standardized training of individuals who serve on REBs, although attempts are currently underway to address this concern (Amdur & Bankert, 2002; Cave & Holm, 2002; Macpherson, 1999; McCarthy, 1998;

National Council on Ethics in Human Research, 2001; Penn State University, 2001; University of Minnesota, 2003; Wilson, Neff-Smith, Phillips, & Fletcher, 1993). This is important because lack of standardized training is likely to lead to inconsistent interpretation and application of legislation and policy with regard to ethics review. However, most committees comprise volunteers, many of whom have considerable additional responsibilities in academics or research, and REB membership responsibilities can be intimidating.

According to the U.S. Department of Health and Human Service's Inspector General (DHHS-IG), ethics boards face many challenges including managed care, commercialization, multi-site trials, high REB workloads, minimal REB oversight of approved studies, conflicts of interest, insufficient training of REB members and investigators and lack of REB self-studies (Grob, 1998). REBs are already overloaded (Amdur & Bankert, 2002; Lynn, 2004), often move slowly, and are quite formal (Lynn, 2004), inclined to 'tinker' with protocols, including multi-site protocols, and focused on their local institution (i.e. hospital or university) rather than on the larger network, which is the realm of most HHSOs (Jamrozik, 2000).

Amdur makes recommendations to U.S. based REBs that could be applied to ethics review boards operating anywhere in the world. Specifically he states that REBs should remain focused strictly on what is required to comply with federal regulations in order to control administrative burden. He further suggests that REBs should keep in mind that they are not intended to be editorial services, a medical records department, a confidentiality committee, a risk management department, an office of patient financial services, or data safety monitoring board (Amdur & Bankert, 2002). Any of these roles will, "distract the IRB from its fundamental responsibilities (and) will compromise IRB function" (Amdur & Bankert, 2002). All of these recommendations may be helpful and fair game for overburdened REBs. However, they do little to address the concerns of HHSOs who operate outside of the mandate of most REBs, but who need to be certain that they are treating their clients who participate in systematic studies according to the highest ethical standards.

Even if REBs could find the capacity to address the needs of HHSOs and had the inclination to do so, current REB practice might not be welcomed by HHSOs because of the many issues that REBs face. In North America there is a tendency to take a "one size fits all" approach to REB review (Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004) that might be challenging for the varied methodologies employed by HHSOs when conducting studies. When combined with the challenges noted above, the result is that REBs are usually unable to quickly expedite low risk projects or projects that have already been reviewed by one or several other qualified REBs,[9] and unable to spend more time on high risk projects.

Given the current challenges that REBs face, it is unlikely they would be eager to take on the additional burden of reviewing systematic investigations

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[9] For instance, the REB of Health Canada reviews all applications of research involving human subjects, even those that have been previously reviewed/approved by another REB that is in compliance with the TCPS. For an extreme example of how the requirement for approval from multiple REBs is creating significant barriers to research without providing any additional safety for participants, see (Jamrozik & Kolybaba, 1999).

from other organizations, such as HHSOs. Many REBs would consider review of protocols from HHSO's to be outside of their mandate, as well as beyond their resource capacity. This may be a realistic assessment, but it still leaves HHSOs in the position of needing to make replicable, defensible and fair decisions regarding the level of ethical review given to the many systematic projects that they carry out as part of their daily activities and responsibilities.

Variables Attributable to Current Conditions: Canada, U.S. and New Zealand

This section briefly examines the REB systems in Canada, the United States, and New Zealand. Each takes a significantly different approach to REB review. Consequently, each may offer some insight into how best to assist HHSOs that require access to ethical review.

Canada takes a policy approach to REB review via the TCPS (Interagency Advisory Panel on Research Ethics, 2003), with additional legislation from various political bodies and policy from professional associations. The United States has taken a legislative approach via the Federal Regulation Title 45, Section 46 – Protection of Human Subjects (Cohen, 1999; Department of Health and Human Services, 2001; Fischer, 2001; General Accounting Office, 1999; Grob, 1998; J. S. Jones et al., 1996; Schneider, 2001). New Zealand takes a populist approach, in that laypeople conduct ethical reviews, and is governed by national policy and legislation (New Zealand Ministry of Health, 2002).

In Canada and the United States the review system is operated by experts, usually volunteers from the academic community, and, in general, only proposals from the academic community are reviewed (Corman, 2005). In New

Zealand the first layer of ethics review is run by boards where the majority of participants must be laypeople. The second layer of specialized boards are run by experts, mostly from academia (New Zealand Ministry of Health, 2002). However, a unique attribute of the New Zealand system is that anyone may approach an REB for advice or participate in the REB system, including being involved in the discussion of proposals, as this process takes place in a community forum that is publicly advertised.

The Canadian TCPS (June, 2003) states that the organizers of the policy, "will consider funding (or continued funding) only to individuals and institutions that certify compliance with this policy regarding research involving human subjects" (p.i.1). The Tri-Council Policy Statement represents an agreement of the three major national funding bodies for university based research. Consequently the TCPS usually forms the basis of policy and practice at Canadian universities (University of Calgary, 2003; University of Calgary Research Office, 1999). Although the TCPS takes precedence, legislative documents are in place, and are growing in number, that must also be taken into consideration when HHSOs establish procedures regarding ethics review for studies involving human participants.

Within Alberta the HIA indicates that program evaluation and quality assurance work are exempt from review and that custodians of health care information can share *individually identifiable* information in order to carry out work in these areas. However, the Act does not operationally define either "program evaluation" or "quality assurance" and does not offer any mechanism to differentiate such activities from research. Under the Act research must be reviewed by one of several specifically identified REBs within the province before access to health information is granted by any health care custodian (Ministry of Health and Wellness (Alberta), 2001). The Act has already significantly changed the landscape of client confidentiality and protection of individuals from harm – if harm can be considered invasion of privacy. For example, in 2003, Alberta utilized the HIA to ban the sale of physicians' prescribing information without the physician's consent (Dunleavy, 2003).[10]

A number of other policy and position statements exist that impact HHSOs in Canada, such as the Commission de L'ethique de la science et de la technologie (Commission de L'ethique de la science et de la technologie, 2003). Further, there is some evidence that additional legislation related to privacy and sharing of information with regard to HHSO data is on the way. The 2002 Speech From the Throne to open the Second Session of the Thirty-Seventh Parliament of Canada stated that the Canadian federal government, "will work with provinces to implement a national system for the governance of research involving humans, including national research ethics and standards" (Government of Canada, 2002). Also, the National Council on Ethics in Human Research (NCEHR) is investigating the possibility of accrediting human research protection programs in Canada (National Council on Ethics in Human Research,

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[10] The consent issue surrounded physician consent rather than individual consent to release their records. Most, if not all, REB procedures are focused on individual consent except in those circumstances where social tradition and culture warrant group decision making, such as in the case of the Maori of New Zealand. The Alberta decision in this case warrants further investigation into the issue of who has the right to provide consent to the information which is held by HHSOs.

2001; Department of Health and Human Services, October 1, 1997; Health Canada, 2002).

Canadian organizations must also work with the Freedom of Information and Protection of Privacy (FIOP) Acts that are in place in provinces such as Alberta and British Columbia, and the Personal Information Protection and Electronic Documents (PIPEDA) assented to by the Federal government on April 13, 2000 (Government of Canada, 2000). Each university or HHSO may add additional policy to the TCPS, federal and provincial legislation. The web of policy and legislation with regard to ethics review of projects involving human participants is becoming quite complex in Canada and elsewhere.

McDonald (2001) believes that the current Canadian system of oversight is too narrowly focused on obtaining REB approval and participant consent. There are considerable gaps in the system, including, but not limited to, lack of a built-in learning system or accreditation so that REBs can learn the results of the studies they approve and consequently increase their accuracy at predicting the impact of future studies. The Canadian system is “woefully under-resourced”: most universities spend nothing on their REBs. At the national level, twice is much is spent on overseeing research involving animals as is spent on research involving humans (McDonald, 2001). McDonald advocates the inclusion of all available experts in the ethics review process including sociologists, anthropologists, clinical specialists and other researchers in the life and social sciences, and states that, “some of the most important evidence would likely come from those most affected by the research – namely research subjects, their families and communities" (p.19). He further suggests that Canada should move away from the "slice in time" approach to REB review to include considerations of both what happened before the proposal was sent to the REB and oversight, follow-up and dissemination activities of the work once it has been approved.

The United States ethics review process is governed by the Department of Health and Human Serivces Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). This legislation applies to all research involving human participants that is funded by the U.S. federal government. In total there are 17 agencies that fall into this category. However, as is the case in Canada, Title 45, Part 46 also allows for state or local laws or regulations which may provide additional protection for human subjects (section 46.101, part f). There are significant other documents that must be considered by organizations operating in the United States. For example, the Belmont Report (Gabriele, 2003; The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979); the National Bioethics Advisory Commission (National Bioethics Advisory Commission, 2001); and the National Committee for Quality Assurance (NCQA) (The National Committee for Quality Assurance, 2002) all have policy documents that speak to the issue of ethics review. In addition, state governments can apply additional standards as can universities, research organizations and HHSOs. The United States has the additional interest of for-profit REBs that are beginning to emerge.

New Zealand takes a different approach via a two-tiered process. The first tier uses a populist approach with some substantially different features than either Canada or the United States, including the fact that REBs discussions are open to the public and that the majority of REB members must be laypeople (New Zealand Ministry of Health, 2002). At the second tier, where the first tier sends any decisions that they are not able to resolve at the first tier level, members tend to be experts in research ethics, primarily from various academic disciplines. Accreditation of REBs is already in place and each of the REBs are encouraged to apply. If accreditation is granted, the boards and their members are protected from any legal matters that may arise from their decisions. The New Zealand system is significantly different from either the Canadian or the U.S. systems and is worthy of investigation in a number of regards. It would, for instance, be interesting to determine whether participants feel more protected as a result of the open forum within which the New Zealand REBs operate. It would also be of value to examine whether the system in place in New Zealand is more efficient in terms of turnaround time and related costs than the systems operating in the United States or Canada. The New Zealand system is only tangential to the current dissertation in that it offers some intriguing possibilities with regard to how a system of ethical review might work for HHSOs. For those who would like to learn more about the New Zealand system, some of the key characteristics and additional references are included in Appendix E.

The juxtaposition of the approaches taken by these three countries provides rich ground for identifying the points of divergence and convergence on the decision-making variables that this dissertation is attempting to isolate.

Web-based survey domains

What follows is a brief examination of each of the four domains that were used to group variables identified in the literature. They formed the foundation of the web-based survey in this dissertation. The section begins with a table that presents all of the domains and variables along with their corresponding questions as they appeared in the final survey. For those who wish to see a close approximation of what the survey actually looked like on the web, please refer to Appendix C. At the end of the section a table summarizes the domains, the variables associated with each domain, and a selection of citations for each. The citations are not meant to be exhaustive, only to serve as examples. The summary table clearly ties the results of the data collected in the literature review as well as the information gathered via expert and layperson interviews to the final web-survey questions that forms the heart of this dissertation. Each domain is a research topic unto itself and there is much literature and debate regarding each. The variables within domains sometimes overlap, making it difficult to discuss each without some repetition, but every effort has been made to minimize duplication in this document.

Domain 1: Informed Consent

Within the final survey, the domain of “informed consent” is comprised of several variables including undue influence, inability to consent, deception, conflict of interest and secondary use of data. Each of these can be broken down into many component parts. However, in order to keep the survey parsimonious, only the most important aspect of each variable as indicated by SME interviews and the literature was included in the survey.

Informed consent is one of the cornerstones of REB philosophy and practice. Although the Nuremberg Trial served as a lightening rod that spurred considerable activity with regard to the creation of research ethics policies, such policies existed in Germany prior to WWII. Many of the philosophical underpinnings of the pre WWII German codes found their way into the Nuremberg Code and the documents that built upon it, including the principle of informed consent and ability to consent. For example, the 1900 Berlin Code of Ethics is the first modern code of ethics (Annas & Grodin, 1992; Sass, 1983). The Berlin Code established three standards that prohibited any *medical intervention* that was not required for diagnostic, healing or immunization purpose[11] in some circumstances. The exclusions were as follows:

1. If the human subject was a *minor* or *not competent* due to other reasons (*inability to consent*).
2. If the human subject had not given *unambiguous consent* (*informed consent*)**.**
3. If the consent was not preceded by a *proper explanation of the possible negative consequences* of the intervention *(informed consent*). (Der Minister der Geistlichen ec. Angelegenheiten. Studt, 29 December 1900).

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[11] The debate between ethical standards that apply, or should apply, to clinical (treatment) studies and those that should apply to non-clinical work is still a hotly debated topic today.

The principles of the Belmont Report of April 18, 1979 (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm) are reflective of the Nuremberg Code. The Report specifically speaks of *respect for persons, beneficence and justice* and spells out standards, such as the need for *informed consent*, to uphold the basic ethical principles. These principles and applications are mirrored in many of the policy documents that exist today in universities, government, and research organizations in the western world (Annas & Grodin, 1992; New Zealand Ministry of Health, 2002). The Belmont report specifically speaks to the issue of *participant autonomy**.*** This means that participation has to be *voluntary* and based on informed consent.

The Belmont report also emphasizes the idea of beneficience. This variable, captured in within the domain of *risk of harm,* focuses on the members of the larger society and their obligation to recognize longer term *benefits and risks* that may result from the improvement of knowledge, and from the development of novel medical, psychotherapeutic, and social procedures. Beneficience implies that the scientific community has an obligation to *proactively protect* human participants. The current REB process leaves decision-making regarding the larger societal issues and the interaction between development of scientific knowledge and long term benefit to society largely in the hands of the scientists and those who fund them. This creates a basic conflict of interest between the “research society” and the larger society, which has not yet been resolved or widely discussed in North America. It would be a valuable aspect of informed consent to investigate via further research.

From the Canadian perspective, the TCPS Schedule A speaks to a number of variables within the domain of *informed consent*. For example, Schedule A states that studies must be reviewed: (a) Whether the subjects are from *inside or outside the institution (informed consent, routine data collection, non-routine data collection, implied vs. formal consent)*; (b) whether the subjects are *paid or unpaid (undue influence)*; (c) whether the *research is conducted inside or outside of the institution (undue influence)*; and (d) whether the *focus of the research is the subject (quality assurance, HHSO use only, routine data collection)*.

The HIA also speaks to informed consent. For example, if an REB makes recommendations regarding the need to obtain consent from any individual who is the subject of the health information to be used, according to the Act section (27 (1) d), the applicant organization must comply with this request.

Within the U.S. ethics review system a great deal of emphasis is placed on informed consent and legal concerns (Bosk, 2001; Brody, Gluck, & Aragon, 1997; Cassell & Young, 2002; Corrigan, 2003; D'Auria, 1999; Delfosse; Fisher, 2003; Lowman & Palys, 2002; Mello, Studdert, & Brennan, 2003; National Association for the Mentally Ill, 2001; Noah, 2002; Palys & Lowman, 2002; Patullo, 1987; Truog, Robinson, & Randolph, 1999). The U.S. IRB system rests on two sets of federal regulations, the Food and Drug Administration (FDA) Drugs and Devices, and the Department of Health and Human Services (DHHS)

Office for Human Research Protection (OHRP) (Department of Health and Human Services, 2001). According to Edgar & Rothman, the two goals of IRBs are: (a) to determine whether the *benefits of the project outweigh the risks;* and (b) to ensure that all the relevant information is contained in the *informed consent document* (Edgar & Rothman, 1995). However, Lafrate and Frentzen (2001) contend that the role of IRBs in the United States are threefold: (1) protection of human subjects from *physical, emotional and economic harm*; (2) assessment of *research risk including benefit* to the subject and *research methodology*; and (3) *protection of the university* by ensuring that it is operating in compliance with relevant regulations.

REB review impacts the ability of HHSOs to access to information that is critical to improve service delivery and outcomes for clients. Some legislation and policy speaks to this need. For example, "under (U.S. Government Printing Office) federal privacy regulations that went into effect in April, 2003, health care providers may use *individually identifiable health information for quality assurance without obtaining patient consent*" (Lo & Groman, 2003, p.1483).

The informed consent literature is quite extensive on some issues such as obtaining informed consent from *unique or disadvantaged populations*. The essential issue is whether it is possible to obtain *informed consent* from certain kinds of people and what process should be utilized if informed consent is required from such persons. Dr. Henry K. Beecher published a critical survey of twenty-two research projects conducted in the United States after the Nuremberg Code was established and determined that, in the majority of cases, the research subjects did not truly understand the implications of the study or what was being asked of them (Pullman, 2001). This is perhaps what drove Pullman to add a second component to *informed consent* in order for patients to be safeguarded in the research process, namely, *“intelligent, informed, conscientious, compassionate, responsible investigators (qualifications of researchers)*” (p. 113).

With regard to informed consent, some systematic investigations that involve human participants in the U.S. are entitled to be exempt from REB review. Exemption from review would also mean that the study was exempt from asking for informed consent, although not all would agree that this should be the case (Patullo, 1987). The regulations do not specify who has the authority to decide if a study is exempt. Consequently, “some organizations choose not to exempt any projects” (Prentice & Oki, 2002). For those organizations that forge ahead, they must be able to demonstrate very little, if any, associated risk of harm to participants in the study. The categories of exempt research include:

1. Normal educational practices and settings.
2. Anonymous educational tests, surveys, interviews or observations.
3. Identifiable subjects in special circumstances.
4. Collection or study of existing data.
5. Public benefit or service programs.
6. Taste and food evaluation acceptance studies.

Some population groups are excluded from the above, including prisoners, pregnant women, fetuses and human in vitro fertilization, children, observation of a minor’s public behavior unless the investigator does not participate in the activities being observed, the decisionally impaired, the homeless or nursing home residents (Prentice & Oki, 2002). It can be surmised from the above that these groups may be unable to provide *informed consent* to participate in a study due to *undue influence*, or *inability to consent*. These are often the groups with whom HHSOs work. It is important to note that exemption #4 (collection or study of existing data) only applies to *anonymous* data (*secondary use of data).*

The Belmont report speaks to the issue of *informed consent*, although it does so in terms of *respect for persons***.** Respect for persons is one of three primary ethical principles espoused in the Report. The Report expands the concept of respect for persons by stating that respect for persons incorporates two ethical convictions:

a) individuals should be treated as autonomous agents.
b) persons with diminished autonomy are entitled to protection.

According to The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, an “autonomous” person is, “an individual capable of deliberation about personal goals and of acting under the direction of such deliberations” (1979, p.4). The Commission further states that:

> to respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or

> to act without information necessary to make a considered judgment, when there are no compelling reasons to do so (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979, p.4).

Clearly a balance must be struck between treating an individual as an autonomous agent and determining at what point *diminished capacity* (*inability to consent)* becomes of sufficient concern to require protection. This is not an easy balance to strike, nor is it a concept that is easy to capture in a reductionist approach to ethics. It requires considered thought in each situation, and perhaps ongoing adjustment throughout a project. On the one hand, respect for persons may require that prisoners not be denied the right to participate in research. On the other hand, subtle pressures may be exerted upon prisoners that could unduly influence their participation because, in essence, they are unable to give informed consent. Consequently the issue of whether to allow prisoners to “volunteer” or to “protect” them is a balancing act. The same may be said of other groups of people that share common characteristics or circumstances such as the Maoiri of New Zealand. In Maoiri culture decisions are made by group consensus, as is the case with some aboriginal tribes in North America. Consequently, although HHSOs may work with individual prisoners or aboriginal people on a daily basis, the organizations cannot assume that individualistic approach to informed consent is appropriate or possible in such circumstances.

Domain 2: Intended Use

“Intended use” deals with the purpose of the project, the qualifications of those who carry out the work and, indirectly, the protection of privacy of those who participate. From the Canadian TCPS perspective, intended use is a consideration when determining the need to seek REB review. The TCPS explicitly stipulates that, quality assurance, which is intended to improve programs, services or systems, is distinct from research. The TCPS indicates in Article 1.1, subsection (d) that, “quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review” (p. 1.1). However, if one examines the TCPS Appendix 1, one might be forgiven for thinking that all projects, including quality assurance and program evaluation, should be sent for REB review. Schedule A states that studies must be submitted for REB review regardless of (a) whether the research is to be published or not *(academic publication, professional conference presentation, HHSO internal use only)*; (b) whether the research is primarily for teaching or training purposes or (c) whether the primary purpose is the acquisition of knowledge *(quality assurance, program evaluation, generalizability, distributive justice)* (Interagency Advisory Panel on Research Ethics, 2003).

The HIA also speaks to intended use. According to the HIA, the project leader must: (a) submit a proposal to a designated REB; and (b) comply with any recommendations made by the ethics committee (27 (1) d). Designated REBs are specifically required to consider the *importance of the research (intended use)*. However, as legislation and policies impacting systematic investigations involving human participants increase, along with concerns about privacy, some REBs and HHSOs are turning to more concrete methods of decision making regarding whether a project requires REB review. For example, some REBs have tended towards using more concrete project characteristics, such as intended use, to differentiate those projects that should be reviewed from those that should not. For example, “some REBs consider a project to be research if the results are to be *published* or *disseminated beyond the clinical unit*” (Lo & Groman, 2003, p.1483).

From the U.S. perspective, the Centers for Disease Control and Prevention consider intended use to be, “the major difference between research and non-research” (Snider, 1999, p.2). The CDC perspective is that the primary intent of research is to generate knowledge that can be generalized to populations other than the sample used in the study. Non-research is intended to:

> prevent or control disease or injury and improve health, or to improve a public health program or service. In some cases, that knowledge may be generalizable, but the primary intention of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered (Snider, 1999; p.2).

The principle of generalizability arises in the area of intended use, and it overlaps with methodology. Generalizability has often been used as the primary criteria to differentiate research (those studies that need review) from non-research (Department of Health and Human Services, 2001; Ministry of Health and Wellness (Alberta), 2001; The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). Unfortunately, respected international organizations, such as the Council for International Organizations of Medical Sciences (CIOMS) have made statements that contradict policies within some jurisdictions such as the U.S. For instance, the CIOMS (1991) International Guidelines for Ethical Review of Epidemiological Studies states that:

> the defining attribute of research is that it is designed to produce new, *generalizable knowledge*, as distinct from knowledge pertaining only to a particular individual or program. For instance, a governmental or hospital department may want to examine patients' records to determine the safety and efficacy of a facility, unit or procedure. If the examination is for research purposes, the proposal should be submitted to the committee that considers the ethical features of research proposals. However, if it is for the purpose of program evaluation, conducted perhaps by staff of the institution to evaluate a therapeutic program for its effects, the proposal may not need to be submitted to ethical review; on the contrary, it could be considered poor practice and unethical not to undertake this type of quality assurance (Council for International Organizations of Medical Sciences (CIOMS), 1991, p. 14).

Domain 3: Study Methodology

"Methodology" concerns the planned steps to be followed throughout a study including, if applicable, the study sample, procedures, measures and so on. This domain often raises the issue of whether it is possible, or fruitful, to attempt to define research. An in-depth discussion of "what is research" is beyond the scope of this paper. However, some background may be useful to the reader and a more indepth discussion is provided in Appendix A.

During the time when the Nuremberg Code was proclaimed, research was primarily experimental and relatively easy to identify, but this has changed over the past few decades. Non-experimental methods have become an accepted part of academic research. The Canadian TCPS has attempted to address the range of methodologies that are now accepted as "research" by stating in Schedule A that all studies must be reviewed regardless of whether the research is observational, experimental, correlational or descriptive (Interagency Advisory Panel on Research Ethics, 2003). This "one-size-fits-all" approach to REB review is causing considerable disagreement in academia (American Association of University Professors report, 2001; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004).

Although it is now generally accepted in academia and beyond that there are many approaches to research other than the experimental model, the current literature review indicates that the majority of published works on the ethical implications of research focus on biomedical issues and experimental models. The emphasis on protecting human participants from harm when taking part in a medical experiments or new clinical interventions is easy to understand: the risks in such endeavors can be significant, perhaps even life threatening. Medical research studies, “tend to generate controversy in proportion as the harms they pose to subjects are dramatic and dangerous” (Beauchamp, 1982, p. 215). Since biomedical research can result in significant risk of harm, it has necessarily and justifiably maintained center stage of the ethical debate.

There have only been a few voices, such as King, Henderson & Stein and Cassarett in the United States (D. Casarett, 2001; D. Casarett et al., 2000; D. J. Casarett, 1999; King et al., 1999), SSHRC in Canada (Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004) and Jamrozik in Australia (Bradshaw, Jamrozik, Jelfs, & Le, 2000; Jamrozik, 1992, 1997, 2000; Jamrozik & Kolybaba, 1999) speaking to the problems associated with applying a single standard to all academic work involving human participants while ignoring the needs of community-based and non-academic researchers. As King (1999) explains:

> the range of disciplines engaged in research with human subjects is broad...and includes the perspectives of internal medicine, pediatrics, psychiatry, surgery, preventive medicine, dentistry, nursing, epidemiology, public health, sociology, anthropology, ethics, philosophy, history, law, health policy and health services research (King et al., 1999).

Each of these disciplines has a unique history, with accompanying values and perspectives that must be considered in any regulations designed to protect human participants involved in systematic studies. As such, it is unlikely that any one REB would have experience in all academic disciplines. This has made some disciplines uncomfortable regarding the ability or interest of REBs to adapt to methodologies with which they are unfamiliar (American Association of University Professors report, 2001).

The Belmont report speaks to a number of issues related to methodology. In particular, in a matter related to *clinical equipoise*, the methodology must allow for early termination of the experiment by the subject, as well as by the researcher (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). Further, all of the steps carried out in the methodology need to be documented, and, from the perspective of the Belmont Report, the methodology must ensure that, "*persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well being*" (p.5). In other words, the study team has an obligation to proactively ensure the participant is not harmed by the study process. In this regard it lends support to the notion that clinical equipoise and the ability for the participant as well as the study leader to stop the study, or the participant's involvement in it, at any time is of critical concern (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). The U.S. and CIOMS are in agreement that the creation of new and generalizable knowledge is the methodological hallmark of studies that require REB review. They are not in agreement regarding whether systematic investigations involving human participants, such as program evaluation, should be subjected to ethical review.

The Canadian TCPS addresses the issue of methodology in more concrete ways. Schedule A specifically states that a study should be reviewed: (a) whether a similar project has been approved elsewhere or not (prior approval of qualified REB); (b) whether the research is a pilot study or a fully developed project (non-routine data collection); and (c) whether the research is to acquire basic or applied knowledge (random sampling, random assignment, routine data collection, non-routine data collection, generalizability) (Interagency Advisory Panel on Research Ethics, 2003).

Domain 4: Risk of Harm to Participants

The 1900 Berlin Code of Ethics (Annas & Grodin, 1992) raised the issue of *qualifications to carry out research*. Medical interventions that were not for diagnostic, healing or immunization purposes were only to be carried out by the medical director himself or those with his special authorization. The Belmont report echoed this perspective in the statements that in order to *minimize risk of rarm*, the researcher must be qualified to carry out the work, all unnecessary physical and mental suffering and injury must be eliminated, and any risk must be balanced by potential for utilization. Further, the risk must be offset by a *benefit to society*: Risks and benefits must be equally born by all groups (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979).

The Canadian TCPS guidelines also speak to the domain of risk of harm and the variables that make up this domain via Schedule A of the TCPS. Schedule A states that each study must be reviewed by a qualified REB: (a) whether the research is funded or not *(conflict of interest); (b)* Whether the funding is external or not ***(****conflict of interest)***;** (c) whether the research is conducted by staff or by students *(qualifications of project leader)***;** (d) whether the research is conducted in person or remotely (e.g., by mail, electronic mail, fax or telephone) (*non-invasive procedures, parallel to risk in everyday life, electronic recording with or without knowledge*)**;** or (e) whether the information is collected directly from subjects or from existing records not in the public domain *(secondary use of data)***.** The TCPS also explicitly states that these standards apply regardless of whether the study is being carried out within Canada or outside its borders (Interagency Advisory Panel on Research Ethics, 2003). The HIA also is concerned with the qualifications of the researcher and the adequacy of safeguards to protect privacy (Ministry of Health and Wellness (Alberta), 2001).

The U.S. perspective with regard to harm was discussed in the Informed Consent domain above. Essentially, the REBS that report to both the Food and Drug Administration (FDA) Drugs and Devices, and the Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP) (Department of Health and Human Services, 2001) are committed to ensuring that the benefits of any systematic study involving human participants outweighs the risks (Edgar & Rothman, 1995; Lafrate & Frentzen, 2001). The Belmont report also lends strong support to the notion that participants in systematic studies must be protected from harm (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979).

The U.S. system of review allows for two options other than full REB review. These include exemption from review and expedited review. Both rest on the premise that the work to be undertaken involves little risk of harm to potential participants. It appears that both were intended to reduce administrative burden on researchers and on REBs. However, the rules and regulations applying to expedited reviews under DHHS are more complex than those in place for exemption from review.[12] There is no evidence that expedited review, "actually results in a faster review and turnaround time" (Oki & Zaia, 2002).

There are two general categories that can qualify for expedited review. The categories are: "(1) Research activities that present no more than *minimal risk* and are listed in the National Institutes of Health guidance document as an "adjunct" to the DHHS and FDA regulations"; and (2) "*minor changes in previously approved research* during the period (or one year or less) for which approval is granted." The criteria for approving research using expedited review include, "*sound research design*" (Amdur & Bankert, 2002) as well as *risk/benefit analysis, equitable selection of participants, informed consent, subject safety, privacy and confidentiality*. Some systematic investigations that may be entitled to expedited review include:

> Research on group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or

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[12] For a full discussion of the Expedited IRB rules, please see (Amdur & Bankert, 2002), pages 114 – 117.

research employing survey, interview, oral history, *focus groups, program evaluation, human factors evaluation, or quality assurance methodologies* (Amdur & Bankert, 2002).

Distributive justice deals with risk in terms of the risk/benefit balance. The predominant question with regard to risk is, “who ought to receive the benefits of research and bear its burdens?” (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. The Belmont Report discusses several widely accepted formulations of just ways to distribute burdens and benefits:

a) To each person an equal share.
b) To each person according to individual need.
c) To each person according to individual effort.
d) To each person according to societal contribution.
e) To each person according to merit.

The Belmont report indicates that these formulations were more commonly associated with social practices such as punishment, taxation and political representation. However, during the 19th and early 20th centuries, experiments were often performed on hospital ward patients who were poor while the benefits flowed to those in private facilities. Then the experience of the Nazi concentration camps (Annas & Grodin, 1992; Lock, 1995; Perley, Fluss, Bankowski, & Simon, 1992), followed by a number of events such as the

Tuskeegee Syphilis study (J. Jones, H., 1981) brought these formulations into the research domain. Consequently, potential participants must be scrutinized in order to determine whether they belong to some class (welfare recipients, racial or ethnic minority groups, persons confined to institutions and so forth) that is being systematically selected because of their easy availability, compromised condition or manipulability other than reasons directly related to the problem being studied (The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). This is a crucial consideration for HHSOs who usually work with disadvantaged populations.

Risk of harm is one of the key issues in the social science and humanities academic disciplines regarding the one-size-fits-all approach to REB review. When federal human subjects protection guidelines were developed in the 1960s and 1970s, social and behavioral science research was subject to the same procedural scrutiny as invasive experimental medical procedures. Many social scientists complained that this placed undue burden on their work, while adding little in the way of real protection for subjects (King et al., 1999), particularly when the proposed study did not follow an experimental methodology. Although some modifications for social science research were made in later revisions (e.g. expedited review, the concept of “minimal risk”), the general framework of treating all human subjects in research identically using a calculus of risks and benefits based on invasive medical procedures has remained intact (Koenig et al., 2003). For an interesting perspective on “standard science” (i.e., experimental research) in comparison to non-experimental work, see Cobern and Loving (2001) and Flyvbjerg (2001).

It appears that there is some consensus that the current REB system of review in most western countries, “imposes a regulatory burden on research institutions and their individual researchers” (American Association of University Professors report, 2001, p.1), and that the “main impetus for the development of REBS was concern about *informed consent and risks* associated with clinical and biomedical research” (p.2). There also appears to be some agreement that obtaining *informed consent* may be a way of offloading the responsibility for the research onto the shoulders of participants, thereby ostensibly protecting the researcher and the organization from disgruntled participants (American Association of University Professors report, 2001) and others in the social science arena (Ringheim, 1995). There is a belief that, “while the subjects of social science may experience unease, discomfort, or embarrassment, these are *risks*, in the words of the Common Rule, that are, “*ordinarily encountered in daily life*” (American Association of University Professors report, 2001, p.3).

Based on the above, in combination with the data collected from the preliminary interviews, layperson focus groups, subject matter expert surveys and follow-up interviews and information from the Dissertation Advisory Committee, the final domains, variables and questions designed to address the key issues within each variable for the web-based study were developed. They are presented in Table 4 below. Table 5, also presented below, provides a selection of citations to support the inclusion of each variable on the final web-based survey.

Table 4

Final survey domains, variables and questions by domain, including examples

Domain	Q #	Variable	Survey Question
Informed Consent	1	Undue influence	The project leader is the participant's boss or therapist.
	2	Undue influence	The participant is ill and the project involves use of a treatment that may help them get better.
	3	Inability to consent	The participant is cognitively impaired or is a child.
	4	Inability to consent	The project procedure is complex and technical. It will be difficult for non-technical people to understand.
	5	Undue influence	The participant is from a minority, marginalized or otherwise disadvantaged group.
	6	Deception	The true purpose of the project will not be revealed to the participants for scientific reasons.
	9	Conflict of interest – internal	The project leader or a member of the team has a vested interest in the outcome of the proposed project.
	40	Secondary use of data	The data for the project has been collected for another purpose. (EXAMPLE: The project team members are clinicians who treat women experiencing high risk pregnancies. The team wants to use the information collected for clinical treatment purposes to develop a process to treat high risk pregnancies in general).
Intended Use	8	Quality assurance	The sole purpose of the project is to improve the quality of a service.
	21	Quality assurance or program evaluation	The project intends to answer questions that have been raised by the staff of a Human Service Organization. (EXAMPLE: front line staff are concerned that clients are having difficulty accessing services. The executive team establishes a project team to investigate the issue).

Domain	Q #	Variable	Survey Question
Intended Use	28	Academic publication	The project leader intends to publish the work in a journal.
	29	Professional conference presentation	The project leader intends to present the results of the project at professional conferences.
	30	HHSO use only	The project leader intends to present the results of the project at internal meetings only.
	33	Generalizability	The project leader is seeking to establish general scientific principles that are not related to any program or service. (EXAMPLE: The project team is collecting information from clients at a hospital in order to better understand how to improve client outcomes for ANY CLIENTS of ANY hospital. No plans are in place for the investigation team to work with the data collection site to improve outcomes for their clients).
Methodology	17	Routine data collection	The project involves ongoing routine data collection. (EXAMPLE: The United Way has collected client satisfaction data for the past 10 years for all of the projects it funds. The executive team is now uncertain as to whether they need REB approval to continue this process).
	18	Non-routine data collection	The project involves a special, time-limited data collection process. (EXAMPLE: A non-profit organization is interested in understanding why donations have dropped off in the past several months. The project proposes to call previous donors who have not donated recently in order to better understand the situation. A questionnaire has been developed for the purpose which will take place on a one-time basis).
	19	Protection of privacy – anonymity	The project involves the review of anonymous information only. (EXAMPLE: The project team is interested in how to prevent death by suicide across the entire country. They intend to review the data collected routinely by the national health authority after it has been stripped of all individually identifiable information).

Domain	Q #	Variable	Survey Question
Methodology	20	Implied consent vs. formal consent	The project involves collection of opinions or suggestions from people who are willing to speak to the project team. (EXAMPLE: The project team is attempting to understand the preference of patients regarding food services. They telephone a few recent patients to ask their opinion about how their eating habits have changed as a result of their illness and how food services can be improved).
	25	Prior approval of qualified REB	The project has been approved by at least one Research Ethics Board. (EXAMPLE: The proposed work is intended to be carried out across the country in mental health clinics. The clinics are operated by 26 health regions, each with its own REB. One health region REB has already approved the work. However, a number of other health regions are blocking the work until it receives additional approval from their particular Research Ethics Board).
	31	Project team conflict of interest – internal	The project team is employed by the organization specifically for the purpose of carrying out this type of project. (EXAMPLE: The project team is employed as internal program evaluators by a rehabilitation facility).
	32	Project team conflict of interest – external	The project team is comprised of people not employed by the organization. (EXAMPLE: The project team is a group of faculty m embers and graduate students from the local university).
	36	Random sampling	All people from a particular group (population) will have an equal chance of being asked to participate.
	37	Random assignment	The project involves random assignment to treatment and control (treatment as usual) groups). (EXAMPLE: 100 people who suffer from eating disorders have agreed to take part in a study on a new psychotherapy approach. All 100 people are randomly assigned to either “control” (psychotherapy treatment as usual) or “treatment” (the new psychotherapy treatment) groups).

Domain	Q #	Variable	Survey Question
Methodology	38	Clinical equipoise	The process being studied is not known to be any better or worse than treatment as usual. (EXAMPLE: a new process has been developed for organizing hospital emergency departments. It is believed that the new process will be more efficient and result in better outcomes for patients, but no evidence currently exists to support that belief. The project is designed to test out the new process in an urban hospital).
	39	Clinical equipoise	The project leader acknowledges that if they become aware that the process being studied is better or worse than the treatment as usual, the project will be discontinued. (EXAMPLE: A new psychotherapy is being tested among people who have been diagnosed as having borderline personality disorder. As the trial continues the project leader becomes aware of a disturbing pattern of behaviours that are occurring for an unusually high number of clients. The project leader chooses to err on the side of caution and discontinues the study until the reasons for the behaviours can be determined. NOTE: The above is different from the statistical “early stopping rules” used in clinical trial research.
Risk of Harm	7	Secondary data	The project team is only going to review existing data.
	10	Qualifications of project leader	The project leader does not have appropriate qualifications to carry out the work. (EXAMPLE: The project team does not include a qualified researcher, evaluator or quality assurance professional).
	11	Accountability of project leader	The project leader is not a member of an appropriate professional association. (EXAMPLE: the proposed work is a quality assurance project but the project leader does not belong to an acknowledged association for quality assurance professionals).
	12	Qualifications of project leader	The project leader is a student who is not directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of an undergraduate project).

Domain	Q #	Variable	Survey Question
Risk of Harm	13	Qualifications of project leader	The project leader is a student who is directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of a Masters or Doctoral program).
	14[13]	Invasive procedures	The project involves testing a new drug, surgical technique or other invasive procedure
	15	Non-invasive procedures	The project involves the project of a new (non-invasive) process. (EXAMPLE: The proposed work involves the creation of a new court to handle drug related offenses).
	16	Parallel to risk in everyday life	The project involves no risk of harm greater than that which a person might experience in their everyday lives. (EXAMPLE: the project team is interested in the body language of individuals who are waiting to cross at a busy roadway intersection. They intend to observe the individuals from a distance without ever interacting with the people they observe).
	22	Conflict of interest – external	The project has been funded by an external organization that has a vested interest in the result of the project. (EXAMPLE: The proposed work involves the trial of a new questionnaire. The developer of the questionnaire is sponsoring the trial and plans the license the questionnaire if it proves to be useful).
	23	Conflict of interest – internal	The project has been entirely funded by the organization where the work will be carried out. (EXAMPLE: The project will be carried out in health promotion programs that are funded and run by the Regional Health Authority. No external funding has been sought for the project).
	24	Minor adverse effects	The project involves collecting information that might be embarrassing or uncomfortable for participants. (EXAMPLE: The proposed work includes questions about sexual activity or financial problems).

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[13] This item was specifically included as a test of the survey. It was anticipated that 100% of all respondents would indicate that any project including this variable would require REB approval.

Domain	Q #	Variable	Survey Question
Risk of Harm	26	Distributive justice	The individuals who bear the risk of the project are also part of the group who will gain the benefits, if any. (EXAMPLE: The study participants are individuals with physical disabilities and the investigation is to determine the effectiveness of current standards for wheelchair accessibility to public buildings).
	27	Minor adverse effects	The project may cause minor adverse effects. (EXAMPLE: The project might cause slight emotional upset for participants).
	34	Lack of anonymity	Individually identifiable information will be used.
	35	Data linking	Individual identifiable information will be used to link several databases together in order to gather more complete information. (EXAMPLE: A unique lifetime identification number (such as a social insurance number of personal health number) will be used to collect information from the health ministry and a local hospital in order to determine the cost of a health program for all those who used the program).
	41	Electronic recording – with knowledge	The participants will be audio or videotaped. (EXAMPLE: the principal investigator is working with a small group of people and interviewing them individually on four different occasions. Each interview takes two hours. In order to carry on a normal conversation and keep accurate records, the interviews are being recorded with the permission of the participants).
	42	Electronic recording – without knowledge	The participants will be audio or videotaped without their knowledge. (EXAMPLE; A non-profit organization is located in a high security building. In an attempt to determine the level of risk their clients experience in coming to the organization, the project proposes to utilize the surveillance camera video recordings that are routinely used in the building lobby).

Table 5

Summary of citations to support inclusion of domains, variables and survey questions

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Informed Consent	1	Undue influence	The project leader is the participant's boss or therapist.	(Weisz, 1990; Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 2002)
	2	Undue influence	The participant is ill and the project involves use of a treatment that may help them get better.	(Amdur & Bankert, 2002; Annas & Grodin, 1992; King et al., 1999), layperson focus groups
	3	Inability to consent	The participant is cognitively impaired or is a child.	(Smith, 1999; Annas, 1992; Amdur, 2002)
	4	Inability to consent	The project procedure is complex and technical. It will be difficult for non-technical people to understand.	(Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 2002)
	5	Undue influence	The participant is from a minority, marginalized or otherwise disadvantaged group.	(Annas, 1992; Jones, 1981; King, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991; Bankowski, 1985; Amdur, 2002)
	6	Deception	The true purpose of the project will not be revealed to the participants for scientific reasons	(Erwin, 1994; Annas, 1992; King, 1999; Amdur, 2002)
	9	Conflict of interest – internal	The project leader or a member of the team has a vested interest in the outcome of the proposed project.	(Amdur & Bankert, 2002; Lowrance, 1985)
	40	Secondary use of data	The data for the project has been collected for another purpose. (EXAMPLE: The project team consists of clinicians who treat women experiencing high risk pregnancies. The team wants to use the information collected for clinical treatment purposes to develop a process to treat high risk pregnancies in general).	(Council for International Organizations of Medical Sciences (CIOMS), 1991)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Intended Use	8	Quality assurance	The sole purpose of the project is to improve the quality of a service.	(Smith, 1999)
	21	quality assurance or program evaluation	The project intends to answer questions that have been raised by the staff of a Human Service Organization. (EXAMPLE: front line staff are concerned that clients are having difficulty accessing services. The executive team establishes a project team to investigate the issue).	(Amdur & Bankert, 2002)
	28	Academic publication	The project leader intends to publish the work in a journal.	(Amdur & Bankert, 2002; Annas & Grodin, 1992)
	29	Professional conference presentation	The project leader intends to present the results of the project at professional conferences.	(Annas, 1992; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	30	HHSO use only	The project leader intends to present the results of the project at internal meetings only.	(Council for International Organizations of Medical Sciences (CIOMS), 1991)
	33	Generalizability	The project leader is seeking to establish general scientific principles that are not related to any program or service. (EXAMPLE: The project team is collecting information from clients at a hospital in order to better understand how to improve client outcomes for ANY CLIENTS of ANY hospital. No plans are in place for the investigation team to work with the data collection site to improve outcomes for their clients).	(Smith, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991)
Methodology	17	Routine data collection	The project involves ongoing routine data collection. (EXAMPLE: The United Way has collected client satisfaction data for the past 10 years for all of the projects it funds. The executive team is now uncertain as to whether they need REB approval to continue this process).	(Council for International Organizations of Medical Sciences (CIOMS), 1991)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Methodology	18	Non-routine data collection	The project involves a special, time-limited data collection process. (EXAMPLE: A non-profit organization is interested in understanding why donations have dropped off in the past several months. The project proposes to call previous donors who have not donated recently in order to better understand the situation. A questionnaire has been developed for the purpose that will take place on a one-time basis).	(Smith, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	19	Protection of privacy - anonymity	The project involves the review of anonymous information only. (EXAMPLE: The project team is interested in how to prevent death by suicide across the entire country. They intend to review the data collected routinely by the national health authority after it has been stripped of all individually identifiable information).	(Annas, 1992; Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 20021)
	20	Implied consent vs. formal consent	The project involves collection of opinions or suggestions from people who are willing to speak to the project team. (EXAMPLE: The project team is attempting to understand the preference of patients regarding food services. They telephone a few recent patients to ask their opinion about how their eating habits have changed as a result of their illness and how food services can be improved).	(Koenig, Back, & Crawley, 2003)
	36	Random sampling	All people from a particular group (population) will have an equal chance of being asked to participate.	(Smith, 1999; Erwin, 1994; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	37	Random assignment	The project involves random assignment to treatment and control (treatment as usual) groups). (EXAMPLE: 100 people who suffer from eating disorders have agreed to take part in a study on a new psychotherapy approach. All 100 people are randomly assigned to either "control" (psychotherapy treatment as usual) or "treatment" (the new psychotherapy treatment) groups).	(Smith, 1999; Erwin, 1994; Council for International Organizations of Medical Sciences (CIOMS), 1991)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Methodology	38	Clinical equipoise	The process being studied is not known to be any better or worse than treatment as usual. (EXAMPLE: a new process has been developed for organizing hospital emergency departments. It is believed that the new process will be more efficient and result in better outcomes for patients, but no evidence currently exists to support that belief. The project is designed to test out the new process in an urban hospital).	(Smith, 1999; Annas, 1992; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	39	Clinical equipoise	The project leader acknowledges that if they become aware that the process being studied is better or worse than the treatment as usual, the project will be discontinued. (EXAMPLE: A new psychotherapy is being tested among people who have been diagnosed as having borderline personality disorder. As the trial continues the project leader becomes aware of a disturbing pattern of behaviours that are occurring for an unusually high number of clients. The project leader chooses to err on the side of caution and discontinues the study until the reasons for the behaviours can be determined. NOTE: The above is different from the statistical “early stopping rules” used in clinical trial research.	(Smith, 1999)
	32	Project team conflict of interest – external	The project team is comprised of people not employed by the organization. (EXAMPLE: The project team is a group of faculty m embers and graduate students from the local university).	(Council for International Organizations of Medical Sciences (CIOMS), 1991)
	31	Project team conflict of interest – internal	The project team is employed by the organization specifically for the purpose of carrying out this type of project. (EXAMPLE: The project team is employed as internal program evaluators by a rehabilitation facility).	(Council for International Organizations of Medical Sciences (CIOMS), 1991)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Methodology	25	Prior approval of qualified REB	The project has been approved by at least one Research Ethics Board. (EXAMPLE: The proposed work is intended to be carried out across the country in mental health clinics. The clinics are operated by 26 health regions, each with its own REB. One health region REB has already approved the work. However, a number of other health regions are blocking the work until it receives additional approval from their particular Research Ethics Board).	(Amdur & Bankert, 2002; Bradshaw et al., 2000; Jamrozik, 1992, 1997, 2000; Jamrozik & Kolybaba, 1999; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004)
Risk of Harm	7	Secondary data	The project team is only going to review existing data.	(Simon, 2000; Smith, 1999; Amdur, 2002)
	10	Qualifications of project leader	The project leader does not have appropriate qualifications to carry out the work. (EXAMPLE: The project team does not include a qualified researcher, evaluator or quality assurance professional).	(Social Sciences and Humanities Research Council of Canada, 2004; Smith, 1999; Annas, 1992; Natural Sciences and Engineering Research Council of Canada, 2004; Canadian Institutes of Health Research, 2004)
	11	Accountability of project leader	The project leader is not a member of an appropriate professional association. (EXAMPLE: the proposed work is a quality assurance project but the project leader does not belong to an acknowledged association for quality assurance professionals).	(Smith, 1999; Reynolds, 2001; Annas, 1992)
	12	Qualifications of project leader	The project leader is a student who is not directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of an undergraduate project).	(Social Sciences and Humanities Research Council of Canada, 2004; Smith, 1999; Annas, 1992; Natural Sciences and Engineering Research Council of Canada, 2004; Canadian Institutes of Health Research, 2004)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Risk of Harm	13	Qualifications of project leader	The project leader is a student who is directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of a Masters or Doctoral program).	(Social Sciences and Humanities Research Council of Canada, 2004; Smith, 1999; Annas, 1992; Natural Sciences and Engineering Research Council of Canada, 2004; Canadian Institutes of Health Research, 2004)
	14[14]	Invasive procedures	The project involves testing a new drug, surgical technique or other invasive procedure	(Smith, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	15	Non-invasive procedures	The project involves the project of a new (non-invasive) process. (EXAMPLE: The proposed work involves the creation of a new court to handle drug related offenses).	(Smith, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	16	Parallel to risk in everyday life	The project involves no risk of harm greater than that which a person might experience in their everyday lives. (EXAMPLE: the project team is interested in the body language of individuals who are waiting to cross at a busy roadway intersection. They intend to observe the individuals from a distance without ever interacting with the people they observe).	(Amdur, 2002; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	22	Conflict of interest – external organization	The project has been funded by an external organization that has a vested interest in the result of the project. (EXAMPLE: The proposed work involves the trial of a new questionnaire. The developer of the questionnaire is sponsoring the trial and plans the license the questionnaire if it proves to be useful).	(King et al., 1999; Lowrance, 1985)

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[14] This item was specifically included as a test of the survey. It was anticipated that 100% of all respondents would indicate that any project including this variable would require REB approval.

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Risk of Harm	23	Conflict of interest – internal organization	The project has been entirely funded by the organization where the work will be carried out. (EXAMPLE: The project will be carried out in health promotion programs that are funded and run by the Regional Health Authority. No external funding has been sought for the project).	(King, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991)
	24	Minor adverse effects	The project involves collecting information that might be embarrassing or uncomfortable for participants. (EXAMPLE: The proposed work includes questions about sexual activity or financial problems).	(Smith, 1999; Annas, 1992; King, 1999; Amdur, 2002)
	26	Distributive justice	The individuals who bear the risk of the project are also part of the group who will gain the benefits, if any. (EXAMPLE: The study participants are individuals with physical disabilities and the investigation is to determine the effectiveness of current standards for wheelchair accessibility to public buildings).	(Smith, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 2002)
	27	Minor adverse effects	The project may cause minor adverse effects. (EXAMPLE: The project might cause slight emotional upset for participants).	(Smith, 1999; Annas, 1992; King, 1999; Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 2002)
	34	Lack of anonymity	Individually identifiable information will be used.	(Annas, 1992; Council for International Organizations of Medical Sciences (CIOMS), 1991; Amdur, 2002)
	35	Data linking	Individual identifiable information will be used to link several databases together in order to gather more complete information. (EXAMPLE: A unique lifetime identification number (such as a social insurance number of personal health number) will be used to collect information from the health ministry and a local hospital in order to determine the cost of a health program for all those who used the program).	(Council for International Organizations of Medical Sciences (CIOMS), 1991)

Domain	Q #	Variable	Survey Question	Citations to Support Survey Questions
Risk of Harm	41	Electronic recording – with knowledge	The participants will be audio or videotaped. (EXAMPLE: the principal investigator is working with a small group of people and interviewing them individually on four different occasions. Each interview takes two hours. In order to carry on a normal conversation and keep accurate records, the interviews are being recorded with the permission of the participants).	(Erwin, 1994; King, 1999; Amdur, 2002)
	42	Electronic recording – without knowledge	The participants will be audio or videotaped without their knowledge. (EXAMPLE; A non-profit organization is located in a high security building. In an attempt to determine the level of risk their clients experience in coming to the organization, the project proposes to utilize the surveillance camera video recordings that are routinely used in the building lobby).	(Erwin, 1994; King, 1999; Amdur, 2002)

Publication Standards of Peer Reviewed Journals

Protection of human research participants is the most cited reason given for requiring REB review. Although “protection” can be construed in many ways, protection is often espoused to be a valuing of privacy and of a life that is free from unethical conduct of researchers. Publication of research findings is the logical conclusion to undertakings that expands knowledge in a significant way.

Table 6

Publicly available policies regarding REB review for scientific journals (as of January 23, 2003)

Journal Name	Primary Discipline	REB policy in place?	Policy Regarding Research Ethics Review
1. Community Mental Health Journal (CMHJ)	General HHSO Research	No	CMHJ does not have a general policy on REB approval. Many articles are not empirical. Reviewers may reject any article based on lack of REB approval if they believe it is an error in research design.
2. Health Services Research (HSR)	General HHSO Research	No	HSR does not have a rigid policy with respect to REB approval If a manuscript reports on a study that seems problematic with respect to human subject concerns or any other ethical issues related to research design, the reviewers and editors request clarification about the design and REB approval and would take these into account.
3. Journal of Behavioral Health Services and Research (JBHS&R)	General HHSO Research	No	No policy in place.
4. Journal of Community and Applied Social Psychology ((JCASP)	General HHSO Research	No	The editor was unaware of current policy regarding the need for REB approval. Policy is established by John Wiley Publishers.
5. Journal of Community Psychology (JCP)	General HHSO Research	No	JCP assumes that the authors will identify their procedures for protecting subjects but indicated that authors identify such procedures in a variety of ways, depending on the facts of the study and the circumstances. There is no requirement for proof of REB approval.

Journal Name	Primary Discipline	REB Policy in Place?	Policy Regarding Research Ethics Review
6. Canadian Medical Association Journal (CMAJ)[15][16]	Medicine	Yes	A statement is required regarding REB approval for any paper that involves humans as participants. Full name of REB must be provided. When a submission indicates that REB review was not necessary, CMAJ asks for documentation.
7. Lancet	Medicine	Yes	Lancet asks for authors to provide information on REB review along with all reports of RCTs. They rarely seek separate proof of ethics committee approval.
8. Medical Journal of Australia (MJA)	Medicine	Yes	RCTs must follow the CONSORT guidelines. All experimental investigations on human subjects must include a statement that the subjects gave their informed consent. The name of the ethics committee that gave approval for the study should be supplied. Ethical approval may also be required for case reports. Patient anonymity must be preserved, and identifying information should not be published unless it is essential for scientific purposes. If identifying information is essential, authors must provide a signed statement form the patient(s) giving approval for the publication of identifying information, including photographs. Studies involving Aboriginal or Torres Strait Islander subjects must also state that they have been approved by the relevant local Indigenous representatives.

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[15] Referenced Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

[16] Referenced CONSORT standards

Journal	Primary Discipline	REB Policy in Place?	Policy Regarding Research Ethics Review
9. The Journal of the American Medical Association (JAMA)	Medicine	Yes	JAMA requires all authors to obtain REB of all research involving human participants (not only RCTs). If an REB is not available, JAMA requires authors to explain how they have followed the Declaration of Helsinki and how they obtained informed consent. This information must be presented in the methods section of all articles.
10. American Journal of Evaluation (Dehejia & National Bureau of Economic Research.)	Program Evaluation	No	No policy in place.
11. Evaluation and Program Planning (EPP)	Program Evaluation	No	No policy in place.
12. New Directions in Evaluation (NDE)	Program Evaluation	No	No policy in place.
13. Accreditation and Quality Assurance (AJMEDQUAL)	Quality Assurance	No	No policy in place.
14. International Journal for Quality in Health Care (IJQHC)	Quality Assurance	No	No policy in place.
15. International Journal of Health Care Quality Assurance	Quality Assurance	No	No policy in place.
16. Journal of Quality Health Care	Quality Assurance	No	No policy in place.

No journal required actual proof of REB approval; the most stringent approach is to include REB approval in the methods section.

The Information for Authors sections for each journal was reviewed along with associated reference documents cited including the CONSORT guidelines, the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (CMAJ), the Declaration of Helsinki for those organizations or project leaders that do not have access to a formal REB process (JAMA), the U.S. Code of Federal Regulations (JAMA) and the NBAC *Ethical and Policy Issues Involving Human Subjects, Volume 1, 2001* (CMHJ). In each case the editor or publisher was contacted to further enquire as to the policy of the publication regarding whether REB review was required for empirical articles involving human participants. All sixteen journals responded to the enquiry.

The evidence presented in Table 6 makes a strong statement regarding the state of REB review requirements in peer reviewed journals where the work of HHSOs might appear. Clearly medical journals have worked together to determine acceptable standards for virtually every aspect of articles submitted, including clear guidelines regarding REB review. The areas of general HHSO research, including health services research, program evaluation and quality assurance did not have formal policies in place, although most editors were giving serious consideration to the possibility of introducing standards. Since this component of the research was undertaken almost two years ago, and there has been a great deal of public debate regarding standards for REBs and publication of scientific work, it may be a worthwhile venture to revisit the policies of each journal to determine whether standards are now in place.

When JAMA was queried further with regard to the definition of “research”, they cited the US Code of Federal Regulations that states:

> research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (Department of Health and Human Services, 1997, p.6).

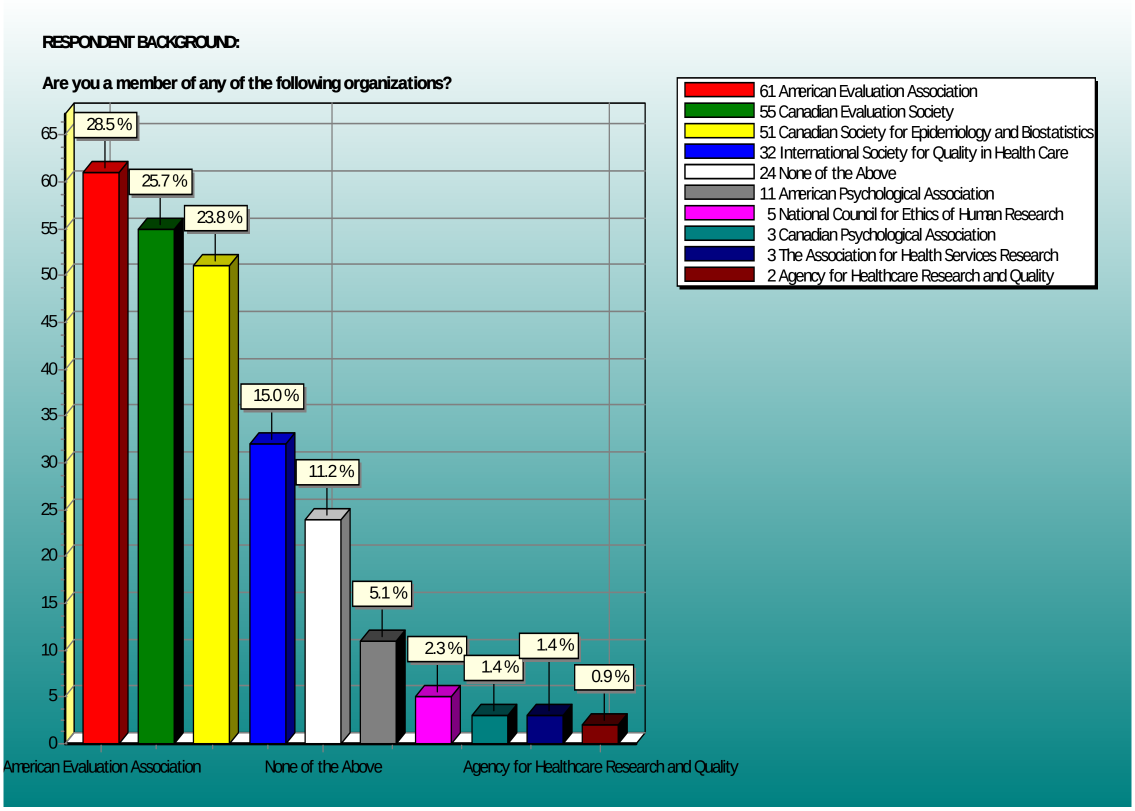
International Web-Based Survey

A total of 214 completed responses were received. Flexibility in the research protocol was necessary in order to engage the participating organizations. Consequently it is not possible to give a precise response rate for all participating agencies. However, the American Evaluation Association followed the proposed protocol precisely as did the Canadian Society for Epidemiology and Biostatisticians. Two hundred and eighty five individuals were randomly selected from the membership list of each organization. APA respondents numbered 61 (a 21% response rate), and CSEB respondents numbered 51 (an 18% response rate). The International Society for Quality in Healthcare hand picked 200 respondents who would be able to respond to the survey based on language and availability of access to the internet. The response rate for this group was 16%. The response rates were disappointing, particularly since the research protocol used the full Dillman contact method of a preliminary letter, information about the survey, and follow-up contacts. This is widely acknowledged as the best way to increase response rates in web-based surveys.

A total of 9 associations and societies were represented as can be seen in Figure 1.

Figure 1

Organizational affiliation of international web-based survey respondents

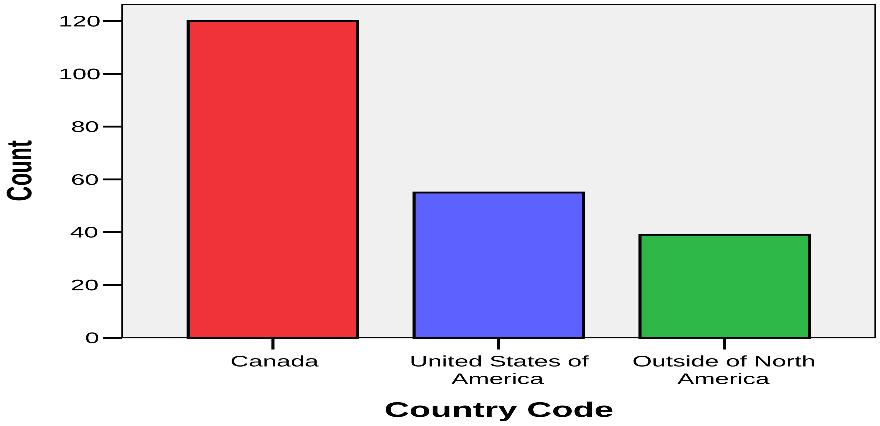


One of the goals in surveying such a broad array of professional associations was to engage individuals who had expertise in a number of domains including research, program evaluation, quality assurance, research ethics and REB procedures. Respondents indicated that 34.6% were experts in research, 44.9% had strong research backgrounds and an additional 16.4% had some knowledge of research for a total of 95.9% who were experienced researchers. Of the 214 respondents, 87.9% had at least some knowledge of program evaluation with the majority considering themselves to have strong or expert evaluation knowledge. Seventy percent of Quality Assurance respondents had at least some knowledge with 12.1% having expert and 23.8% having strong knowledge of quality assurance work. With regard to research ethics, 83.5% had at least some knowledge, with 12.1% being expert, and 36.4% having strong knowledge. With regard to Research Ethics Board Procedures, 50.2% had at least some knowledge with 9.8% having expert knowledge, and 22.4% having strong knowledge of such procedures.

The majority of respondents were from Canada (N=120, 56.3%) and the United States (N=55, 25.8%), but responses were received from a total of 26 countries, as illustrated in Figure 2.

Figure 2

Country of residence of international web-based survey respondents

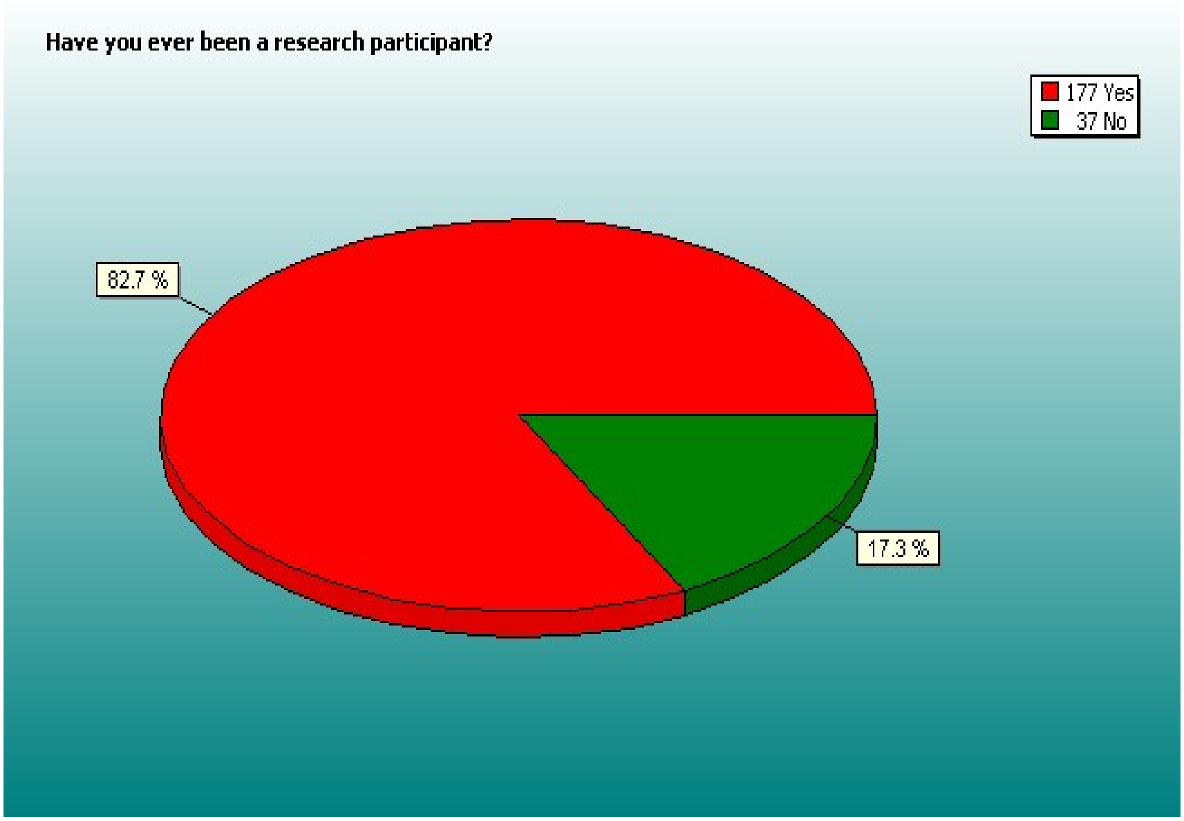


Respondents from outside of North American were fewest in number (N = 39). Response rates from outside of North American included 7 from Australia, 3 from the Cayman Islands, 2 from each of Uruguay, Uzbekistan, the Philippines, the United Kingdom and Japan. A single response was obtained from each of Denmark, Diego Garcia, the Dominican Republic, Chad, Switzerland, Chile, Chatham Island, Taiwan, Itality, South Africa, Ireland, Israel, Argentina, Lebanon, Vatican City and Germany.

Respondents indicated that 82.7% (N=177) had been research participants themselves at least once (Figure 2). With regard to their primary activities in their current positions, 40.8% (N=87) indicated that research was their primary mandate, 30.5% (N = 65) indicated evaluation, 20.2% (N=43) indicated “other” and 8.5% (N=18) indicated that their primary activity in their current position was quality assurance work. At least three respondents indicated that they carried out research work in the area of quality assurance. This clearly shows the blurring of lines between disciplines that necessitates a new look at when work should be submitted to REBs and under what circumstances. Further, all respondents worked in areas that would likely encounter the dilemma of when to apply for REB approval.

Figure 3

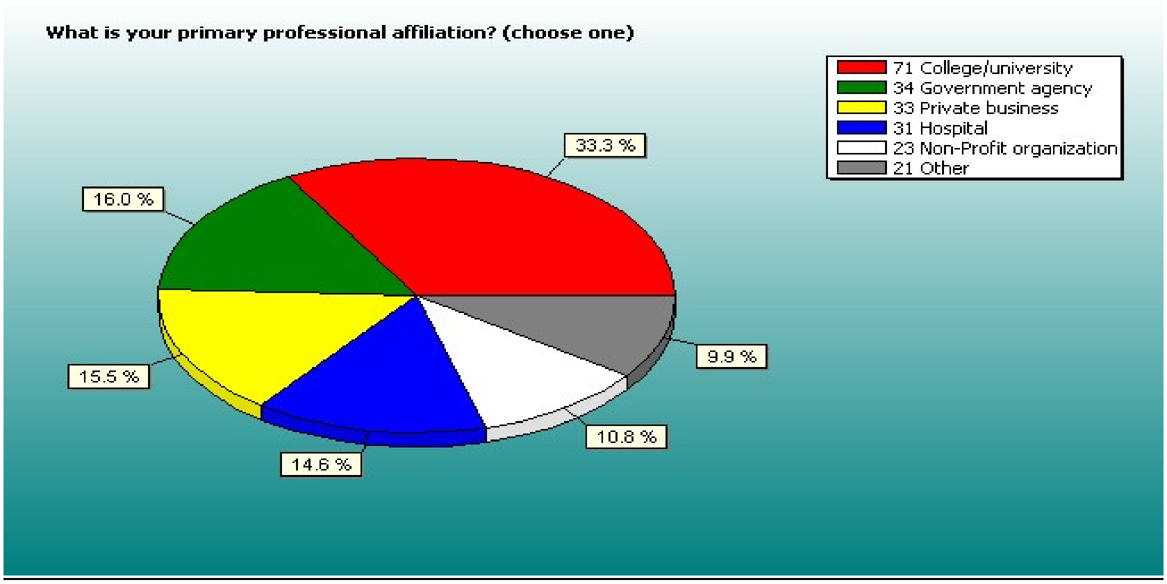
Number of respondents who had been research participants



Respondents were asked to indicate their primary professional affiliation. Findings indicated that 33.3% (N=71) had a primary affiliation with a college or university, 16% (N=34) with a government agency, 15.5% (N=33) with a private business, 14.6% (N=31) with a hospital, 10.8% (N=23) with a non-profit organization and the balance of 9.9% (N=21) with other organizations. Individuals who indicated “other” as their primary professional affiliation were asked to specify their primary professional affiliation in order to ensure that their work would bring them into contact with the issues intended to be addressed by the survey.

Figure 4

Respondents' primary affiliation

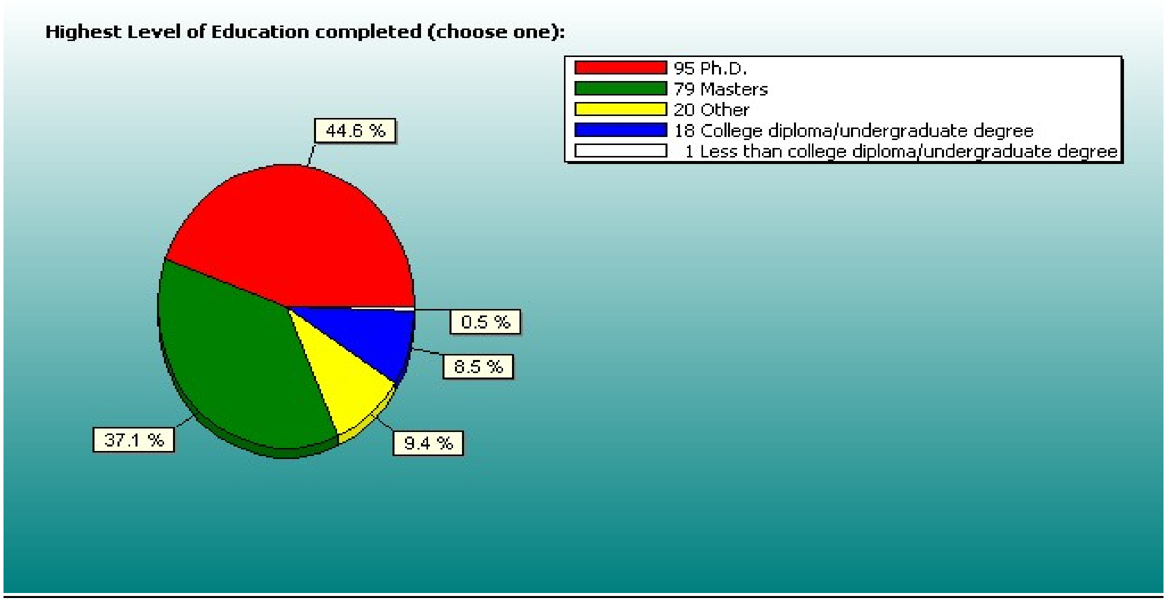


The majority (72.8%, N = 156) had been working in their primary area of activity for at least 5 years. This was also a very well educated sample as 81.7% (N=175) had completed at least a Master's degree (see Figure 5).

Given the above description of the web survey sample, it seems clear that the individuals included in the survey had the knowledge and expertise necessary to address the questions included in the survey in a thoughtful and meaningful way.

Figure 5

Respondents' self-reported highest level of education completed



It was the intention of the study to include only those individuals who had considerable experience in at least one, and hopefully multiple knowledge areas including research, quality assurance, program evaluation, research ethics and REB procedures. Although it was hoped that at least some individuals would be expert across knowledge areas, this was not considered likely. However, it was important to have participants who were highly expert in at least one knowledge area. Consequently, the self-reported participant responses in each of these areas were aggregated. As indicated in Table 7, it was found that 24 (11.2%) respondents considered themselves to be experts in all areas. Thirteen respondents (6.1%) indicated that they were not expert in any of the necessary areas. The 13 individuals who did not consider themselves to have expertise in any of the five key knowledge areas were removed from the quantitative analysis, leaving a total of 201 respondents with at least one area of expert knowledge.

Table 7

Respondent self-reported level of expertise in relevant topic areas (research, program evaluation, quality assurance, research ethics review and administration/oversight)

	Freq	%	Cum %
Superior/expert in 0/5 domains	13	6.1	6.1
Superior/expert in 1/5 domains	37	17.3	23.4
Superior/expert in 2/5 domains	61	28.5	51.9
Superior/expert in 3/5 domains	39	18.2	70.1
Superior/expert in 4/5 domains	40	18.7	88.8
Superior/expert in 5/5 domains	24	11.2	100.0
Total	214	100.0	

All 214 surveys were complete and none of the 41 questions had missing answers. This is likely due to the forced choice nature of the web survey. It was not possible to move on to the next page of questions without first selecting answers for all of the questions on the current page. Each question included a “Not Clear/Undecided” option as a possible answer. Respondents rarely used these options. All answers were checked to ensure that the responses fell within the acceptable ranges. Those respondents who did not consider themselves to have excellent knowledge of at least one relevant knowledge area (research, program evaluation, quality assurance, research ethics or REB procedures) were removed from further analysis, leaving 201 surveys. The thirteen excluded surveys were examined to determine if they differed in any meaningful way from those that were included. Of the 13, twelve were from Canada and one from the United Kingdom. This is an over-representation of Canadians and an under-representation of U.S. respondents. Given the overall survey response, one would expect 7 Canadians and 3 U.S. respondents to consider themselves to not be highly expert in at least one knowledge area. As could be expected, those with college/undergraduate degrees and masters degrees were overrepresented and those with Ph.D.s were overrepresented. Overall, these differences were considered to be somewhat expected, given that the issue in question was self-reported expertise.

Although the analysis initially proposed for the current study was a confirmatory factor analysis, the skewed nature of the responses and insufficient number of respondents necessitated removing this analysis, as the results would likely be unstable and perhaps misleading. Consequently a simple examination of responses is presented below and divided into three categories.

Table 8 shows those domains and variables where there was a high degree (80%+) of agreement among experts that any project including such a variable would clearly require REB review. Table 9 shows domain and variables where there was moderate (50 – 80%) agreement that REB review is clearly required. Table 10 illustrates the remaining domains and variables – those where experts were split in their opinions regarding whether any systematic investigation involving human participants would require REB review. These variables warrant further research.

Table 8

High expert agreement (80%+) on variables that clearly require REB review

Domain	Q #	#	%	Variable	Survey Question
Informed Consent	2	166	82.6	Undue Influence	The participant is ill and the project involves use of a treatment that may help them get better.
	3	188	93.5	Inability to consent	The participant is cognitively impaired or is a child.
	6	170	84.6	Deception	The true purpose of the project will not be revealed to the participants for scientific reasons
Methodology	37	168	83.6	Random assignment	The project involves random assignment to treatment and control (treatment as usual) groups). (EXAMPLE: 100 people who suffer from eating disorders have agreed to take part in a study on a new psychotherapy approach. All 100 people are randomly assigned to either "control" (psychotherapy treatment as usual) or "treatment" (the new psychotherapy treatment) groups).
Risk of Harm	14-15	198	98.5	Invasive procedures	The project involves testing a new drug, surgical technique or other invasive procedure
	24	173	80.8	Minor adverse effects	The project involves collecting information that might be embarrassing or uncomfortable for participants. (EXAMPLE: The proposed work includes questions about sexual activity or financial problems).
	27	165	82.1	Minor adverse effects	The project may cause minor adverse effects. (EXAMPLE: The project might cause slight emotional upset for participants).
	34	170	84.6	Lack of anonymity	Individually identifiable information will be used.
	35	162	80.6	Data linking	Individual identifiable information will be used to link several databases together in order to gather more complete information. (EXAMPLE: A unique lifetime identification number (such as a social insurance number of personal health number) will be used to collect information from the health ministry and a local hospital in order to determine the cost of a health program for all those who used the program).
	42	173	86.1	Electronic recording – without knowledge	The participants will be audio or videotaped without their knowledge. (EXAMPLE; A non-profit organization is located in a high security building. In an attempt to determine the level of risk their clients experience in coming to the organization, the project proposes to utilize the surveillance camera video recordings that are routinely used in the building lobby).

Table 9

Moderate expert agreement (50%-79%) on variables that <u>clearly</u> require REB review

Domain	Q #	#	%	Variable	Survey Question
Informed Consent	1	140	69.7	Undue Influence	The project leader is the participant's boss or therapist.
	9	149	74.1	Conflict of Interest – internal	The project leader or a member of the team has a vested interest in the outcome of the proposed project.
Methodology	38	107	53.2	Clinical equipoise	The process being studied is not known to be any better or worse than treatment as usual. (EXAMPLE: a new process has been developed for organizing hospital emergency departments. It is believed that the new process will be more efficient and result in better outcomes for patients, but no evidence currently exists to support that belief. The project is designed to test out the new process in an urban hospital).
	39	152	75.6	Clinical equipoise	The project leader acknowledges that if they become aware that the process being studied is better or worse than the treatment as usual, the project will be discontinued. (EXAMPLE: A new psychotherapy is being tested among people who have been diagnosed as having borderline personality disorder. As the trial continues the project leader becomes aware of a disturbing pattern of behaviours that are occurring for an unusually high number of clients. The project leader chooses to err on the side of caution and discontinues the study until the reasons for the behaviours can be determined. NOTE: The above is different from the statistical "early stopping rules" used in clinical trial research.
Risk of Harm	10	127	63.2	Qualifications of project leader	The project leader does not have appropriate qualifications to carry out the work. (EXAMPLE: The project team does not include a qualified researcher, evaluator or quality assurance professional).
	12	111	55.2	Qualifications of project leader	The project leader is a student who is not directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of an undergraduate project).

Domain	Q #	#	%	Variable	Survey Question
	22	144	71.6	Conflict of interest - external	The project has been funded by an external organization that has a vested interest in the result of the project. (EXAMPLE: The proposed work involves the trial of a new questionnaire. The developer of the questionnaire is sponsoring the trial and plans the license the questionnaire if it proves to be useful).
	26	103	51.2	Distributive justice	The individuals who bear the risk of the project are also part of the group who will gain the benefits, if any. (EXAMPLE: The study participants are individuals with physical disabilities and the investigation is to determine the effectiveness of current standards for wheelchair accessibility to public buildings).
	41	126	62.7	Electronic recording – with knowledge	The participants will be audio or videotaped. (EXAMPLE: the principal investigator is working with a small group of people and interviewing them individually on four different occasions. Each interview takes two hours. In order to carry on a normal conversation and keep accurate records, the interviews are being recorded with the permission of the participants).

Table 10

Divergent expert opinion: variables that require further research

Domain	Q #	Answer Options	#	%	Variable	Survey Question
Informed Consent	4	Clearly Needs Review	87	43.3	Inability to consent	The project procedure is complex and technical. It will be difficult for non-technical people to understand.
		May Need Review	84	41.8		
		Does Not Need Review	15	7.5		
		Not Clear/Undecided	15	7.5		
	5	Clearly Needs Review	81	40.3	Undue Influence	The participant is from a minority, marginalized or otherwise disadvantaged group.
		May Need Review	99	49.3		
		Does Not Need Review	16	8.0		
		Not Clear/Undecided	5	2.5		
	40	Clearly Needs Review	95	47.3	Secondary use of data	The data for the project has been collected for another purpose. (EXAMPLE: The project team are clinicians who treat women experiencing high risk pregnancies. The team wants to use the information collected for clinical treatment purposes to develop a process to treat high risk pregnancies in general).
		May Need Review	86	42.8		
		Does Not Need Review	17	8.5		
		Not Clear/Undecided	3	1.5		
Intended Use	8	Clearly Needs Review	13	6.5	Quality assurance	The sole purpose of the project is to improve the quality of a service.
		May Need Review	143	71.1		
		Does Not Need Review	34	16.9		
		Not Clear/Undecided	11	5.5		
	21	Clearly Needs Review	31	15.4	Quality assurance or program evaluation	The project intends to answer questions that have been raised by the staff of a Human Service Organization. (EXAMPLE: front line staff are concerned that clients are having difficulty accessing services. The executive team establishes a project team to investigate the issue).
		May Need Review	97	48.3		
		Does Not Need Review	69	34.3		
		Not Clear/Undecided	4	2.0		
	28	Clearly Needs Review	67	33.3	Academic publication	The project leader intends to publish the work in a journal.
		May Need Review	92	45.8		
		Does Not Need Review	31	15.4		
		Not Clear/Undecided	11	5.5		

Domain	Q #	Answer Options	#	%	Variable	Survey Question
Intended Use	29	Clearly Needs Review	49	24.4	Professional conference presentation	The project leader intends to present the results of the project at professional conferences.
		May Need Review	107	53.2		
		Does Not Need Review	34	16.9		
		Not Clear/Undecided	11	5.5		
	30	Clearly Needs Review	28	13.9	HHSO use only	The project leader intends to present the results of the project at internal meetings only.
		May Need Review	101	50.2		
		Does Not Need Review	54	26.9		
		Not Clear/Undecided	18	9.0		
	33	Clearly Needs Review	84	41.8	Generalizability	The project leader is seeking to establish general scientific principles that are not related to any program or service. (EXAMPLE: The project team is collecting information from clients at a hospital in order to better understand how to improve client outcomes for ANY CLIENTS of ANY hospital. No plans are in place for the investigation team to work with the data collection site to improve outcomes for their clients).
		May Need Review	84	41.8		
		Does Not Need Review	25	12.4		
		Not Clear/Undecided	8	4.0		
Methodology	17	Clearly Needs Review	25	12.4	Routine data collection	The project involves ongoing routine data collection. (EXAMPLE: The United Way has collected client satisfaction data for the past 10 years for all of the projects it funds. The executive team is now uncertain as to whether they need REB approval to continue this process).
		May Need Review	93	46.3		
		Does Not Need Review	80	39.8		
		Not Clear/Undecided	3	1.5		
	18	Clearly Needs Review	38	18.9	Non-routine data collection	The project involves a special, time-limited data collection process. (EXAMPLE: A non-profit organization is interested in understanding why donations have dropped off in the past several months. The project proposes to call previous donors who have not donated recently in order to better understand the situation. A questionnaire has been developed for the purpose that will take place on a one-time basis).
		May Need Review	98	48.8		
		Does Not Need Review	62	30.8		
		Not Clear/Undecided	3	1.5		

Domain	Q #	Answer Options	#	%	Variable	Survey Question
	20	Clearly Needs Review	50	24.9	Implied consent vs. formal consent	The project involves collection of opinions or suggestions from people who are willing to speak to the project team. (EXAMPLE: The project team is attempting to understand the preference of patients regarding food services. They telephone a few recent patients to ask their opinion about how their eating habits have changed as a result of their illness and how food services can be improved).
		May Need Review	100	49.8		
		Does Not Need Review	50	24.9		
		Not Clear/Undecided	1	.5		
	25	Clearly Needs Review	81	40.3	Prior approval of qualified REB	The project has been approved by at least one Research Ethics Board. (EXAMPLE: The proposed work is intended to be carried out across the country in mental health clinics. The clinics are operated by 26 health regions, each with its own REB. One health region REB has already approved the work. However, a number of other health regions are blocking the work until it receives additional approval from their particular Research Ethics Board).
		May Need Review	71	35.3		
		Does Not Need Review	39	19.4		
		Not Clear/Undecided	10	5.0		
	31	Clearly Needs Review	25	12.4	Project team conflict of interest – internal	The project team is employed by the organization specifically for the purpose of carrying out this type of project. (EXAMPLE: The project team is employed as internal program evaluators by a rehabilitation facility).
		May Need Review	130	64.7		
		Does Not Need Review	33	16.4		
		Not Clear/Undecided	13	6.5		
Risk of Harm	7	Clearly Needs Review	26	12.9	Secondary data	The project team is only going to review existing data.
		May Need Review	106	52.7		
		Does Not Need Review	65	32.3		
		Not Clear/Undecided	4	2.0		
	11	Clearly Needs Review	38	18.9	Accountability of project leader	The project leader is not a member of an appropriate professional association. (EXAMPLE: the proposed work is a quality assurance project but the project leader does not belong to an acknowledged association for quality assurance professionals).
		May Need Review	93	46.3		
		Does Not Need Review	50	24.9		
		Not Clear/Undecided	20	10.0		

Domain	Q #	Answer Options	#	%	Variable	Survey Question
	13	Clearly Needs Review	57	28.4	Qualifications of project leader	The project leader is a student who is directly supervised by a qualified individual. (EXAMPLE: the proposed work is part of a Masters or Doctoral program).
		May Need Review	116	57.7		
		Does Not Need Review	26	12.9		
		Not Clear/Undecided	2	1.0		
	15	Clearly Needs Review	99	49.3	Non-invasive procedures	The project involves the project of a new (non-invasive) process. (EXAMPLE: The proposed work involves the creation of a new court to handle drug related offenses).
		May Need Review	83	41.3		
		Does Not Need Review	15	7.5		
		Not Clear/Undecided	4	2.0		
	16	Clearly Needs Review	39	19.4	Parallel to risk in everyday life	The project involves no risk of harm greater than that that a person might experience in their everyday lives. (EXAMPLE: the project team is interested in the body language of individuals who are waiting to cross at a busy roadway intersection. They intend to observe the individuals from a distance without ever interacting with the people they observe).
		May Need Review	82	40.8		
		Does Not Need Review	78	38.8		
		Not Clear/Undecided	2	1.0		
	23	Clearly Needs Review	54	26.9	Conflict of interest – internal	The project has been entirely funded by the organization where the work will be carried out. (EXAMPLE: The project will be carried out in health promotion programs that are funded and run by the Regional Health Authority. No external funding has been sought for the project).
		May Need Review	114	56.7		
		Does Not Need Review	19	9.5		
		Not Clear/Undecided	14	7.0		

Only one variable indicated that experts agreed moderately (50% - 79% agreement) that no review would be necessary if the variable was included in a study. This was survey item # 19 where the domain was *risk of harm* and the variable was *protection of privacy – anonymity in the specific situation where the project involved the review of anonymous data only***.** A slim majority of respondents, 54.2%, indicated that REB review was clearly not necessary in this instance. However, as can be seen from Table 10, there were several other instances where a large number of respondents believed that REB review was not necessary. This is an important point to consider because it clearly indicates that although experts have a high degree of agreement on some variables, they do not on others. By drawing out the variables of contention it becomes possible to discuss the areas of divergence and, perhaps, to begin to address these issues in order to ensure greater consistency of decision making regarding whether to seek REB review. Further, these variables may prove useful in discussions that are aimed at increasing the consistency of decision making between REBs.

In order to be thorough, respondents were asked if there were characteristics of systematic projects that clearly distinguish between those projects that should go for REB review and those that should not, that had not been captured in the survey. The responses are presented in Table 11.

Of the 72 who answered “yes”, 3 left their responses blank and 3 provided answers that could not be interpreted with certainty. The remainder provided at least one, and as many as five additional points that they believed should be considered when deciding whether a project requires review. The most frequently provided responses to this question were items that had been addressed within the survey. For instance, 31 of the 172 total responses (18%) indicated that any *risk of harm* should be a differentiating factor between those studies that require review and those that do not. Survey question #16 addressed the issue of harm directly (*The project involves no risk of harm greater than that which a person might experience in their everyday lives*). Several respondents mentioned that "harm" did not need to be physical, mental or emotional. The harm might be the potential for economic loss, loss of reputation, or the potential legal ramifications for answering honestly. The issue of protecting participants from potential legal fallout from participation was a strong theme among those who were concerned about harms.

Respondents also provided additional detail regarding the conflict of interest variable. This issue was addressed in questions #1 (*The project leader is the participant's boss or therapist), #9 (The project leader or a member of the team has a vested interest in the outcome of the proposed project), and #22 (The project has been funded by an external organization that has a vested interest in the result of the study*). However, 16 of the total responses (9.3%) spoke to the issue of conflict of interest, specifically to concerns about potentially coercive relationships (e.g., physician-patient, teacher-student, line administration-employee), where the sponsoring organization stands to benefit from the study results, or where the recruiter, such as a physician, may be paid to recruit subjects. One particularly interesting response concerning conflict of interest indicated that established researchers may have a potential conflict of interest if they have worked in the same field for years and their reputation would be affected if current results were not supportive of previous ones.

Table 11

Qualitative data from respondents identifying additional key variables

	Freq.	%	Cumulative Percent
Potential risk/harm (legal, physical, psychological)	31	18.0	18.0
Conflict of interest	16	9.3	27.3
Individually identifable information	16	9.3	36.6
Disadvantaged group (minors, ill, powerless, incarcerated)	15	8.7	45.3
Combination of factors	11	6.4	51.7
Deception	9	5.2	57.0
Purpose of the project	8	4.7	61.6
Method (generalizable, random sample/selection)	6	3.5	65.1
Secondary use of data	6	3.5	68.6
Direct contact with people	5	2.9	71.5
New drugs, treatments or therapies (unknown efficacy)	5	2.9	74.4
Need for informed consent	5	2.9	77.3
Methodological inadequacy (including research bias)	5	2.9	80.2
Intent to publish/disseminate	5	2.9	83.1
Routine evaluation	3	1.7	84.9
Intellectual property rights	3	1.7	86.6
Compensation	2	1.2	87.8
Invasiveness	2	1.2	89.0
Use of biological samples	2	1.2	90.1
Surveys	2	1.2	91.3
Quality assurance	2	1.2	92.4
Qualifications of project lead	2	1.2	93.6
Administrative burden on participant	2	1.2	94.8
Participatory research (whole community)	1	.6	95.3
Imbalance of harms/benefits	1	.6	95.9
New treatment based on evidence (no review needed)	1	.6	96.5
Infringement of individual rights	1	.6	97.1
University affiliation	1	.6	97.7
Archival data	1	.6	98.3
Anything not covered by legislation	1	.6	98.8
Any human participation (including just data)	1	.6	99.4
Use of health information	1	.6	100.0
Total	172	100.0	

The issue of individually identifiable data was mentioned in 9.3% of answers although survey questions #19 (*The project involves the review of anonymous information only*), #34 (*Individually identifiable information will be used), and #35 (Individually identifiable information will be used to link several databases together in order to gather more complete information*) all dealt with this consideration. The issue of working with disadvantaged groups, was the fourth most frequent response. Survey question #5 (*The participant is from a minority, marginalized or otherwise disadvantaged group*) dealt with this factor.

Overall the responses to survey item #43 provides support for the notion that the major variables of importance were included in the main survey. The detail in the responses adds support to the assertion that survey respondents were well versed in the nuances and subtleties that must be considered in making decisions regarding the need for REB review.

It should also be noted that 6.4% (N=11) responses indicated that the decision to seek REB approval is based on a combination of factors. This is clearly an area that requires additional research.

The final question of the survey (#144) asked respondents to provide the top 5 most important project characteristics that should be considered when deciding whether any project involving human participants should go for ethical review. The responses are provided in Table 12.

Participants were able to select variables based on the survey, or to enter new variables that they believed were critical but that were not included in the survey. Consequently, responses to question #44 were divided into two parts.

The first part was an analysis of the numeric responses. These responses were directly related to the variables included in the survey. The second part consisted of variables that were not included in the survey (novel variables). A review of the responses provided in Tables 12 and 13 indicates that the variables included in the survey were exhaustive of the great majority of variables used by survey respondents to make decisions about REB review for studies. In short, the process used to develop the web-based survey resulted in a thorough but parsimonious list of the key domains and variables that most experts take into consideration when determining whether a study requires ethical review.

Table 12

Expert opinion on the top five variables included in survey that must be considered when deciding whether a project should go for REB review

		Frequency	Percent	Cumulative Percent
Valid	Novel Intervention (Invasive)	112	13.5	13.5
	Impaired Capacity	96	11.6	25.0
	Individually Identifiable Data will be used	82	9.9	34.9
	Deception (not told true purpose of study)	71	8.5	43.4
	Deception (electronically recorded without knowledge)	59	7.1	50.5
	Constraints & Undue Influence (Relationships)	46	5.5	56.1
	Constraints & Undue Influence (Participant Circumstanc	41	4.9	61.0
	Conflict of Interest	38	4.6	65.6
	Potential Risk of Stress or Indignity	35	4.2	69.8
	Potential Risk of Harm	34	4.1	73.9
	Conflict of Interest (For-Profit External Funding)	32	3.9	77.7
	Electronic Linking of Databases	27	3.2	81.0
	Experimentation (Random Assignment)	26	3.1	84.1
	Potential Coercion (Disadvantaged groups)	23	2.8	86.9
	Qualifications (Team Lead Insufficient)	18	2.2	89.0
	Qualifications (Unsupervised Student)	17	2.0	91.1
	Novel Intervention (Non-Invasive)	14	1.7	92.8
	Electronic Recording with Consent	13	1.6	94.3
	Explanation of adverse consequences	10	1.2	95.5

Survey respondents were also asked if there were any variables that the web-based survey had overlooked that they regularly considered in their decision-making process. This question was included as an additional method of verifying that all possible variables had been included and, if not, that additional variables could be identified for future research. Although quite a few respondents answered question #43, further investigations into their responses indicated that the great majority of variables mentioned simply used different words to describe the variables that had been included in the survey. Results are presented in Table 13 below. Where possible, survey question numbers have been included after each variable in table 13 to indicate where the variable was included in the survey.

Table 13

Expert response to web-based survey question #43 (Have any important variables been overlooked in this survey)?

	Freq.	%	Cumulative Percent
Potential harm to human participants	34	23.1	23.1
Conflict of interest (9, 22)	27	18.4	41.5
Disadvantaged participants (2, 3, & 5)	17	11.6	53.1
Experiments (generalizable, random sample/selection)	12	8.2	61.2
Qualifications of Research team (10, 12)	11	7.5	68.7
Changing original purpose of data collection (unauthorized secondary	6	4.1	72.8
Any methods involving deception or omission of important facts	6	4.1	76.9
Dissemination of results (28, 29, 30)	5	3.4	80.3
Potential Coercion	4	2.7	83.0
All projects using data from human beings	4	2.7	85.7
Directly involves human participants	4	2.7	88.4
Invasion of privacy	4	2.7	91.2
Intended Use of Results	2	1.4	92.5
What the REGULATIONS require	2	1.4	93.9
What the institutional policies require	2	1.4	95.2
New processes, invasive or non-invasive	2	1.4	96.6
No opportunity to consent	1	.7	97.3
Potential impact on participants (2, 14, 39)	1	.7	98.0
Qualifications of Researcher (10, 12)	1	.7	98.6
University Affiliation	1	.7	99.3
What the GUIDANCE from agencies state	1	.7	100.0
Total	147	100.0	

CHAPTER FOUR: DISCUSSION

Review

The intention of this dissertation is to determine if international experts from the areas of quality assurance, program evaluation, research across academic disciplines and settings, REB experts and those who must manage such endeavors agree on the variables they utilize to determine whether a project requires REB review. Based on the results discussed above, several conclusions can be drawn in this regard. First, the methods employed in the current research appropriately identified the domains and variables that were of most importance in making such decisions. Second, the web-based survey garnered responses from individuals who demonstrated very high levels of education and expertise in at least one of the key knowledge areas and had the necessary background to answer the survey questions in a considered manner.

Most importantly from the perspective of HHSOs and their unique needs, some consensus does exist on several variables that indicate that a study needs formal ethical review. Ten variables were identified that resulted 80%+ of survey respondents agreeing that if any of the ten variables existed in a proposed project, that the project required ethics review. The survey results also identified those variables where there was moderate agreement (50% - 79% of respondents) that the presence of a variable would warrant ethics review. Perhaps of equal importance is the tangential benefit that the survey identified those areas where experts did not agree on whether the presence of particular variables warrant ethics review. This latter category is an area that needs additional research. It adds to the discussion regarding whether REB members should complete standardized training and also to the issue of accreditation for REBs.

Although this dissertation intends to identify areas where experts agree on which domains and variables warrant REB review, it is perhaps equally important to identify those areas, if any, where experts agree that no review is warranted. Where investigators were using anonymous data only, the majority of respondents agreed that no REB review was necessary. Several other variables did not have majority agreement that REB review was necessary but did demonstrate that there is considerable disagreement regarding the need for REB review among experts. Variables where 25% - 49% of respondents believed that *ethics review was not necessary* were presented in Table 11, but it may be helpful to pull out these variables for closer examination. They include the following:

Table 14

Divergent expert opinion: variables where a significant minority (25% - 49%) of respondents indicated that no REB review was necessary if a specific variable was present in the study

Domain	Q #	Responses		Variable	Survey Question
		#	%		
Informed Consent	N/A	N/A	N/A	N/A	No variables reached cutoff criteria
Intended Use	21	69	34.3	Quality assurance or program evaluation	The project intends to answer questions that have been raised by the staff of a Human Services Organization. (EXAMPLE: front line staff are concerned that clients are having difficulty accessing services. The executive team establishes a project team to investigate the issue).
	30	54	26.9	HHSO use only	The project leader intends to present the results of the project at internal meetings only.
Methodology	17	80	39.8	Routine data collection	The project involves ongoing routine data collection. (EXAMPLE: The United Way has collected client satisfaction data for the past 10 years for all of the projects it funds. The executive team is now uncertain as to whether they need REB approval to continue this process).
	18	62	30.8	Non-routine data collection	The project involves a special, time-limited data collection process. (EXAMPLE: A non-profit organization is interested in understanding why donations have dropped off in the past several months. The project proposes to call previous donors who have not donated recently in order to better understand the situation. A questionnaire has been developed for the purpose that will take place on a one-time basis).

Domain	**Q #**	**Responses**		**Variable**	**Survey Question**
		#	**%**		
	20	50	24.9	Implied consent vs. formal consent	The project involves collection of opinions or suggestions from people who are willing to speak to the project team. (EXAMPLE: The project team is attempting to understand the preference of patients regarding food services. They telephone a few recent patients to ask their opinion about how their eating habits have changed as a result of their illness and how food services can be improved).
Risk of Harm	7	65	32.3	Secondary data	The project team is only going to review existing data.
	11	50	24.9	Accountability of project leader	The project leader is not a member of an appropriate professional association. (EXAMPLE: the proposed work is a quality assurance project but the project leader does not belong to an acknowledged association for quality assurance professionals).
	16	78	38.8	Parallel to risk in everyday life	The project involves no risk of harm greater than that that a person might experience in their everyday lives. (EXAMPLE: the project team is interested in the body language of individuals who are waiting to cross at a busy roadway intersection. They intend to observe the individuals from a distance without ever interacting with the people they observe).

Ninety percent of the experts who completed the survey agreed that two variables required full REB review. These items were: (1) if the project involves testing a new drug, surgical technique or other invasive procedure; and (2) when the intended subjects are cognitively impaired or children. Eight other variables achieved agreement ratings of 80% - 90%. These included: (1) when subjects will be audio or videotaped without their knowledge; (2) when the true purpose of the study will not be revealed to subjects; (3) when individually identifiable information will be used; (4) when the study involves random assignment to treatment and control groups; (5) when the study may cause minor adverse effects; (6) if the participant is ill and the study involves the availability of a treatment that may help them get better; (7) if the study involves collecting information that might be embarrassing or uncomfortable for subjects; and (8) when individually identifiable information will be used to link several databases together in order to gather more complete information.

Based on the above, it was possible to develop a REDG to assist HHSOs to determine whether their projects require REB review. Since a confirmatory factor analysis was not possible, the REDG should be considered the beginning of such work rather than an end unto itself. There is clearly more research to do regarding the combination of variables that may impact such decision making that may be better answered by structural equation modeling than by the current approach. It is critical to be aware that no instrument alone can take responsibility for making ethical decisions with regard to human activities. However, the REDG can serve as a starting point for decisions within HHSOs regarding the issues that are considered critical to ethical treatment of human participants in any systematic investigation, regardless of whether that undertaking is called research, program evaluation, quality assurance, or some other name.

PROTOTYPE OF RESEARCH ETHICS DECISION GUIDE FOR HEALTH AND HUMAN SERVICE ORGANIZATIONS[17]

If you or your organization are considering implementing a project that involves human participants and that involves **ANY** of the factors listed below, it is advisable to seek out the opinion of a qualified Research Ethics Review Board.

Name of Project: ____

Project Leader/Contact:
____

#	Project Variables	Present?
1	The project involves testing a new drug, surgical technique or other invasive procedure	
2	The participant is cognitively impaired or a child.	
3	The participants will be audio or videotaped without their knowledge	
4	The true purpose of the study will not be revealed to the participants.	
5	Individually identifiable information will be used.	
6	The project involves random assignment to treatment and control (treatment as usual) groups.	
7	The project may cause minor adverse effects.	
8	The participant is ill and the project involves use of a treatment that may help them get better.	
9	The project involves collecting information that might be embarrassing or uncomfortable for participants.	
10	Individually identifiable information will be used to link several databases together in order to gather more complete information.	

Decision: ☐ Seek REB approval ☐ Do Not Seek REB approval

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[17] Copyright belongs to Helen Gardiner, University of Calgary. Permission is granted to reprint or distribute the REDG for any non-commercial purpose. However, the instrument is not to be altered in any way without the express permission of the author.

The REDG provides a tool that may be of assistance to those who are in doubt regarding whether their work requires REB review. However, this is only one step in the paradigm shift that appears to be taking place internationally. More stakeholders are becoming aware that control over research, including the research agenda and standards for ethical review, is too important to leave in the hands of a narrowly trained group that may not have the broad understanding and conceptual agility necessary to comprehend the challenges and possible solutions to the ethical dilemmas that researchers face internationally (King et al., 1999). This work is one piece of the ongoing dialogue of how to best protect human participants in systematic data collection projects, regardless of whether they are called research, program evaluation, quality assurance, anthropology, medical sociology, ethnography, participatory research, or any other name.

From the above it appears that the survey developed and used in the current work covers the vast majority of considerations that subject-matter experts believe should be taken into account when deciding whether a study requires REB review. As an additional step of analysis the survey data were divided into geographical groups to determine whether there were differences among countries. For the purpose of this analysis, which should only be considered as a preliminary look at potential differences between geographic groups and their perspective on REB review, the data was divided into three geographic groups, Canada, the U.S.A. and countries outside of North America. This breakdown reflects the survey response pattern rather than any philosophical or theoretical basis. There is reason to believe that there are philosophical differences between Canada and the United States with regard to REB review by virture of the approaches that each country has taken to the process. However, this cannot be said for countries represented by respondents outside of North America. In most cases there were only one or two responses from each country outside of North America that participated. Consequently, the responses were divided up into the three geographical groups as a convenience sample to begin exploring the possibility that there may be differences or similarities in the values held across disciplines in Canada, the United States and Non-North American countries. Hopefully this preliminary analysis may be useful for future research specific to the topic.

There is a high degree of agreement across all geographic groups included in the survey on the 10 variables that are hallmarks of those studies that require review if the variable is present in a proposed study. When the data is broken down into geographic groups, distinct patterns emerge. For example, all three groups agree on the need for REB review whenever a project involved any of five variables: (1) when the project involves testing a new drug, surgical technique or other invasive procedure; (2) when the intended participants are cognitively impaired or children; (3) when individually identifiable information will be used; (4) when the project involves random assignment to treatment and control (treatment as usual) groups; and (5) when the participants will be audio or videotaped without their knowledge.

Canada and the United States have high congruency in their beliefs regarding which projects should go for REB review. It is perhaps not surprising that, out of the three geographic groups, Canada takes the most conservative stance in that it includes two items that respondents from the United States and the Non-North American groups do not. These included: (1) when the participant is ill and the project involves use of a treatment that may help them get better; and (2) when individually identifiable information will be used to link several databases together in order to gather more complete information. However, it should be noted that the level of agreement decided upon for cutoff criteria was quite high (80%+ agreement among respondents on any given item), and that both the United States and the respondents from outside of North America had at least 70% agreement on each of these two items. In summary, the data support the premise that the REDG should be applicable across geographic settings.

It is also clear from the literature review and data collected for this dissertation that the growth in legislation, policy and procedures that are intended to ensure the safety of participants in research is making it difficult for any organization - academic, HHSO or others - to carry on systematic investigations involving humans. In the last two decades there has been an, “explosion in the promulgation of policies regarding research with human subjects, making it difficult to get a clear view of the large picture of research ethics” (Sugarman, Mastoianni, & Kahn, 1998). Entire books are being dedicated to assisting review boards and those who may apply to them to understand the ever-changing landscape (Amdur & Bankert, 2002; Eckstein, 2003; Sugarman et al., 1998).

The administrative burden is considerable on all parties concerned, including REB members, those who must apply and, to some extent, the participants who must often struggle to understand incomprehensible consent documents. There is great uncertainty within HHSOs regarding when to approach REBs, what standards should be applied to determine the scientific integrity of the projects reviewed, and how to best protect the university or research institution from litigation. The system in North America is relatively closed to all except those who are associated with traditional research organizations, although there are projects that take place outside of those venues that include at least one of the variables identified by survey respondents as warranting REB review. Most importantly, there appears to be relatively little evidence that the large and growing bureaucracy surrounding ethics approval protects participants from harm.

It appears that there is a void between intention (to protect human beings when they participate in systematic investigations) and the reality (all human subjects research is reviewed in academic settings, virtually none in HHSOs). However, there is a small but growing literature that challenges the status quo. For example, this dissertation contains several citations from authors who believe REB practice should be changed in North America to adapt to non-experimental methods of research, and that the REB decision-making process should becom more transparent. This is heartening because many of the decisions that are made by REBs have serious implications for the entire population, perhaps only of a small geographic area, but often for entire countries or the world. Serious decisions regarding medical treatments, genetic research, reproductive therapies, genetically enhanced foods and so forth, are complex, but the ramifications have the potential to affect all of humanity. The current REB system in North America is inadequate to address such far-reaching issues. The REB system is staffed by volunteers, often overworked and provided with few or no resources to assist them. Although most REBs consider it important to have at least one layperson on the committee, in reality this is difficult to do. Often there is a massive amount of paperwork to handle and meetings take place during the hours when most individuals work. University professors are expected to participate in university life outside of their own teaching and research. Consequently, although such individuals are not mandated to sit on REBs specifically, if they choose to do so, one may consider that they are paid for their participation. This is not usually the case for individuals who are not university faculty, and there is usually no remuneration for participation, at least in Canada, the United States and the U.K., for such individuals (Smith,1999). Also, the jargon of many specialties makes it difficult for an average person from the community to make sense of the proposals and not be overwhelmed by the process.

Given the challenges faced by REBs it is quite unlikely that they would be willing or able to be of assistance to HHSOs regarding projects that involve human participants. HHSOs may not welcome the assistance even if it were offered. However, there exists a great deal of uncertainty within HHSOs regarding what the “best practice” is for determining whether a project involving human beings requires ethical review of some sort. Hopefully the REDG will help to screen out the projects that most obviously require such review. However, it is a beginning to a process that will have to unfold according to HHSO needs and abilities as well as political will. It is clear that the current process (or lack of process) may actually be hampering much needed and good quality research from proceeding due to bureaucratic redundancy, such as that experienced by Jamrozik and colleagues in Australia (Bradshaw et al., 2000; Jamrozik, 1992, 1997, 2000; Jamrozik & Kolybaba, 1999). A national vision and policy is required that will address the needs of all those who carry out studies involving human participants. Such a policy must recognize that research is not just medical in nature, that it takes many forms, uses many methods, and takes place in an increasingly diverse number of settings.

None of these comments are intended to imply that the current North American REB system should be discarded. Based on the empirical findings of the current study, it is clear that the North American system is based on the values that are common to experts internationally, regardless of the rules in their own jurisdictions. There is, for instance, virtually unanimous agreement that new and invasive medical treatments must seek REB approval. Further, the values espoused in The Belmont Report appear to be aligned with what informed individuals consider to be of importance when making decisions regarding whether or not to seek REB approval.

The survey results also show that although there is agreement on ten variables that clearly indicate a study should go for review, and that there is moderate agreement on another 9, that there are 23 other variables where experts do not agree. These variables will hopefully serve as the jumping off point for further discussion and research with a view to increasing the consistency and transparency of REB and HHSO decision making. The New Zealand system in combination with the REB system(s) in North America offers a good deal of guidance on how to establish a system of ethical review that would work well for HHSOs and the people they serve. Other systems may also offer solutions to the challenges HHSOs face regarding ethical review of systematic studies involving people. For example, the system of licensing researchers and insisting on community consultation and agreement prior to a license being granted that is currently operating in the North West Territories may be a solution more palatable and manageable to the North American penchant for individuality.

Regardless of the direction taken, any change will likely meet with resistance on a number of fronts. For instance, there may be arguments made regarding the expense of any new undertaking, or that the public is not really interested in “academic work,” that the general public would not be able to understand the complexities of many of the proposals that come before REBs, or that government should not become involved in helping to establish ethics policy for HHSOs. However, if the goal is to protect human participants, particularly those who are disadvantaged as is usually the case for clients of HHSOs, such prospects must at least be considered.

It is clear that the traditional ways of overseeing the ethics of research are insufficient to address the issues faced by researchers from a broad array of disciplines as well as those not traditionally thought of as researchers, including program evaluators and quality assurance professional. The complexity of the issues that must be addressed by the research community continue to grow in scope, and a growing number of partners, such as funders and organizations, must be included in the discussion of how to gather the knowledge needed by HHSOs to best serve their constituents, while protecting the rights of the individuals or groups they collect information from.

Although much of the current discussion revolves around how to improve the current REB process by increasing the scope of review, improving the clarity of legislation, disentangling methodological debates, harmonizing professional ethical codes of conduct with jurisdictional legislation and so forth, few, if any of these approaches are likely to achieve the desired goal of funding, approving and sustaining excellent studies that result in useful information while at the same time protect human participants and groups from errors and abuse. History is the best predictor of the future and we have had more than 60 years of legislated review of research and yet we still hear stories of abuse of human participants in the experimental research realm. As recently as March 25, 2005, a discussion was taking place on the NCEHR listserv regarding experimental research projects that had gone so far wrong as to warrant legal action. Further, there is mounting evidence that the current REB systems in place throughout first world countries are inefficient and may in fact prevent good quality research from proceeding without demonstrating any further evidence of protecting human subjects (Jamrozik, 1992, 1997, 2000; Jamrozik & Kolybaba, 1999).

Limitations

There are several additional topics that should have appeared in the international survey, including:

(a) the use of experimental treatment in emergency situations;

(b) whether direct client contact (as opposed to file review or review of electronic databases) is an important distinguishing variable;

(c) whether the invasiveness or nature of questions to be asked is important (i.e. questions about sleeping patterns as opposed to illicit drug use); and

(d) the impact of having a disadvantaged population (such as the mentally ill) as the intended participant group.

Obtaining a representative sample and using the same protocol for each sample was challenging. As with all field research, the Principal Investigator had to work within the limitations and abilities of the groups that agreed to participate. Although it was a major accomplishment to obtain permission from the Canadian Evaluation Society, the American Evaluation Association, the Canadian Society for Epidemiology and Biostatistics, and The International Society for Quality in Healthcare to participate, each organization had requirements regarding how their members were to be contacted. Consequently, the study sample has limitations with regard to geography (most respondents are from Canada and the United States), representativeness (it was impossible to calculate response rate in situations such as the Canadian Society for Epidemiology and Biostatistics where a precise count of members was not available or in the case of the Canadian Evaluation Association where the survey was posted on the website), and size. The study sample was further limited by the fact that the only those people who belonged to one of the organizations had access to the survey. There was also the consideration of terminology. If the survey had been available in a variety of languages it might have been possible to obtain a greater number of respondents from outside North America. This is an important consideration, particularly since 300 respondents were required in order to carry out a confirmatory factor analysis. To that end, the author intends to continue to pursue this line of investigation through her post doctoral program at the University of British Columbia.

Future Research

REB review, its domain of authority, appropriate structure, operating protocols and, most importantly, when to apply for REB review, are not simple areas to investigate. The current research has attempted to address one component of this area: the issue of when HHSOs should apply for ethics review in an empirically valid fashion. Although the results of the international survey and interviews with stakeholder groups hopefully provides insights into which issues are considered important in REB review and which are not, the resulting REDG is only one step in a more sophisticated understanding of when to apply for REB review. More work is required in this area.

It would be helpful to develop a theoretical model of decision making for REBs utilizing a policy-capturing process[18] to allocate weights to each of the factors that subject matter experts and survey respondents indicated were of importance in determining when a study should be submitted for review. If such

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[18] Policy-capturing is a qualitative research technique used primarily by social scientists, particularly those in business and political science. It involves the gathering together of policy documents and, sometimes, espoused policy that has not been formalized, and analyzing them in detail in order to determine the current state of policy on a particular issue such as privacy or the need for REB review. It may also include interviews with individuals responsible for establishing policy and/or those people whose lives are impacted by the policy in question.

a model were to be developed it would then be possible to standardize the decision regarding whether a proposal should be reviewed by the full REB committee, receive expedited review, or no review in a process that could be automated based on a standardized set of questions to be answered by any individual seeking access to REB review. However, it is important to avoid an emphasis on developing increasingly more precise mathematical models of decision making regarding when to apply for REB review if it is done so at the expense of considering the philosophical and political issues that necessarily influence the decision-making process.

Some of the more important research issues surrounding REB review involve policy research. The most pressing of these is the membership, training and the role of REBs. At a minimum, REBs should not be cloistered away in the academic and research organizations where they currently operate in most western countries. As the research questions being addressed increasingly impact society at large - for example stem cell research, the issue of research with end-of-life participants or treatment for those addicted to street drugs, cloning, genetic “enhancement” of food sources and human beings to mention just a few - have serious implications for the entire community. The community should be not just invited, but encouraged to participate in determining whether such research should go forward.

Further, consideration should be given to adjusting the one-size-fits-all approach most REBs use to review all studies, including social science work, so that REBs can quickly process those studies that have a low risk of harm, so that they have more time to pay attention to high risk studies. Accreditation for REBs may help in this regard. Several attempts have been made to differentiate studies that require REB review from those that do not (Bellin & Dubler, 2001; Casarett et al., 2000; Lo & Groman, 2003; Lynn, 2004). However, the focus of such work often concentrates on one or two characteristics, such as whether the intention is to publish the results, or whether a particular methodology, such as a randomized control trial, will be employed. Frequently the unstated assumption is that conventional research means quantitative studies intended to show statistical significance and generate generalizable results. The literature is relatively silent on the role and place of qualitative research (Poses & Levitt, 2000), or systematic studies involving human participants that take place outside of traditional research venues. Consequently, the debate in North America is rather narrowly focused on specific issues, particularly the issue of informed consent, and on tinkering with the current REB system, often in the form of more, bigger or better regulations and policies. Research that expands this horizon will be of benefit to all concerned.

The expanded horizon should also consider the possibility that the current North American ethics review structure[19] does not need mere tinkering, but a dramatic overhaul. The work of McDonald (McDonald, 2001), Cobern (Cobern & Loving, 2001) and King, Henderson & Stein (1999), as well as the "rights

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[19] The current REB structure is not entirely uniform in North America. However, in general, all academic studies involving human participants are required to submit to REB review as are traditional research organizations such as teaching hospitals. Studies which involve human participants but are carried out in the community are not generally expected to be submitted to REB review, although this area is very grey, particularly if individuals with academic appointments are involved in community studies. In virtually all cases the REB reviews both ethical issues and scientific quality.

revolution” perspective of Micheal Ignatieff (2000), support this perspective, and investigators should be able to fearlessly approach such a possibility. For example, the work of King et. al focuses on creating a, “more coherent, inclusive and balanced approach to the ethics of research” (p.6). The authors support their case by pointing out that: (a) despite 30 years of U.S. regulations, there are still stories of errors and abuse in current day U.S. based research involving humans; (b) U.S. values are not universal; and (c) regulations are not enough. They conclude that, “regulations address some questions – for example, how to design and carry out a good informed consent process – but do not answer them completely or well” (p.4). Although King and colleagues speak primarily to the U.S. review system, the same comments can be applied to other western countries. Their work recognizes the need to review what kinds of assumptions are made in current North American REB practice, and what kind of thought processes are considered acceptable. They explore the implications of applying standards relevant to natural science research to other forms of knowledge development, regardless of whether such standards are meaningful. King et. al also question the assumption that REBs, which are a relatively recent phenomenon, are the natural guardians of the public trust with regard to research and protecting human participants.

Some serious investigation could also be given to the licensing of researchers, program evaluators and quality improvement professionals in order to ensure people dealing with sensitive information have the appropriate ethics training.

Currently there are several interesting approaches to REB review and protecting human participants that may be quite helpful in developing the best possible system for review. For example, in the Canadian Northwest Territories (NWT), researchers must now be licensed and work for a minimum of 3 months with the communities they intend to include in their research before applying for final REB approval (Aurora Research Institute, 2004).

The REB process from the perspective of laypersons also warrants further investigation. The focus groups included in the present study indicated that they elect to be in studies on the basis of factors that had little to do with REB involvement. Trust in the person who extends the invitation appears to be important, as is the potential prospect of whether the participant might gain something from the study. With regard to the latter point, the potential gain did not have to involve access to new medications or treatments. There was general consensus within the layperson focus groups that study participants gain a sense of contributing to the community and potentially helping other individuals like themselves.

REB review has many outstanding questions that must be dealt with if countries that are committed to research and improvement in HHSOs intend to both protect the privacy, dignity and safety of its constituents while fostering research and its related disciplines of program evaluation and quality improvement in HHSO settings.

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APPENDIX A

The Futility of Attempting to Define"Research"

It is tempting to try and operationally define the terms "research", "program evaluation" and "quality assurance". Several authors have attempted to do this (Beaudin, 2000; Bellin & Dubler, 2001; Brett & Grodin, 1991; Casarett, 2001; Casarett, Karlawish, & Sugarman, 2000; Choo, 1998; Cretin, Keeler, Lynn, Batalden, & Berwisk, 2000; Emanuel, Wendler, & Grady, 2000; Fishman, 1991; Freedman, Fuks, & Weijer, 1992; Harold I. Goldberg, 2000; Heathington, 1988; Henry & Wright, 2001; Hensley, 1988; Levine, 1976; Margo, 2001; Mays & Pope, 2000; Samsa & Matchar, 2000; Stewart, 1988; Vogelsang, 1999; Werner, 2000; Zabora, 1997) likely in the hope that operationalized definitions will gain wide acceptance and thereby end the confusion regarding need for ethical review, usually within academia and traditional research settings, although such an accomplishment would have obvious ramifications for HHSOs and government policy makers too. At first glance this seems to be a promising area of investigation. However, as this study progressed it became clear that such an investigation is not likely to ever bear fruit. This appendix has been included in the hope that a summary of answers to the "what is research" question, and the reasons why it is not possible to operationally define research, program evaluation, quality assurance, etc., may save our valuable resources by focusing them in a more promising direction.

This dissertation literature review did not locate any academic or grey literature that addressed all types of systematic investigations that involve human participants. However, there are several key articles that compare two or three systematic approaches. From a theoretical perspective there are many distinguishing features that could potentially differentiate between research and evaluation. However, definitions fail to cover every eventuality, and the features of each definition overlap to such an extent that, although they may differ in intent or philosophy, in practice they can be virtually indistinguishable. For example, there is a growing use of RCTs in quality assurance work (Samsa & Matchar, 2000), and RCT has been in use in program evaluation for quite some time (Bickman & Rog, 1992; Cordray, Bloom, Light, & American Evaluation Association., 1987; Grembowski, 2001; Owen & Rogers, 1999; Telfair, Leviton, Merchant, & American Evaluation Association., 1999; Wholey, Hatry, & Newcomer, 1994). Goldberg suggests that Continuous Quality Improvement should use experimental methodology as the primary mode of investigation. Goldberg states that, "the principles of the scientific method (RCTs) should be applied to any proposed manipulation of the delivery system that might substantively affect health care costs or outcomes" (Harold I. Goldberg, 2000). Regardless, some have suggested that research should be differentiated from other systematic projects such as quality assurance based on function rather than label. For example, Bellin & Dubler (2001) suggest that quality assurance in health care is a moral obligation, one that, "is expected by patients and required by certifying agencies such as the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality assurance" (p.1514). The moral imperative of quality assurance is contrasted with research, which is viewed as, “an optional external activity based on the physician-patient relationship” (p.1514). Although these issues are explored further by Bellin & Dubler (2001), ultimately they suggest that prospective quality assurance undertakings should be reviewed by a REB to ensure that they do not compromise patient autonomy or safety. Smith further suggests that if the investigator in a medical setting is in doubt regarding whether their undertaking is research, they should submit the project for review to an independent ethics committee, even if they are only conducting an audit (Smith, 1999).

Research, program evaluation and quality assurance can all be systematic. Each can use qualitative, quantitative or mixed methodologies. All can be published in peer review journals or presented at professional conferences. Further, it is now possible to obtain a Ph.D. in both program evaluation and quality assurance (Sinn, 2002).

The current dissertation used the simplified notion of separating out systematic endeavours into experimental and non-experimental work. Some investigators have attempted to differentiate research from non-research based on theoretical notions. For example, Werner’s work, presented in Table 15 describes the theoretical differences between research and program evaluation.

Table 15

Potential Differentiating Characteristics of Research and Evaluation (Werner, 2000)

Characteristic	**Research**	**Evaluation**
Orientation	Conclusion general	Decision contextual
Emphasis	"Scientific truth"	Value in context Immediacy
Focus	Theories and Laws	Programs, projects, processes
Inquiry Objective	Explanation Causation	Description Causal Links
Motivation of the Inquirer	Curiosity	Needs of identifiable clients
Role of Value	What role?	Central, key
Criteria of Excellence	Internal and external validity Reliability	Joint Committee Standards
Generalizability	High, desired	Low
Utility of Results	Low emphasis	High emphasis
Methods	Discipline Based	Multidisciplinary

There are a number of problems with this approach. The first is that it implicitly assumes that "research" is conducted from an experimental framework as can be gleaned from its emphasis on scientific truth, discovering laws, the need for reliability and validity, and so forth. The assumption that experimental methodology is the only acceptable method of conducting research is no longer the norm. Reputable researchers take a variety of ontological and epistemological approaches, including the qualitatively based constructivist paradigm (Bhopal, 1999; Datta, 1994; Erde, 1999; Guba & Lincoln, 1989; Kuhn, 1970; Lincoln & Guba, 2000; Salomon, 1991). Without the crisp inclusion/exclusion criteria of control groups and laboratory settings as the hallmark of “research”, the argument for differentiating along these lines collapses.

The second problem is that Werner’s work assumes that program evaluators follow the standards of The Joint Committee on Standards for Educational Evaluation. Evaluation is multidisciplinary and undertaken in many countries, not just the United States where the Joint Committee standards were established. Consequently the ethnocentric perspective taken in this argument makes it unlikely that all evaluators, or even the majority, would adhere to a particular set of professional standards. Given the further point that the Joint Committee standards speak primarily to those who work in educational evaluation, it becomes clear that adherence to Joint Committee standards is unlikely to be a useful differentiating factor.

The third problem with Werner’s proposed framework is that distinguishing dimensions may vary depending on perspective. For example, a study that has great utility to program evaluation may have no utility to researchers, and vice versa. Emphasis is placed on the theoretical distinctions between research and program evaluation and does not speak to how the process of either research or program evaluation is carried out in practice. The methodology proposed in each project is where the potential harm to humans is introduced. For example, if individuals are being surveyed about their illegal drug use, the risk is the same regardless of whether the endeavor is labeled research, program evaluation or quality assurance. Consequently, although Werner's work looks promising, it does little to provide HHSOs, academics or government policy makers with a practical guide to differentiating those projects that require review from those that do not.

Notable experts have concluded there is no practical difference between research and program evaluation. Michael Scriven states, "many attempts have been made to distinguish program evaluation from research – typically, other social science research – for example, in terms of generalizability, replicability, and data types" (Scriven, 1991). Despite these efforts there is still no consensus regarding the differences. Even researchers who focus on differentiating research from non-research, such as Friedlander (Friedlander, 1995), fail to operationally define their terms, and resort instead to reasoning by analogy. Many professional organizations have developed definitions of research, program evaluation, quality assurance and other endeavors that involve systematic data collection human participants.

There is little hope of reaching consensus on such definitions with sufficient agreement to make an impact on the issue of which projects should receive REB review.[20] Even if such an agreement could be made, it would have little utility as each approach continues to evolve over time.

Without exception, legal and policy statements that attempt to differentiate those projects that need review from those that do not, are not accompanied by operationalized definitions of what is meant by research or non-research in a meaningful way. The definition of what is research is left up to the scientific community. As Cobern & Loving state, "what ultimately qualifies as science is determined by *consensus within the scientific community*" (Cobern & Loving, 2001). Unfortunately, the scientific community is not a homogeneous group, and science itself is a living, evolving process of discovery. Consequently, attempting to qualify science by referring to the scientific community as though it were a homogenous group is in reality a political decision since the scientific community with the power to make decisions regarding what is research and what is not will necessarily be the same group who are positioned within the current political structure to develop and implement policy and legislation. It also does little in terms of addressing the question at hand regarding the attempt to define research (Cobern & Loving, 2001; Doyal, 2004; Lindenauer, Benjamin, Naglieri-Prescod, Fitzgerald, & Pekow, 2002; Lynn, 2004).

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[20] A table of definitions from prominent professional associations and legal documents has been included for review. Although this is by no means a complete listing of definitions currently utilized by relevant organizations, it is intended to illustrate that even the experts have not established distinct definitions which could be utilized by legislative bodies and REBs to distinguish between those projects which should be subject to REB review and those which should not.

Given the above quandary, HHSOs and REBs, must make assumptions regarding what research is. The literature across disciplines still places emphasis on the traditional experimental model and, in particular, medical investigations, particularly RCTs, as research and the dominant paradigm in legislative and policy documents directed at the REB process in North America. It is remarkable how often research is equated with *medical* research, often without explanation or explicit acknowledgement by the writer. For instance, in the recently published Manual for Research Ethics Committees (Eckstein, 2003), the introduction begins, “Members of RECs[21] have the responsibility of ensuring that *medical* research on humans is conducted in an ethical manner” (p. xvii). Although the manual speaks to research processes - such as observational and epidemiological research, social survey research, qualitative research and the challenges that complementary and alterative medicine place before RECs - the emphasis is clearly on medical research. Even the excellent manual for U.S. IRBs[22], Institutional Review Board, Management and Function, assumes that readers will all understand what “research” is[23]. The manual specifically addresses many of the more difficult issues avoided by other texts such as issues based on study population, design or category. However, little direction is provided regarding which studies should be submitted for REB review. Consequently, at least within North America, there appears to a double standard

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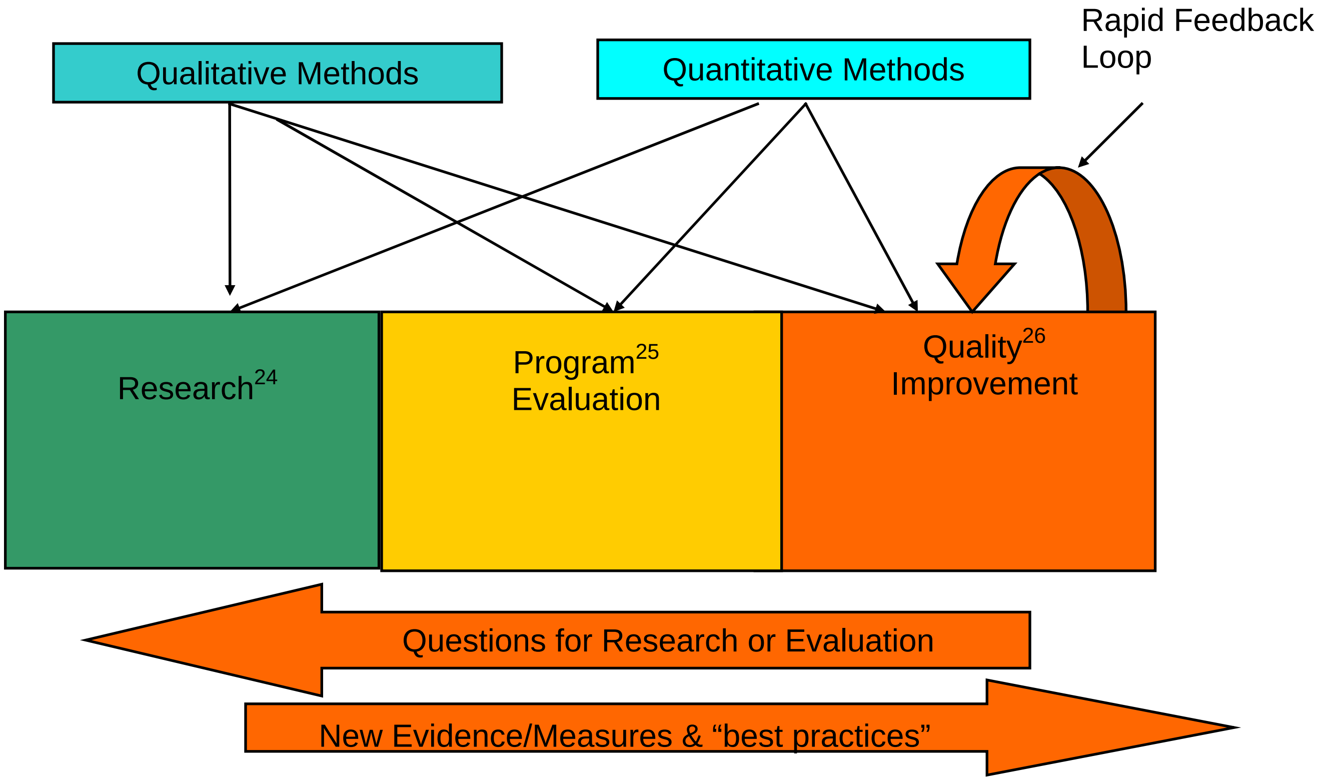
[21] REC, or Research Ethics Committees is the term most frequently used in the United Kingdom to refer to Research Ethics Boards

[22] Institutional Review Board

[23] Institutional Review Board: Management and Function (Amdur & Bankert, 2002) is an excellent reference book for understanding how REBs function and the many difficult issues that they face.

for REB review. If a project is undertaken within a traditional research organization, such as a university, it is a virtual certainty that the project will require REB review, regardless of any other factors, much to the chagrin of some investigators (American Association of University Professors report, 2001; King, Henderson, & Stein, 1999; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004). If the same study were undertaken by a private consulting company there would likely be no impetus for review. Systematic data collection studies that involve human participants exist on a continuum that overlaps. As can be seen in Figure 6 (below) and the accompanying list of characteristics of each component, research, program evaluation and quality assurance all can use qualitative, quantitative or mixed methods. Furthermore, although Lynn indicates quality assurance is different than other undertakings, such as program evaluation or research, because, “quality assurance always feeds back measurements rapidly to the care system that is generating the data, which leads to an ongoing shaping of the intervention” (Lynn, 2004), this may not be exclusive to quality assurance. Program evaluation, at least as the author of this dissertation has designed and implemented evaluations, uses rapid feedback loops, as do some experimental methods. Regardless, the rapid feedback loop has been included in Figure 6 as one of the hallmarks of quality assurance since such a mechanism is considered to be critical to quality assurance projects, but much less so in either program evaluation or research. It should also be pointed out that none of the characteristics on the continuum belong exclusively to one domain. Although it may be possible to state that all RCTs include random assignment to groups, it is not possible to say that *only* RCTs use this method. Further, program evaluation is, “a genuinely interdisciplinary and multi-method field of professional practice” (Micheal Quinn Patton, 1997). Several years attendance at the American Evaluation Association and Canadian Evaluation Society annual conferences has shown that evaluators come from a wide variety of academic disciplines. Therefore, Figure 6 has been developed based on the attributes, practical and philosophical considerations most often associated with each approach to systematic investigation. The current research has attempted to identify and isolate which of the variables across approaches are considered by experts to be the most important flags that indicate that a project should go for review. Since ten variables did emerge that had 80%+ agreement among experts that the inclusion of any of the ten variables in a study indicated that the study must go for review, It may be possible, in future research, to assign weights to such variables.

Figure 6: Framework for project distinction in systematic projects involving human participants*



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Explanatory Notes Related to Figure 6

[24] *Research Characteristics:* Time is limited. Agenda is set by the researcher. Usually, it is funded by grants and carried out by specialists. The intention is often to publish or present the work at professional associations. The goal is often on generalizability of findings. Generalizability is achieved either via random assignment & statistical analysis (experimental model) or via credibility, transferability, dependability, confirmability, and authenticity in qualitative work (Mertens, 1998) Often there is no direct benefit to participant but proposed value to society. Study results can often be replicated, particularly in the natural sciences.

In natural science and biomedical work, the risk can be quite high. Within this paradigm, the Randomized Control Trial is the "gold standard", the reasoning is deductive and the focus is on validity, theoretical sampling and staying disengaged from participants. Natural science and biomedical work is often the focus of legislative and policy documents due to its high risk potential.

In social science and those studies that use qualitative methods, the risk is often minimal. Methods are variable (i.e. biography, case study, ethnography, grounded theory, phenomenology) and have standards for quality of the work. Focus is on questions that are not easily quantified. Uses inductive reasoning, authenticity, purposive sampling, thick description and interaction with participants.

[25] *Program Evaluation Characteristics:* Time limited. Agenda set by organization. Usually led by specialists, often individuals trained in applied research. Intention is to address organizational questions regarding the program. Minimal risk, with potential for direct benefit to participants. Usually funded by government (non-grant) or organizational dollars. Some projects have the intention to publish the results, but primary goal is to report to organization/program. Level of evaluation may vary from micro (program) to macro (health care system). Uses methods from a wide variety of domains including experimental designs and non-experimental approaches. Consequently, may be indistinguishable from "research" based on methodology. Often involves selection or development of new measures and related processes.

[26] *Quality Assurance Characteristics:* Ongoing, routine data collection with continuous and rapid feedback loop. Agenda set by organization. Usually carried out by existing organization staff (i.e. nursing staff or social workers who are employed by the organization). Usually minimal risk, with maximum potential for direct benefit to participants. Concerned with improving process, usually at a micro (i.e. hospital unit) level. Always internally funded. It is rare for quality assurance projects to be published and there is usually no focus on achieving generalizability. Informs accreditation and is specifically exempt from most legislation.

As can be seen from the above, each approach to systematic investigations has characteristics that are commonly associated with it and not with other domains, which could potentially be used for variables regarding the need for REB review. For example, the researcher almost always sets the research agenda and the evaluation agenda is almost always set by the organization. However, this is not the case 100% of the time. Consequently, even variables such as these have little utility in differentiating research, program evaluation, quality assurance and other systematic work. Further, variables such as who sets the agenda or the intention to publish the resulting work only form one aspect of the decision making process which is likely to go on in the minds of individuals who undertake such work, or the REB members or policy makers who must protect human participants. However, despite the challenges of defining program evaluation, research, quality assurance and other systematic work that involves human beings, organizations cannot simply stand still until a perfect solution is found. Consequently, many organizations have defined such work in order to meet their needs. The following table presents some of the resulting definitions from top organizations in each area.

Table 16

Example definitions of program evaluation, quality assurance, research and related topics[27]

Approach		**Definition**	**Source**
Program Evaluation	1[28]	1. to ascertain or set the amount or value of. 2. to judge or assess the worth of.	(Gilmour, 2003)
Program Evaluation	2	A person trained in evaluation has the skills to conduct rigorous research, but a researcher would probably have to acquire additional training if he/she were to become an evaluator.	(Gall, Borg, & Gall, 1996)
Program Evaluation	3	The distinction between research and evaluation can be overstated as well as understated. The principle difference is the degree to which the findings are generalizable beyond their application to a given product, program or local. Almost always the steps taken by the researcher to attain generalizability tend to make his inquiries artificial or irrelevant in the eyes of the practitioner. The evaluator sacrifices the opportunity to manipulate and control but gains relevance to the immediate situation. Researcher and evaluator work within the same inquiry paradigm but play different management roles and appeal to different audiences.	Stake & Denny (1969), quoted in (Worthen & Sanders, 1987) p. 29

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[27] References for all definitions are provided at the end of this appendix.
[28] The numbering of definitions is not intended to indicate the importance of the definition.

Approach		Definition	Source
Program Evaluation	4	Evaluation, as a particular kind of investigative discipline is distinguished from, for example, traditional empirical research in the social sciences or from literary criticism, criminalistics, or investigative reporting, partly by its extraordinary multidisciplinarity.	(Scriven, 1991) p.141
Program Evaluation	5	A diligent investigation of a program's characteristics and merits. Its purpose is to provide information on the effectiveness of projects so as to optimize the outcomes, efficiency, and quality of health care. Evaluations can analyze a program's structure, activities, and organization and examine its political and social environment. They can also appraise the achievement of a project's goals and objectives and the extent of its impacts and costs.	(Fink, 1993)
Program Evaluation	6	The systematic application of social research procedures for assessing the conceptualization, design, implementation and utility of social intervention programs.	(Rossi & Freeman, 1993)
Program Evaluation	7	Leaders concur that rigid scientific models without participation do not work well in community evaluations.	(Telfair et al., 1999)
Program Evaluation	8	Evaluation, is the systematic examination and assessment of features of a program or other intervention in order to produce knowledge that different stakeholders can use for a variety of purposes.	(World Health Organization, 2001), p. 26
Program Evaluation	9	The American Evaluation Association recognizes more than 100 types of evaluation.	(World Health Organization, 2001), p.24
Quality Assurance	1	When broadly defined, quality assurance includes all that we do to safeguard and promote the quality of health care…we do this partly by designing a system of health care that has the capability of performing well. Partly we do it by constantly examining that performance to make sure that it continues to be good. Thus, we identify two arms to quality assurance: one we can call system design. The other arm has had a variety of names: "monitoring", "review", "surveillance", "management" and so on. Regrettably, none of these is fully adequate, because the meaning to be conveyed, as we shall see, is rather complex.	(Donabedian, April, 1990), p.1
Quality Assurance	3	Objectives of the Program for the Quality Assurance of Medical Care: ❑ Standardize health-related activities in order to assure the quality of the services provided to the population. ❑ To propose the necessary measures to safeguard such quality, including	("National Programme for the Quality Assurance of Medical Care," December 23, 1997)

Approach		Definition	Source
		❑ Formulation of organizational and operational standards for procedural manuals of health services ❑ Formulation of production and performance standards for health services ❑ Technical advice and cooperation for the benefit of jurisdictions, health care establishments, and bodies contributing to standard setting and the various aspects associated with the implementation and development of the Program ❑ Formulation of standards governing the supervision and control of compliance with the Program ❑ The evaluation of the quality of medical care services ❑ The accreditation of health services ❑ Analysis of the impact of the results obtained ❑ Degree of consumer satisfaction The Program's normative framework takes into account the ethical criteria relating to patients' rights, the protection of the dignity of the human person, the efficacy and efficiency of health activities, and social solidarity and equity	
Quality Improve.	4	Small-scale cycles of interventions that are linked to assessment and that have the goal of improving the process, outcome, and efficiency of complex systems of healthcare.	(Casarett et al., 2000) p.2275
Research	1	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.	(Department of Health and Human Services, 2001)
Research	2	There are 12 characteristics of inquiry that distinguish between 'pure' forms of research and evaluation': Motivation of the inquirer, objective of the inquiry, law vs. description, role of explanation, autonomy of the inquiry, properties of the phenomenon assessed, generalizability of the phenomenon studied, criteria for judging the activity, identifiable clients, relevance of time, disciplinary base, and preparation.	(Worthen & Sanders, 1987), p.29
Research	3	Systematic investigation to establish facts or collect information on a subject.	(Gilmour, 2003)
Research	4	Involves observation, identification, description, experimental investigation and theoretical explanation for the purpose of developing knowledge. NOTE: AHE treats experimental research, evaluative research and Informative Research in a uniform way: all are subject to an internal ethics review (the Research Coordination Committee) UNLESS "the program evaluation and quality improvement activities initiated	(Alberta Mental Health Board, 1999; Rossi & Freeman, 1993)

Approach		Definition	Source
		within the hospital are directly related to ongoing service delivery.	
Research	5	The generation of data about persons, through intervention or otherwise, that goes beyond that necessary for the individual persons' immediate well-being.	(Medical Research Council, 2001).[29]
Research	6	(In reference to the MRC research definition) this over-inclusive definition does not acknowledge the fundamental distinction between exploratory/explanatory research and the quality assurance reviews and evaluations that should go on within every hospital and every doctor's office. As a practical example of the latter, although today drugs are investigated (researched) more than ever before, reports about unusual side-effects (or their incidence if dose related) may arise after their introduction into practice. Most physicians would not see the confidential reporting of such occurrences to a central database or a reputable medical journal as research that warrants a fully informed consent. Indeed, it may be impossible to get such consent; the patient may have moved. Responsible reporting is needed and any definition of formal research must permit the continuation of good clinical and program evaluation practices.	(The Canadian Psychiatric Association, 2001)
Research	7	The scientifically designed comparison of the two treatments with the random allocation of patients to them, however, defines the activity as research. All such studies must be reviewed by an ethics committee.	(Smith, 1999) (p.9)
Research	8	When you say that you are undertaking a research study to find out answers to a question, you are implying that the process: 1. is being undertaken within a framework of a study of philosophies; 2. uses procedures, methods and techniques that have been tested for their validity and reliability; and 3. is designed to be unbiased and objective. Your philosophical orientation may stem from one of the two paradigms in research – positivism and naturalism – and the academic discipline in which you have been trained.	(Kumar, 1996) (p.4)
Research	9	Research is an endeavour to study or obtain knowledge through the use of a systematic approach with the intent of clarification. This includes activities that attempt to discover new facts, information, or new applications or existing knowledge.	(Aurora Research Institute, 2004)

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[29] The MRCC also states "sociological studies and consultation of the patient's record, for purposes exceeding the patient's health care, constitute research with a human subject."

Related Definitions:

Approach/Term	Definition	Source
Minimal Risk (U.S.)	the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during performance of routine physical or psychological examinations or tests.	(Amdur & Bankert, 2002) (p.114)
Quality Assurance vs. Quality Improvement	Quality Assurance (QA) was introduced in the 1980's for the purpose of monitoring standards. It was criticized for focusing on individual performance, attempting to correct standard deficiencies when the standards were arbitrarily set, targeting particular aspects of performance rather than the effects of the whole process, having little or no communication with respect to the study of findings or corrective measures and often lacked an identifiable central body responsible for direct organization-wide quality assurance initiatives. Quality Improvement (QI) was introduced to Canadian healthcare organizations in the mid 1990's. The emphasis is no longer on worker blame. QI uses the 85/15 rule (85% of all errors are process related and 15% of all errors are worker or employee related). The methods of data collection are the same (i.e. infection control and incident reporting, chart review audits, treatment outcome measures and listening to client/patients) but the focus is on how the process can be improved to meet the needs of patient/clients, not in establishing blame.	(Alberta Mental Health Board, 2000) p.1.
Evaluation Research	The systematic collection of information about the activities, characteristics, and outcomes of programs for use by specific people to reduce uncertainties, improve effectiveness, and make decisions with regard to what those programs are doing and affecting.	(M.Q. Patton, 1987), p.15
Evaluation	The systematic assessment of the worth or merit of some object.	(Stufflebeam & Shinkfield, 1985)

The above table demonstrates that efforts have been made to operationalize the definition of research. However, “this has proved difficult and often yields irrational guidance with regard to protection of patients. Society needs a workable way to separate activities that will improve care, on the one hand, and those that constitute research, on the other” (Lynn, 2004).

Hopefully it is clear that the definitional route holds no promise of resolving the issue of which projects should be submitted for REB review, either within academic and traditional research settings or in HHSOs. Some have made this realization and used it to build an argument that the current REB system should be expanded (Appelbaum, 2000) or provided additional resources (Henry & Wright, 2001) so that the current process could review a wider range of projects. For instance, some commentators suggest that quality assurance needs its own oversight system based on who benefits from the quality assurance project, the magnitude of the anticipated benefit, or how likely the anticipated benefits are to materialize (Bellin & Dubler, 2001; Lo & Groman, 2003). Lo & Groman further suggest that each quality assurance project should be approached uniquely, “to distinguish different levels of potential benefit and risk to subjects” (Lo & Groman, 2003). Further, Goldberg (H. I. Goldberg, 1990) suggests that non-academic administrators of health organizations are under growing pressure to determine the impact of changes made in health care delivery on productivity, length of stay and client outcomes and to share their results with others such as accreditation agencies. “Experimental designs may even be employed in such situations” (H. I. Goldberg, 1990). Consequently, there seems to be a reasonable argument that such undertakings, regardless of whether they are called research, program evaluation or quality assurance, should be subjected to REB review.

Although Lo & Groman are speaking of quality assurance, their suggestion could potentially apply to all systematic projects involving human participants. It could be suggested that each should be approached with a view to understanding the potential risks and benefits to human participants, regardless of what the project is called or the methodology utilized. However, there is considerable debate regarding whether the current REB oversight system is the best method within which to consider such projects because of the challenges faced by the current system, discussed in the main dissertation document, and because of the one-size-fits-all review tendency of most REBs (American Association of University Professors report, 2001; King et al., 1999; Report of the Social Sciences and Humanities Research Ethics Special Working Committee, 2004).

Others take a different perspective, indicating that the current system is experiencing a constant “bureaucratic creep” of expanding jurisdiction, policy and power (Henry & Wright, 2001). They advocate quick action to come to consensus on policy in this area and warn that:

> if some adverse ruling pushes quality assurance towards research review, improvement will be greatly slowed and professional responsibility for quality will wither. If congressional or executive branch action exempts quality assurance from oversight, patients will be left at risk of harms. Surely we can craft a workable approach, but doing so will require thoughtful leadership, development of a body of scholarship, and possibly

> trials of various strategies in small systems that would be an intriguing and important application of quality assurance refinement of its own procedures and regulatory policies (Lynn, 2004).

There is little agreement in North America regarding the approach to take with regard to reforming current REB practices, and much of the debate is centred around the mandate of REBs, the definition of research, and how to protect human participants. This dissertation does not intend to offer solutions on how to implement such reforms. That is an enormous topic currently being reviewed by experts in many countries. However, it is certain that reform is needed as witnessed by the, “continuing stories of error and abuse in American research with human subjects, despite a nearly thirty-year experience in applying detailed federal regulations to shape and govern the design and conduct of that research” (King et al., 1999). However, each system of review such as that found in Canada, the United States and New Zealand offer guidance with regard to how to implement such changes.

This thorny issue has serious implications for HHSOs, particularly since they are under increasing pressure to “prove” that the work they do is effective via program evaluation and quality assurance studies using methods that would (Cathexis Consulting, 2002; Gardiner & Cairns, 2003a, 2003b, 2004) be called “research” if they took place within an academic setting (Culhane, Eldridge, Rosenheck, & Wilkins, 1998; Dickey, 2000; Gardiner & Cairns, 2002; Gelberg, Andersen, & Leake, 2000; Golden, Currie, Greaves, & Latimer, 1999; Morrell-Bellai, Goering, & Boydell, 2000; Tischler, Vostanis, Bellerby, & Cumella, 2002). Further, there is an increasing expectation that HHSOs will be accredited for the quality of their programs and service delivery as demonstrated by the creation of the Canadian Council for Health Services Accreditation (CCHSA) and the Commission on the Accreditation of Rehabilitation Facilities (Pellegrin, Carfk, & Edwards). In order to become successfully accredited, HHSOs must be able to demonstrate their effectiveness, using whatever means are at their disposal, including program evaluation and quality assurance study results.

Hopefully, the debate regarding “what is research” will move in more useful directions. In any event, HHSOs must be included in the debate since they can and do carry out systematic studies with human participants that have the potential for harm.

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APPENDIX B

Subject Matter Expert Letter, Vignettes and Questions

LETTER TO SUBJECT MATTER EXPERTS

Dear (Name of Subject Matter Expert):

A few days from now you will be contacted to ask for your participation on an advisory panel designed to gather your knowledge on the research ethics review process. The advisory panel is an important component of research being conducted by the University of Calgary, in conjunction with the Alberta Mental Health Board. The goal of this research is to investigate the critical factors utilized by experts such as yourself in determining which projects involving human participants should be subject to full Research Ethics Board (REB) review. We are specifically pursuing this project because of concerns among staff and variation in practice among staff and managers about which, among the various systematic projects (QA, evaluation, research) in our services, need REB review.

The old question of what constitutes research is being asked with new intensity. This question – what is research – leads to a very deep agenda. It is also an agenda with high stakes for it pertains to matters of legitimacy, authority and ultimately to who possesses the power to publish and promote. However, attempts to operationally distinguish the various systematic endeavours of “research” from “program evaluation” or “quality assurance” have been made by experts before and have not been very successful in terms of practical application. Consequently the issue of when and why to apply for REB review might benefit from being re-examined in the light of the principles and practices relevant to the ethical treatment of human beings as espoused by experts from multiple disciplines and settings. Your expertise will be very valuable in gaining a better understanding of this complex issue.

The research project was designed to achieve three objectives, (1) to raise the level of conversation regarding research ethics board (REB) review in all systematic investigations that involve human participants, (2) to make explicit the values that support the espoused policies and practices of REB systems and (3) to develop a valid, useful and psychometrically sound Ethics Decision Guide (EDG). The EDG is intended for practitioners (university researchers, community researchers, program evaluators, quality assurance personnel, and so forth) to ensure they access REB review when appropriate and not when unnecessary. The EDG may also help to increase the transparency of the REB process and the reliability of decision making with regard to REB review.

The literature has been exhaustively searched to establish all of the factors regarded as important for REB review across disciplines and settings. The next step is to interview REB chairs and experts who are currently responsible for REBs in order to learn from their experience.

The panel of experts from Alberta will be asked to participate in a number of ways as detailed below. The total amount of time commitment will be approximately 8 hours in the next six to nine months. The specific tasks being asked of the Alberta panel of experts are as follows:

#1. Read and analyze a package of six vignettes and comment on whether they should be submitted for research ethics review. A short explanation will be requested for each decision. The vignettes are based on carefully selected factual instances[30] where considerable disagreement has surrounded the decision of whether or not to submit for REB review. (2 hours)

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[30] Please note that although factual instances have been utilized to develop the vignettes, all identifying details have been removed or altered sufficiently to disguise the origin of the projects.

#2. Review the domains (i.e. risk of harm) and decision criteria (i.e. individually identifiable information) included on the draft Decision Guide and provide constructive comments. (1 hour)
#3. Participate in a semi-structured interview intended to review feedback from the vignettes and draft EDG comments and to further isolate the critical factors that determine whether any project should be submitted to REB review. (1 – 2 hours)
#4. Review a package of vignettes utilizing the draft EDG to make decisions. Provide feedback on the process (2 hours)
#5. Review the final version of the validated EDG and provide comments (1 hour). If panel members are sufficiently interested, a copy of the final research paper will also be distributed for comment.

It is important to recognize that the domain of this project is not restricted to research that takes place in traditional venues such as universities or teaching hospitals. It is a serious attempt to objectively and consistently differentiate those projects that need to go for ethical review from those that do not, regardless of what the project is called or the setting in which it is conducted. It is anticipated that the results will be disseminated widely and that the Decision Guide will be made publicly available.

Thank you for your consideration.

Sincerely,

Helen Gardiner, Ph.D. (Candidate)
Principal Investigator
University of Calgary, Applied Psychology

Carol Adair, Ph.D.
Director of Research
Alberta Mental Health Board

Once participation had been confirmed, each SME was sent a package of six vignettes and asked to answer questions about each. The goal was to identify those variables that clearly differentiated studies that should seek REB review from those that did not require such review. All vignettes had been extracted from actual situations where decisions had been made by a qualified REB regarding whether the projects required REB review. Consequently, it was possible to determine whether the SMEs agreed with the rulings of the review boards.

ETHICS VIGNETTE #1
Determining the Effectiveness of a Drug Treatment Court

The Department of Justice and the Ministry of the Attorney General have responded to the growing concern that the traditional approach to prosecution of drug dependent offenders fails to address the issue of recidivism among offenders. The response has been to establish a number of Drug Treatment Courts throughout the province of Alberta. Individuals who are selected by the Crown based on specific eligibility criteria including the criminal history of the individual, the nature of the current charges, an assessment of drug dependency and so forth can be diverted to the Drug Treatment Court (DTC) and mandated to treatment rather than jail time.

Participants have seven days from their initial acceptance to opt out of the program. If the offender is approved for the program and commits to it, they plead guilty to the offense and are released on bail. If not, they are referred back to the regular judicial system. Once in the program they must participate in a customized program that includes treatment for physical addiction, mental health counseling and other support services to address such issues as literacy, nutrition, parenting and employment. The progress of the participants is monitored by a DTC team consisting of the judge, prosecutor, defense counsel, case managers and treatment providers. Participants are required to make regular appearances in court and are subject to both periodic and random drug testing.

A participant's successful completion of the program is determined by participation for a minimum of one year, a period of stability and compliance, commitment to either employment or education and the recommendation of the DTC team. If the participant fails to complete the program, they are referred back to the judicial system where their prior guilty plea as well as their participation in the program is taken into consideration for sentencing.

A request for proposals to complete an evaluation of the Drug Treatment Court has been circulated throughout the province. It is expected that a non-randomized experimental design involving an intervention group and a comparison group will be adopted for purposes of conducting the study. The intervention and comparison groups will be tracked for a period of time and compared on a number of dimensions including demographics, recidivism, drug use, and quality of life as well as various well-being measures. Program retention, completion and termination levels, and the use of sanctions and rewards while participants are in the program, will be important aspects of both the process and outcome components of the study.

A team of university researchers submitted a proposal to carry out the evaluation work and have been awarded the contract. As is customary for the team, they have undertaken the proposal under the umbrella of the consulting office that has been set up in their department specifically to provide a mechanism for the faculty to successfully bid on projects. Faculty are not paid for their work on the projects but any students who work on the projects or who manage the projects are paid. The reward for faculty is a closer connection to community groups and the potential to establish relationships which will allow them to carry out their own research work and the opportunity for publication of results from studies such as the DTC. The investigative team intends to publish the results from the study.

ETHICS VIGNETTE #2

Aggression During Morning Dressing Routines at the Watertown Hospital Geriatric Unit

Aggression during morning routines, particularly dressing routines, is a concern among patients in the Watertown Hospital Geriatric Unit (WHGU). Many of the patients in the unit suffer from dementia and are often aggressive or violent with nursing staff during the morning activities. The hospital administration has been working with the multidisciplinary treatment team in order to find solutions to the problem. After some investigation it was determined that psychological space and physical space on the units may be a possible trigger for increased patient aggression. The WHGU decided that they would act upon this information in order to improve the quality of life for their patients and also for their staff.

As a result of the determination that psychological and/or physical space constraints might be at the core of the aggression problem, the WHGU arranged for students from the gerontology undergraduate program at Watertown University (WU) to work with patients on the unit. Students take one client at a time off of the unit to a park on hospital grounds. Their only role is to ensure the safety of the patient (this usually means ensuring that the patients do not wander off of hospital grounds) while watching the patient from a safe distance. This allows the client some privacy and permits the gerontology students to gain an understanding of the impact of Alzhiemer's disease. Students are senior undergraduates who are carefully screened for the practicum placement. They are provided with additional training by the WHGU, mentored by staff and faculty and provided with cellular phones while working in case of emergencies.

The WHGU is now interested in determining the effectiveness of the intervention. They have asked one of the Managers to determine whether patients are less aggressive with nursing staff during morning dressing routines, now that they have more physical and psychological space on a regular basis. The Manager has determined that aggression will be measured by three variables: patient aggression incident reports, patient seclusion hours and frequency of administration of PRN medications (used to calm patients during an aggressive episode). These variables will be examined retrospectively using existing patient files and records. Variable frequencies will be tabulated for the six months prior to the implementation of the intervention and for the six months following implementation and compared. Additionally, staff and patient satisfaction surveys will be administered to obtain feedback on the overall perception of both the process and activities involved in the intervention. For those patients who are too severely impaired to respond to self-report instruments, family members will be invited to provide information by proxy. Input will also be sought from the WU gerontology students regarding their interaction with staff, clients and the utility of the learning experience.

Information collected by the Manager will be utilized among the WHGU staff to determine whether the outdoor intervention should continue. There has been some mention in the staff meetings that a peer review article should be developed for publication if the program is found to be effective.

ETHICS VIGNETTE #3
Creating a Measure for Lifelong Learning in Adults

Promoting Lifelong Learning has received increased attention recently from the educational and business communities. Scholars and trend forecasters, looking towards the needs of the 21st century, have reached nearly unanimous agreement about the importance of a constantly improving and technologically competent workforce that can compete in global markets (McCoombs, 1991). For example, American Psychologist recently devoted an entire issue to Lifelong Learning as it relates to intelligence (Volume 52, No. 10). The Academy of Management Executive dedicated two editions (X, No. 4 and XI, No. 1) to Lifelong Learning in the workplace. An increasing number of books are addressing issues that directly relate to Lifelong Learning or are tangential to it such as When Giants Learn to Dance (Kanter, 1989) and Organizational Learning (Cohen & Sproull, 1996). A Research Network for New Approaches to Lifelong Learning has recently been established at the Ontario Institute for Studies in Education. Simply picking up a business journal or newspaper will likely result in an article or two that directly reflects the need to keep organizations and their employees learning.

Despite all of the public discussion of Lifelong Learning, there is considerable confusion as to how to operationally define Lifelong Learning and how to measure its existence and change in organizations. Consequently, a Human Resources Manager at Omega Company has proposed a project designed to address this issue. His proposal is to develop a measurement instrument to study Lifelong Learning in employee groups and the factors that differentiate them. A second goal of the study is to develop a profile of Lifelong Learner types.

In addition to carrying out a thorough examination of the literature, the Manager intends to conduct interviews with subject matter experts (SMEs) as part of the survey refinement process. Once the measurement instrument is in its final form it will be sent to three organizations that represent different occupational types and, theoretically, different learner types: routine, technical and professional workers. Employees from each of the organizations will be requested to complete the survey. The survey is anonymous and asks questions about basic demographics (age, gender, whether they are professionally licensed, marital status, number of dependents, ages of dependents, highest level of education completed). It also asks forced choice questions that tap a number of domains including their goal orientation, personal resources, self efficacy, work resources and work role salience. Answers from each of these questions will be factor analyzed. Qualitative responses will also be sought on what plans the individual respondents have made for learning over the next six months, what new knowledge or skills they have learned or enhanced over the past 6 months and what, if anything, has made it difficult to participate in lifelong learning/professional development.

All results will be presented in aggregate form only. Although the primary purpose is to develop an instrument to measure lifelong learning and gain a greater understanding of the factors that affect lifelong learning, the Manager is contemplating publishing a peer review journal article to disseminate results.

ETHICS VIGNETTE #4
Psychiatric Crisis Intervention

The Madison General Hospital (MGH) has noticed a significant increase in the wait time in the emergency department over the past number of years. The number of complaints, both from staff and from the patients and community have increased correspondingly, particularly for psychiatric emergency situations. Due to staff shortages and other constraints, patients presenting with psychiatric emergencies are often kept waiting for considerably longer than other patients. The recent suicide of a psychiatric emergency patient who was kept waiting in excess of 27 hours galvanized hospital administration to find tenable solutions to the problem. The literature was reviewed for possible solutions and, consequently, funding was applied for and successfully obtained to establish a separate psychiatric emergency unit for a three year pilot period. One of the requirements of the funding is that an evaluation of the psychiatric emergency unit must be undertaken in order to determine the effect on wait times in general emergency, the wait times for psychiatric emergency clients in particular, the efficacy of the psychiatric emergency department in stabilizing clients as quickly as possible and returning them to the community, determining the impact of the unit on staff, patient and community satisfaction as well as a number of other issues.

The evaluation of the MGH Psychiatric Emergency Unit (PEU) is being carried out by an internal evaluation team. Several members of the team are medical professionals who have joint appointments to the hospital and Madison university. The team has planned an evaluation protocol that will be implemented as soon as the PEU is opened. Patients will arrive at the PEU in much the same manner as general emergency: by ambulance, family, friends, police, community agencies and so forth. Once they arrive, they will be asked to sign a consent form to participate in the evaluation and then asked to complete a standard self report measurement instrument to determine baseline information on a number of relevant criteria. This information will be compared with clinician proxy instruments intended to capture the clinician's perspective. DSM IV diagnosis will be included in the dataset. Clients will then be admitted and provided with treatment deemed appropriate for their particular situation, including admission to the long-term psychiatric unit if necessary. At discharge the same measurement instruments will be completed in order to provide pre/post comparison data to evaluate the efficacy of the interventions provided. Clients will be contacted 7 days post discharge and requested to complete a standardized client satisfaction survey intended for the adult psychiatric population and that is suitable for telephone administration. Community and staff satisfaction will be assessed in a similar manner annually.

Although the primary intention of the evaluation is for internal hospital management purposes, the evaluation team is considering publication of the results if the unit is successfully achieving its goals.

ETHICS VIGNETTE #5
Intervention to Increase Delivery of Preventive Services

Several regions responsible for health care delivery have banded together to develop better delivery systems for six preventative care services offered in their regions. The services include blood pressure monitoring, Pap smear, cholesterol monitoring, tobacco use cessation, breast examination and mammography. Staff have developed a process intended to improve the quality of service delivery. The process has three major components: leadership involvement, training and networking and consulting, all of which focus on teaching participating clinic staff how to employ classic continuous quality improvement change steps including (1) identifying the problem, (2) collecting enough data to understand their current care process, (3) analyzing the data to understand the problems and their root causes in the current process, (4) developing alternative solutions, (5) generating and developing specific recommendations, (6) implementing the recommendations and (7) evaluating and improving the process in an iterative cycle through the above steps as needed.

All clinics eligible for recruitment in the regions were contacted. Sixty-four clinics were successfully recruited to participate. The participating clinics were then randomly assigned to improve delivery of preventative care services (intervention group) or to provide usual care (control group). All participating clinics completed a baseline survey and were then matched on the basis of three measures potentially predictive of ability to improve the delivery of preventative services: size (the number of primary care clinicians treating adults), readiness to systematically improve preventative services, and existing quality-based organizational culture. All clinics from the intervention group are working with multidisciplinary teams who guide them through the improvement process with the goal of increasing the rate of preventative services provided to patients.

The regions have established a careful process to determine the utility of the quality improvement process. Evaluation surveys are conducted at the end of each training session. Evaluation surveys are also planned for the end of the intervention (24 months after the initial start date) and at 1-year post intervention cessation. The regions plan to evaluate the success of the intervention using two primary outcome measures: the number of patients who are up-to-date on prevention services and the number of patients who were offered prevention services if they were not up to date. A patient will be considered up-to-date if a chart audit indicates that the patient received one of the preventative services within 3 months of a primary care visit. Results from intervention vs. control group clinics will be compared. All patients will be asked for written informed consent for medical record audits.

ETHICS VIGNETTE #6
A Case Study of On Campus Violence

With increasingly frequent incidents of campus violence, a small, growing scholarly literature about the subject is emerging. For instance, authors have reported on racial, courtship and sexually coercive, and hazing violence. For the American College Personnel Association, Roark and Roark reviewed the forms of physical, sexual and psychological violence on college campuses and suggested guidelines for prevention strategies. However, one form of campus violence that has not been examined is that of gun violence.

Student gun violence is on the rise across colleges. Recent campus reports indicate that violent crimes from thefts and burglaries to assaults and homicides are on the rise at colleges and universities. College campuses have been shocked by killings such as those at The University of Iowa, The University of Florida, Concordia University in Montreal and the University of Montreal-Ecole Polytechnique. Incidents such as these raise critical concerns, such as psychological trauma, campus safety and disruption of campus life. Aside from an occasional newspaper report, the postsecondary literature is silent on campus reactions to these tragedies; to understand them one must turn to studies about gun violence in the public school literature.

An incident on the campus of a large public university in a Midwestern city has led a faculty member to undertake an investigation that may lend valuable understanding in this area. The incident involved a graduate student attempting to shoot a number of classmates. When his gun jammed, the student fled and was later captured by police.

The faculty member has proposed a qualitative study that will be limited to the reactions of groups on campus. In the constructionist tradition the study will incorporate the paradigm assumptions of an emerging design, a context-depending inquiry, and an inductive data analysis. The faculty member also proposes to limit the study by time (8 months) and by a single case (the campus community). Consistent with case study design, the proposal suggests that the students involved in the incident will be interviewed. In addition campus administrators and student newspaper reporters will be interviewed to provide multiple sources of information for initial interviews. Additional informants will be included as the process unfolds. The semi-structured interview process will consist of four_questions: What has been your role in the incident? What has happened since the event that you have been involved in? What has been the impact of this incident on the university community? To whom should we talk to find out more about the campus reaction to the incident? Data will also be gathered from observation, documents and visual materials.

The results are intended for distribution within the university, at conferences and in the academic press.

QUESTIONS FOR EACH VIGNETTE

#1. Is this a research project, program evaluation or quality assurance? Please explain your answer.

#2. Would your answer to #1 be different if the winning contract was awarded to a private consulting company as opposed to a team of researchers from a University? Why or why not?

#3. Should the team submit their proposal for ethics review? ☐ Yes ☐ No Why or why not?

If they should submit their proposal for ethics review, please select the most appropriate course of action from the following options

- ☐ **Full Research Ethics Board Review**
- ☐ **Ethical Consultation (External)**
- ☐ **Ethical Consultation (Internal)**
- ☐ **Other (please explain)**

#4. Each of the following items emerged from the research ethics literature as being important to consider in research ethics. Keeping the above vignette in mind, please indicate how much importance should be placed on each item in this case using the following scale: **0 = Does not apply**

1	**2**	**3**	**4**	**5**	**6**	**7**
Not at All Important			**Somewhat Important**			**Critically Important**

Variable	Description	Rating
Constraints and Undue Influence	There are potentially constraining circumstances and inducements that could unduly influence an individual's decision to participate.	
Impaired Capacity	Potential participants may not be given all of the information they need to determine whether or not they wish to participate. They may not be capable of understanding that information~~.~~	
Deception	The data collection protocol may require some level of deception	
Informed Consent	Participants may not be asked for informed consent or, if they are asked, they may not be able to give consent. Specific considerations might be: • Whether the participants are adults. • Whether the participants are of sound mind~~.~~ • Whether there is any possibility that potential participants might perceive refusal to consent with withholding of services or adverse results~~.~~ • Whether the consent form is sufficiently comprehensive~~.~~ • Whether the consent form is written in language suitable to the intended participants.	
Assumption of Risk	Would a rational~~e~~ person assume that their participation in the situation under study implies their consent? (i.e. would a client expect the organization to routinely attempt to	

Variable	Description	Rating
	improve their performance or accountability in this area)?	
Invasive Questions	The information to be collected is potentially invasive (i.e. data about sexual behaviour, drug/alcohol use, family functioning, finances, etc.).	
Manipulation	The investigator will manipulate the way participants are managed in a way that is novel or additional to the usual procedure.	
Risk of Stress and/or Indignity	There is a risk of stress and/or indignity (discomfort, embarrassment, feelings of inadequacy, etc.) to the participants.	
Sharing of Information	Individually identifiable information may be shared with someone outside of the research team.	
Data Collection Outside of Program	Information will be collected from outside of the program (i.e. from employers or education staff).	
Direct Client Contact	The data collection protocol require the project team to contact the client directly to obtain information.	
Distributive Justice	The project will have to be designed in such a way that the individuals who bear the burden of risk are not those who will also benefit from the results.	
Electronic Recording	Participants may be audio or video taped.	
Individually Identifiable Information	Individually identifiable information will be collected.	
Risk of Injury	There is a risk of injury (physical, psychological, material) to the participants.	
Withholding Treatment	Participants will be randomly assigned to conditions (i.e. an "experimental" and a "control" group), and appropriate treatment might be withheld from one or more of the groups such that the participants might be harmed in some way.	
Novel Intervention	The primary focus of the project is a test or treatment that is novel or additional to the usual procedure.	
Public Presentations	Individuals may be identified in a public forum (i.e. presentations, print) outside of the research team.	
Qualifications of Principal Investigator for Clinical Trials	The Principal Investigator does not have at least the following qualifications: • Ph.D. • Graduate level research design • Graduate level statistics • 3 – 5 years experience • Current membership in a professional association with an established code of ethics.	
Qualifications of Principal Investigator for Non-Clinical Trials	The Principal Investigator does not have at least the following qualifications: • M.Sc. • Graduate level research design • Graduate level statistics • 3 – 5 years experience • Current membership in a professional association with an established code of ethics.	
Random Assignment	Participants will be randomly assigned to conditions (i.e. an "experimental" and "control" group).	
Random Selection	Participants will be randomly selected from a population.	

Variable	**Description**	**Rating**
Novel Process	The primary focus of the project is a change in standard operating process~~.~~	
Clinical Practice Improvement	The primary goal of the project is to establish standards for clinical practice.	
Scientific Truth	The primary goal of the project is to add to understanding of generalizable scientific truth.	
For-Profit External Funding	The project has been funded by an external organization that may be perceived as having a vested interest in the outcome.	
Non-Profit External Funding	The project has been funded by an external agency that requires ethical review (i.e. AHFMR, MRC, NSERC, SSHRC)	
Process Effectiveness	The primary goal of the project is to improve the current processes of a specific program or organization.	
Program Effectiveness	The primary goal of the project is to determine the effectiveness of a specific program or organization.	

#5. Are there other ethical considerations that concern you about this project and that were not covered by the items included in question #3? ☐ Yes ☐ No

If "Yes", what are they?

APPENDIX C: INTERNATIONAL ELECTRONIC SURVEY

Ethics Decision Guide Survey

Thank you for deciding to participate in this study. Your thoughts and experiences will be of great help to the research and furthering the understanding of when systematic projects in health and human service organizations should be sent for Research Ethics Board (REB) review, ***regardless of whether they are called "research", "program evaluation" or "quality assurance"***.

It may be helpful to know that REBs are responsible for protecting participants of research studies and for ensuring the scientific quality of projects. Originally they were established to review medical research studies. However, over time they began to review social science research. As the definition of "research" expanded to include qualitative and quantitative work, it became difficult to determine which projects required REB review. Although many stakeholders recognize there is a considerable difference in the risks involved in carrying out a clinical trial for a new medication when compared to a qualitative study that involves only conversations between adults, there are no standards or instruments available to assist project leaders to determine which projects require REB review and which do not.

This study is intended to gather information that will lend clarity to the debate. From the information you provide an instrument, tentatively called the Research Ethics Guide, will be developed. In the next stage of the project, the items will be ranked, weighted and scaled according to the importance given by respondents to the survey. Non-discriminating items will be eliminated so that the final instrument will be as parsimonious as possible. Future research is planned to establish the reliability and validity of the instrument. The final instrument will be available in the public domain.

The ***Ethics Decision Guide Survey*** consists of 42 multiple choice questions followed by 2 open ended questions. It takes approximately 20 minutes to complete. To complete the survey, please answer the questions and then click "submit survey". The data will be transmitted automatically. All responses are anonymous.

RESPONDENT BACKGROUND:

Are you a member of any of the following organizations?

☐ American Evaluation Association
☐ American Psychological Association
☐ Canadian Evaluation Society
☐ Canadian Psychological Association
☐ Canadian Society for Epidemiology and Biostatistics
☐ International Society for Quality in Health Care
☐ Agency for Healthcare Research and Quality
☐ National Committee for Quality Assurance
☐ National Council for Ethics of Human Research
☐ The Association for Health Services Research
☐ National Assembly of Health and Human Service Organizations
☐ None of the Above

Have you ever been a research participant?

○ Yes ○ No

Have you ever served on any type of Research Ethics Board (REB)?

○ Yes ○ No

How much knowledge do you consider yourself to have about each of the following where 1=no knowledge, 3=some knowledge and 5=expert:

	1	2	3	4	5
1 Research	○	○	○	○	○
2 Program Evaluation	○	○	○	○	○
3 Quality Assurance	○	○	○	○	○
4 Research Ethics	○	○	○	○	○
5 REB Procedures	○	○	○	○	○

In which country do you live (select one)?

What is your primary professional affiliation? (choose one)

○ College/university
○ Government agency
○ Hospital
○ Private business
○ Non-Profit organization
○ Other (please specify)

If you selected other please specify:

What is your primary activity in your current position? (choose one)

○ Research
○ Evaluation
○ Quality Assurance
○ Other (please specify)

If you selected other please specify:

How long have you been working in your primary activity? (choose one)

○ Less than 5 years
○ 5 to 9 years
○ 10 to 14 years
○ 15 to 19 years
○ More than 20 years
○ Other (please specify)

If you selected other please specify:

Highest Level of Education completed (choose one):

○ Less than college diploma/undergraduate degree
○ College diploma/undergraduate degree
○ Masters
○ Ph.D.
○ Other (please specify)

If you selected other please specify:

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Ethics Decision Guide Survey

MAIN SURVEY:

Please read the following items. Think about how you would react if you were reviewing a project that included the situation described in the item. Think about what you would recommend to the project team if they asked you whether their project required ethical review.

Then, please rate each item according to the following scale:

1 = CLEARLY NEEDS SOME LEVEL OF ETHICAL REVIEW
2 = MAY REQUIRE ETHICAL REVIEW
3 = DOES NOT REQUIRE ETHICAL REVIEW
N/C = NOT CLEAR/UNDECIDED

Whenever you select **1 = CLEARLY NEEDS SOME LEVEL OF ETHICAL REVIEW** please answer the follow-up question to clarify whether you believe the item requires

(a) an entire REB committee review (FULL REVIEW), OR

(b) review by least one member of an REB committee who can decide whether the project requires a full review or not (EXPEDITED REVIEW).

Please choose ONLY ONE ANSWER PER QUESTION. Also, please remember that we are interested in YOUR OPINION of which items are useful for health and human service organizations to discriminate between those projects that need REB review and those that do not. We are not concerned with legislation in your area or policy that applies to your organization or practice. Here is the first question:

1. The project lead is the participant's boss or therapist.

○ 1 = Clearly needs some level of ethical review
○ 2 = May require ethical review
○ 3 = Does require ethical review
○ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead is the participant's boss or therapist*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

2. The participant is ill and the project involves use of a treatment that may help them get better.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The participant is ill and the project involves use of a treatment that may help them get better*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

3. The participant is cognitively impaired or is a child.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The participant is cognitively impaired or is a child*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

4. The project procedure is complex and technical. It will be difficult for non-technical people to understand.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project procedure is complex and technical. It will be difficult for non-technical people to understand*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

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5. The participant is from a minority, marginalized or otherwise disadvantaged group.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF REB REVIEW, please tell us which decision you believe should be made if this item (i.e. *The participant is from a minority, marginalized or otherwise disadvantaged group*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

6. The true purpose of the study will not be revealed to the participants for scientific reasons.

☐ 1 = Clearly requires some level of ethical review.
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The true purpose of the study will not be revealed to the participants for scientific reasons*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

7. The project team is only going to review existing data.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project team is only going to review existing data*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

8. The sole purpose of the project is to improve the quality of a service.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The sole purpose of the project is to improve the quality of a service*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

9. The project lead or a member of the team has a vested interest in the outcome of the proposed project.

(EXAMPLE: The proposed work involves an investigation into the effectiveness of a psychotherapy treatment program by a team of individuals employed by the treatment organization.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead or a member of the team has a vested interest in the outcome of the proposed project*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

10. The project lead does not have appropriate qualifications to carry out the work.
(EXAMPLE: the project team does not include a qualified researcher, evaluator or quality assurance professional.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead does not have appropriate qualifications to carry out the work*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

11. The project lead is not a member of an appropriate professional association.
(EXAMPLE: the proposed work is a quality assurance project but the project leader does not belong to an acknowledged association for quality assurance professionals.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead is not a member of an appropriate professional association*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

12. The project lead is a student who is not directly supervised by a qualified individual.

(EXAMPLE: the proposed work is part of an undergraduate project.)

○ 1 = Clearly requires some level of ethical review
○ 2 = May require ethical review
○ 3 = Does not require ethical review
○ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead is a student who is not directly supervised by a qualified individual*) is present in the project.

○ 1 = Review by an entire REB (FULL REVIEW).
○ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
○ N/C = Not Clear/Uncertain

13. The project lead is a student who is directly supervised by a qualified individual.

(EXAMPLE: the proposed work is part of a Masters or Doctoral program.)

○ 1 = Clearly requires some level of ethical review
○ 2 = May require ethical review
○ 3 = Does not require ethical review
○ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead is a student who is directly supervised by a qualified individual*) is present in the project.

○ 1 = Review by an entire REB (FULL REVIEW).
○ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
○ N/C = Not Clear/Uncertain

14. The project involves testing a new drug, surgical technique or other invasive procedure.

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves testing a new drug, surgical technique or other invasive procedure*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

15. The project involves the study of a new (non-invasive) process.

(EXAMPLE: The proposed work involves the creation of a new court to handle drug related offenses.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves the study of a new (non-invasive) process*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

16. The project involves no risk of harm greater than that which a person might experience in their everyday lives.

(EXAMPLE: The project team is interested in the body language of individuals who are waiting to cross at a busy roadway intersection. They intend to observe the individuals from a distance without ever interacting with the people they observe.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves no risk of harm greater than that which a person might experience in their everyday lives*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

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17. The project involves ongoing routine data collection.

(EXAMPLE: The United Way has collected client satisfaction data for the past 10 years for all of the projects it funds. The executive team is now uncertain as to whether they need REB approval to continue this process.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves ongoing routine data collection*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

18. The project involves a special, time-limited data collection process.

(EXAMPLE: A non-profit organization is interested in understanding why donations have dropped off in the past several months. The project proposes to call previous donors who have not donated recently in order to better understand the situation. A questionnaire has been developed for the purpose that will take place on a one-time basis.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May review ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves a special, time-limited data collection process*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

19. The project involves the review of anonymous information only.

(EXAMPLE: The project team is interested in how to prevent death by suicide across the entire country. They intend to review the data collected routinely by the national health authority after it has been stripped of all individually identifiable information.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves the review of anonymous information only*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

20. The project involves collection of opinions or suggestions from people who are willing to speak to the project team.

(EXAMPLE: The project team is attempting to understand the preference of patients regarding food services. They telephone a few recent patients to ask their opinion about how their eating habits have changed as a result of their illness and how food services can be improved.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves collection of opinion or suggestion from people who are willing to speak to the project team*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

You are about half way through the survey. Thank you for your thoughtful insights. If you need to take a break, you can exit the survey at the end of any section (before clicking "next page"). You do not have to save your survey. When you come back to the website, WebSurveyor will recognize that you have a survey in progress and will ask you if you want to continue from where you left off. Here's the next question.

21. The project intends to answer questions that have been raised by the staff of a Human Service Organization.

(EXAMPLE: Front line staff are concerned that clients are having difficulty accessing services. The executive team establishes a project team to investigate the issue.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project intends to answer questions that have been raised by the staff of a Human Service Organization*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

22. The project has been funded by an external organization that has a vested interest in the result of the study.

(EXAMPLE: The proposed work involves the trial of a new questionnaire. The developer of the questionnaire is sponsoring the trial and plans to license the questionnaire if it proves to be useful.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project has been funded by an external organization that has a vested interest in the result of the study*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

23. The project has been entirely funded by the organization where the work will be carried out.

(EXAMPLE: The project will be carried out in health promotion programs that are funded and run by the Regional Health Authority. No external funding has been sought for the project.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *<u>The project has been entirely funded by the organization where the work will be carried out</u>*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

24. The project involves collecting information that might be embarrassing or uncomfortable for participants.

(EXAMPLE: The proposed work includes questions about sexual activity or financial problems.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *<u>The project involves collecting information from individuals that might be embarrassing or uncomfortable for participants</u>*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

25. The project has been approved by at least one Research Ethics Board.

(EXAMPLE: The proposed work is intended to be carried out across the country in mental health clinics. The clinics are operated by 26 health regions, each with its own REB. One health region REB has already approved the work. However, a number of other health regions are blocking the work until it receives additional approval from their particular Research Ethics Board.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The investigation has been approved by at least one Research Ethics Board*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

26. The individuals who bear the risk of the project are also part of the group who will gain the benefits, if any.

(EXAMPLE: The study participants are individuals with physical disabilities and the investigation is to determine the effectiveness of current standards for wheelchair accessibility to public buildings.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The individuals who bear the risk of the project are also part of the group who will gain the benefits, if any*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

27. The project may cause minor adverse effects.

(EXAMPLE: The project might cause slight emotional upset for participants.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does Not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project may cause minor adverse effects*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

28. The project lead intends to publish the work in a journal.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead intends to publish the work in a journal*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

29. The project lead intends to present the results of the project at professional conferences.

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead intends to present the results of the project at professional conferences*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

30. The project lead intends to present the results of the project at internal meetings only.

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project lead intends to present the results of the project at internal meetings*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

31. The project team are staff who are employed by the organization specifically for the purpose of carrying out this type of project.

(EXAMPLE: The project team is employed as internal program evaluators by a rehabilitation facility.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project team is part of dedicated staff who are employed by the organization specifically for the purpose of carrying out this type of project*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

32. The project team is comprised of people not employed by the organization. (EXAMPLE: The project team is a group of faculty members and graduate students from the local university.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require some level of ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project team is comprised of people not employed by the organization*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

33. The project lead is seeking to establish general scientific principles that are not related to any program or service.

(EXAMPLE: The project team is collecting information from clients at a hospital in order to better understand how to improve client outcomes for ANY CLIENTS of ANY hospital. No plans are in place for the investigation team to work with the data collection site to improve outcomes for their clients.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The investigator is seeking to establish general scientific principles that are not related to any program or service*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

34. Individually identifiable information will be used.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *Individually identifiable information will be used*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

35. Individually identifiable information will be used to link several databases together in order to gather more complete information.

(EXAMPLE: A unique lifetime identification number (such as a social insurance number or personal health number) will be used to collect information from the health ministry and a local hospital in order to determine the cost of a health program for all those who used the program.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *Individually identifiable information will be used to link several databases together in order to gather more complete information*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

36. All people from a particular group (population) will have an equal chance of being asked to participate.

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *All people from a particular group (population) will have an equal chance of being asked to participate*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

37. The project involves random assignment to treatment and control (treatment as usual) groups.

(EXAMPLE: 100 people who suffer from eating disorders have agreed to take part in a study on a new psychotherapeutic approach. All 100 people are randomly assigned to either “control” (psychotherapy treatment as usual) or "treatment” (the new psychotherapy treatment) groups.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The project involves random assignment to treatment and control (treatment as usual) groups*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

38. The process being studied is not known to be any better or worse than treatment as usual.

(EXAMPLE: A new process has been developed for organizing hospital emergency departments. It is believed that the new process will be more efficient and result in better outcomes for patients, but no evidence currently exists to support that belief. The project is designed to test out the new process in an urban hospital.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The process being studied is not known to be any better or worse than treatment as usual*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

39. The project lead acknowledges that if they become aware that the process being studied is better or worse than treatment as usual, the study will be discontinued.

(EXAMPLE: A new psychotherapy is being tested among people who have been diagnosed as having borderline personality disorder. As the trial continues the project lead becomes aware of a disturbing pattern of behaviors that are occurring for an unusually high number of clients. The project lead chooses to err on the side of caution and discontinues the study until the reasons for the behaviors can be determined.)

NOTE: The above is different from the statistical "early stopping rules" used in clinical trial research.

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The investigator acknowledges that if they become aware during the course of the study that the process being studied is better or worse than treatment as usual, the study will be discontinued*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

40. The data for the project has been collected for another purpose.

(EXAMPLE: The project team are clinicians who treat women experiencing high risk pregnancies. The team wants to use the information collected for clinical treatment purposes to develop a process to treat high risk pregnancies in general.)

☐ 1 = Clearly requires some level of ethical review

☐ 2 = May require ethical review

☐ 3 = Does not require ethical review

☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The data for the project has been collected for another purpose*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

41. The participants will be audio or videotaped.

(EXAMPLE: The principal investigator is working with a small group of people and interviewing them individually on four different occasions. Each interview takes two hours. In order to carry on a normal conversation and keep accurate records, the interviews are being recorded with the permission of the participants.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW, please tell us which decision you believe should be made if this item (i.e. *The participants will be audio or videotaped*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).
☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)
☐ N/C = Not Clear/Uncertain

42. The participants will be audio or videotaped without their knowledge.

(EXAMPLE: A non-profit organization is located in a high security building. In an attempt to determine the level of risk their clients experience in coming to the organization, the project proposes to utilize the surveillance camera video recordings that are routinely used in the building lobby.)

☐ 1 = Clearly requires some level of ethical review
☐ 2 = May require ethical review
☐ 3 = Does not require ethical review
☐ N/C = Not Clear/Undecided

If you indicated on the last question that the item CLEARLY REQUIRES SOME LEVEL OF ETHICAL REVIEW. Can you please tell us which decision you believe should be made if this item (i.e. *<u>The participants will be audio or videotaped without their knowledge</u>*) is present in the project.

☐ 1 = Review by an entire REB (FULL REVIEW).

☐ 2 = Review by at least one member of a REB (EXPEDITED REVIEW)

☐ N/C = Not Clear/Uncertain

43. Are there any characteristics of systematic projects which you believe clearly distinguish between those projects that should go for REB review from those that should not that *<u>HAVE NOT</u>* been discussed above?

☐ Yes

☐ No

Please specify what additional features you believe clearly distinguish between those projects that should go for REB review from those that should not that have not been discussed above.

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Please think about the responses that you have provided throughout the survey. In your opinion, what are the FIVE MOST IMPORTANT project characteristics that you believe are the hallmarks of those projects with *MUST GO FOR REB REVIEW*?" To help you with this final question, we have provided a list of all of the items listed in the survey.

You may answer this question in a number of ways:

(b) Enter in the **NUMBER OF EACH ITEM** that you believe are most important

(b) **TYPE IN YOUR RESPONSE based on the questionnaire items.**

(c) **TYPE IN A RESPONSE that is NOT based on the questionnaire items.** Take this approach if you believe there are critical issues to consider that were not included in the questionnaire.

Regardless of how you answer, please enter only **ONE ANSWER PER BOX.** If you type your responses, please use point form. Your responses do not need to be ranked in order of importance. Here is a recap of all of the items from the questionnaire:

1. The project lead is the participant's boss or therapist.
2. The participant is ill & the project treatment may help them get better.
3. The participant is cognitively impaired or is a child.
4. The project procedure is complex and technical.
5. The participant is from a disadvantaged group.
6. Participants will not be told the true purpose of the study.
7. The project team is going to review existing data only.
8. The sole purpose of the project is to improve the quality of a service.
9. The team has a vested interest in the results of the project.
10. The project lead does not have appropriate qualifications for the work.
11. The project lead is not a member of a professional association.
12. The project lead is an unsupervised student.
13. The project lead is a student who is supervised by a qualified individual.
14. The project involves testing a new drug, or surgical technique.
15. The project involves the study of a new (non-invasive) process.
16. The project involves only an "everyday" level of risk.
17. The project involves ongoing routine data collection only.
18. The project involves a special, time-limited data collection process.
19. The project involves the review of anonymous information only.
20. Data will only be collected from people willing to speak to the team.
21. The project will answer questions raised by staff of the organization.
22. Funding is from an external organization that has an interest in the results. 23. Funding is from the organization where the work will be carried out.
24. The project might be embarrassing or uncomfortable for participants.
25. The investigation has been approved by at least one REB.
26. The participants are part of the group who will gain the benefits, if any.
27. The project may cause minor adverse effects.
28. The team intends to publish the work in a journal.
29. The team intends to present the work at professional conferences.
30. The team intends to present the work at internal meetings only.
31. The team are employed by the org. specifically to carry out this type of project.

32. The team are not employed by the organization.
33. The project is seeking to establish general scientific principles.
34. Individually identifiable information will be used.
35. Individually identifiable information will be used to link databases.
36. All people will have an equal chance of being asked to participate.
37. The project randomly assigns to treatment and control groups.
38. The process being studied is not better or worse than usual treatment.
39. The team will discontinue the study if they become aware that the process being studied is better or worse than treatment as usual.
40. The data for the project has been collected for another purpose.
41. The participants will be audio or videotaped.
42. The participants will be audio/videotaped without their knowledge.

What are the TOP FIVE features that clearly indicate a project MUST GO TO REB REVIEW?

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Thank you for your time and thoughtful effort.

We intend to make the resulting Ethics Decision Guide available in the public domain. The associations who participated in this study will advise their membership when the completed Ethics Decision Guide is available. However, if you wish to be informed directly of the results of this project or to obtain a copy of the completed Ethics Decision Guide instrument, please send an email to:

helen@thegardiners.ca

or contact the Principal Investigator

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Submit Survey

APPENDIX D: SUMMARY OF DILLMAN METHOD OF INTERNET SURVEYING[31]

Chapter One

Cover letter:

Ways of showing personal regard to questionnaire recipients:

- Show respect for the individual who receives it.
- Give respondents reasons why the survey is being done.
- Provide a toll-free number to call with questions.
- Personally address correspondence.

Say Thank you:

- We appreciate very much your help
- Many thanks in advance.
- A follow-up postcard reminder designed as a thank you for the prompt return of "the important questionnaire we sent you recently" (this has been found to produce a response burst nearly equal to that which followed the original mail-out a week or so earlier).

Ask for advice:

- The feeling of being asked for help, advice, or assistance provides a sense of reward to people.
- I am writing to you because the only way we can find out whether the service we provide is really meeting the needs of people like yourself….

Support group values:

- Depending upon the survey population, sponsorship and topic one can often appeal to values shared widely by those who are surveyed.
- Supporting a person's values can instill a sense of reward in individuals.
- Underlies efforts to appeal to respondents on the basis of a study's "social usefulness."

Make the questionnaire interesting:

- Liking to do something is a powerful determinant of behaviour.
- Questionnaires on topics of high salience to recipients are more likely to be returned than those on topics of low salience.
- Questionnaires can be made more interesting to respondents by improving layout and design, ordering questions so the more interesting ones are placed at the beginning and making questions easy to understand and answer.

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[31] Dillman, D. A. (Ed.). (2000). *Mail and Internet Surveys. The Tailored Design Method* (2nd ed.). New York: John Wiley & Sons, Inc.

Give social validation:

- Knowing that other people like themselves have completed a similar action can strongly influence people's willingness to comply with a request.
- To encourage response, telling people that many others have already responded. This encourages them to act in a similar way.

Avoid subordinating language:

- Consider these contrasting statements:
  "For us to help solve the school problems in your community it is necessary for you to complete this questionnaire" versus "Would you please do me a favour?"
  The former implies the respondent is dependent upon the letter writer, whereas the latter suggests that the writer is dependent upon the respondent. People prefer not to be subordinated to others, and will often make great efforts to avoid that (i.e. by not responding).

Avoid embarrassment:

- Respondents can be embarrassed about a lack of knowledge on the issue.
- The costs to an individual are high when great physical or mental effort is required and when embarrassment or anxieties accompany the action.
- Questionnaires often get discarded when the respondent peruses the questionnaire but can't figure out where to start or what the fist question means.
- The lack or response from people who do not read well or who are not used to expressing themselves in writing may be due to this type of social cost.

Avoid inconvenience:

- Not including an envelope lowers response rates.
- The continued presence of a return envelope contributes to the convenience of responding.

Make questionnaires appear short and easy:

- Appearances can be reinforced by indicating in the cover letter that responding should only take a few minutes.
- Respondent friendly questionnaires, with carefully organized questions in easy-to-answer formats can improve response rates.

Ways of Establishing Trust:

- Trust is critical to forming the belief that in the long run the benefits of completing the questionnaire will outweigh the costs of doing so.

Make the task appear important:

- Form letters produced on copy machines, questionnaires that are sloppily constructed or contain questions that are difficult to understand. A lack of follow-up mailings to non-respondents suggests that a questionnaire is relatively unimportant.
- Each contact needs to look important.
- Printing personalized cover letters on letterhead stationary and designing the questionnaire in a way that makes sense to the respondent have a significant role in establishing trust.

Summary of Tailored Design
Schematic overview of the Tailored Design perspective

In summary responding to a questionnaire is viewed as a social exchange. People are seen as more likely to complete and return self-administered questionnaires if they trust that the rewards of doing so will, in the long run, outweigh the costs they expect to incur. The following summarizes this perspective:

A. Tailored Design:
Is the development of survey procedures that create respondent trust and perceptions of increased rewards and reduced costs for being a respondent, which take into account features of the survey situation and have as their goal the overall reduction of survey error.

B. Social exchange and respondent behaviour:
Actions are motivated by the return these actions are expected to bring and in fact, usually do bring, form others. The likelihood of responding to the request to complete a self-administered questionnaire, and doing so accurately, is greater when the respondent trusts that the expected rewards of responding will outweigh the anticipated costs.

C. Many aspects of questionnaire and implementation process can be shaped to create trust and influence the respondent’s expectations for rewards and costs.

D. Exchange concepts:
Must be communicated visually (rather than verbally) through the use of visual design principles for the development of questionnaire and implementation materials.

E. Knowledge
The knowledge of the survey population, sponsorship and survey content must be considered in order to develop the most effective means for increasing rewards, reducing costs, and establishing trust.

F. Successful Tailored Design seeks to reduce survey errors from coverage, sampling, measurement, and non-response.

Designing the Questionnaire Cover Pages

The Front Cover:

- Evidence exists that questionnaire cover designs can improve response rates.
- A questionnaire with predominantly black cover contrast achieved a significantly higher response rate than a low contrast white cover.

Principles for designing separate cover pages are:

- The questionnaire needs to be immediately distinguishable from all other questionnaires that a respondent might receive, while creating a positive first impression.
- A title is included so that in any conversation with the respondent it is easy to identify which questionnaire the respondent is asking about.
- The title like that on a book should be short and simple and written to the respondent not to the organization or agency sponsoring the survey.
- The name and address of the study sponsor are included so the respondent will know where to send the questionnaire in the event the return envelope becomes separated or lost.
- The questionnaire cover is viewed as an extension of the cover letter.
- Identifying a questionnaire clearly as being sent from a well-known and legitimate source is desirable for fostering trust that the survey is legitimate and useful.

The Back Cover:

- The back cover should be kept simple.
- Normally it consists of an invitation to make additional comments, a thank you and plenty of white space.
- Questions are never included on the back page.

Pre-testing

Stage 1: Review by Knowledgeable Colleagues and Analysts

- Have I included all of the necessary questions?
- Can I eliminate some of the questions?
- Did I use categories that will allow me to compare responses to census data or results of other surveys?
- What are the merits of modernizing categories versus keeping categories as they have been used for past studies?

Stage 2: Interviews to Evaluate Cognitive and Motivational Qualities

- Are all the words understood?

- Are all of the questions interpreted in the same way by all respondents?
- Do all of the questions have an answer that can be marked by every respondent?
- Is each respondent likely to read and answer each question?
- Does the mailing package create a positive impression?

Stage 3: A Small Pilot Study

- Have I constructed the response categories for scalar questions so people distribute themselves across categories rather than being concentrated in only one or two of them?
- Do any items from which I hope to build a scale correlate in a way that will allow me to build scales?
- What kind of response rate is the survey likely to obtain?
- Are some questions generating a high item non-response rate?
- Do some variables correlate so highly that for all practical purposes I can eliminate one or more of them?
- Is useful info being obtained from open-ended questions?
- Are entire pages or sections of the questionnaire being skipped?
- What response rate can I expect?

Stage 4: A Final Check. Did we do something silly?

- People who have worked on one revision after another soon lose their ability to detect obvious problems.

Chapter 4
Survey Implementation

The questionnaire is only one part of a well-done survey. Implementation procedures have a much greater influence on response rates. They are:

- Multiple contacts
- The contents of letters
- Appearance of envelopes
- Incentives
- Personalization
- Sponsorship and how it is explained
- Other attributes of the communication process

Five Needed Elements for Achieving High Response Rates

Element 1: Respondent-Friendly Questionnaire

Element 2: Four Contacts by First Class Mail, with an additional Special Contact

1. A brief pre-notice letter that is sent to the respondent a few days prior to the questionnaire, it notes that a questionnaire for an important survey will arrive in a few days and that the person's response would be greatly appreciated.

2. A questionnaire mailing that includes a detailed cover letter explaining why a response is important.

3. A thank you postcard that is sent a few days to a week after the questionnaire. this mailing expresses appreciation for responding and indicates that if the completed questionnaire has not yet been mailed it is hoped that it will be returned soon.

4. A replacement questionnaire that is sent to non-respondents 2-4 weeks after the previous questionnaire mailing. It indicates that the person's completed questionnaire has not yet been received and urges the recipient to respond.

5. A final contact that may be made by telephone a week or so after the fourth contact.

Make each contact have a different look and feel to it. Each communication differs from the previous one and conveys a sense of appropriate renewal of an effort to communicate.

Implementation (page 156)

Each of the following elements should not be thought of as self-standing, but as a part of an overall implementation system for which a change in one part is likely to have unintended consequences for another.

1. *First Contact: Pre-notice Letter*
    - The purpose is to provide a positive and timely notice that the recipient will be receiving a request to help with an important study or survey.
    - Brief, personalized, positively worded, and aimed at building anticipation rather than providing the details or conditions for participation.
    - Sent days or up to 1 week ahead of the actual questionnaire.

- Research has shown that a pre-notice letter will improve response rates.
- In this step use a letter rather than postcard. (20secs memory) (Letter takes longer to open).
- **The Goal** is to convey the idea that something important is about to be sent to the person to whom the letter is addressed.
- Use AMHB stationary.

2. *Second Contact: Questionnaire Mail-out*
   - Sent a few days to a week after the pre-notice.
   - Place information exactly where it is to be used.
   - The mailing contains several elements:
     1. A cover letter
     2. The questionnaire
     3. Any token of appreciation
     4. Return envelope

3. *Third Contact: The Postcard Thank you/Reminder*
   - The postcard follow-up is written not to overcome resistance but rather to jog memories and rearrange priorities.
   - It should arrive just after the original mailing has produced its major effect, but before each person's questionnaire has had time to be buried under more recent mail or thrown away.
   - One week is an appropriate interval of time for making an appeal that if carefully worked conveys a sense of importance.
   - The choice of a postcard format over a letter is deliberate.
   - It should contrast with the pre-notice letter, given that repeated stimuli have less effect than new ones.
   - The function of the postcard is simply to jog one's memory.
   - The precise wording of the card reflects still another concern.
   - The first lives simply state that a questionnaire was sent to the respondent the previous week and why.
   - The second paragraph contains the crucial message that the postcard is designed to convey.
   - People who have already returned their questionnaires are thanked and those who have not are asked to do so "today" a time reference consistent with the importance one wants to convey.
   - Another sentence follows that amplifies the message of how important each recipient is to the success of the study as described in the initial cover letter.
   - The third and final paragraph is an invitation to call for a replacement questionnaire if one is needed.

4. *Fourth Contact: The First Replacement Questionnaire*
    - There is a marked difference between the content of the fourth contact and the three that preceded it
    - This letter has a tome of insistence that the previous contacts lack.
    - Its strongest aspect is the first paragraph, in which recipients are told that their completed questionnaire has not yet been received.
    - This message is one of the strongest forms of personalization, communicating to respondents that they are indeed receiving individual attention.
    - Most of this letter is devoted to a restatement of each respondent's importance to the study in terms quite different form those used in previous mailings.
    - It conveys to the recipient as a means of encouraging response that others have responded.
    - This step needs to show a greater intensity than preceding letters, but not be so strong that potential respondents become disgruntled.

5. *The Invoking of Special Procedures*
    - This request, the final effort to elicit a response, exhibits a greater overall intensity than any of those that preceded it.
    - The wording is somewhat softer than that of the preceding one.
    - The now familiar messages of social usefulness and individual importance are repeated once more, but in words different form any used previously.
    - The important way in which this contact differs from those that precede it is in the packaging and delivery of the request.
    - If one is considering simply sending a third copy of the questionnaire using the same type of envelope and another letter on the same stationery, it is hard to make this stimulus appear different form the second and fourth mailings.
    - The delivery of this final contact differs from all previous contacts because of the packaging, the mode of delivery and the speed by which it is delivered, all of which may be made noticeable before the letter is even opened.
    - The effect being sought is to increase the perception of importance as a legitimate request.

APPENDIX E: THE NEW ZEALAND REB PROCESS – OVERVIEW OF A POPULIST APPROACH TO REVIEW

The New Zealand system of REB review should be considered a potential benchmark for countries struggling with the issue of which projects to submit to REB review and how each project should be approached. A review of documents, websites and an interview with a former New Zealand REB chairperson demonstrates that the New Zealand system of oversight has been designed to be inclusive of the entire community, including minority groups, such as the indigenous peoples of New Zealand. The issue of “what is research” is less pressing here because all community members are invited to seek the advice of the ethics committee that operates in their area. The approach to ethics and the governance system appear to be synchronized with policies and procedures in a manner that suggests thoughtful consideration to maximum flexibility and openness of the oversight system while ensuring public discussion and awareness of high and low risk projects. Composition and membership of the committees are spelled out in the Operational Standard and are quite different from similar standards in North American. For example each REB committee should meet the following standards:

1. Committee should have a balance of experience, knowledge and perspectives;
2. Attention should be paid to cultural diversity, gender balance, and inclusion of people with disabilities;

3. The minimum number of people on a committee should be 10, including a ***lay*** chairperson;
4. 50% of the total membership should be lay members;
5. The committee membership should include expertise and knowledge of both qualitative and quantitative research;
6. One member must be a lawyer;
7. One member must have expertise in ethics;
8. The committee must include individuals possessing a knowledge and understanding of consumer and community issues and perspectives;
9. All committees must have at least two Maori members;
10. Members should possess an attitude that is accepting of the value of other professions and community perspectives.

It is the responsibility of the committee to *assist applicants in achieving a successful review*. Consequently, they take an educational stance in carrying out their work. All members are appointed for 3 years and undergo extensive training in ethical review within 6 months of their appointment. Committees meet on a monthly basis and the meetings are open to the public. Decision making is by consensus. Records of all proposals submitted are kept for a minimum of 10 years and the committee is required to submit an annual report that details the protocols they have reviewed in the past year and all such reports are made public. When research is abandoned or completed, the researchers are required to report to the approving committee and, again, the results of the research, even if the result was to abandon the study, are made public.

The issues of legitimacy, authority, and the issue of who possesses the power to publish and promote has been clearly answered in New Zealand: the authority for making such determinations lies in the hands of the community. There are several characteristics of the New Zealand system of protocol review, that may address critical questions identified in the literature as being important to HHSOs and perhaps also to traditional research settings.

From an organizational perspective, the Ministry of Health of New Zealand is responsible for the ethics committees that operate in New Zealand via the National Ethics Committee. The National Ethics Committee is directly accountable to the Minister of Health and has issued an Operational Standard for Ethics Committees (New Zealand Ministry of Health, 2002) which applies to all ethics committees, “that review the ethics of research and innovative practice and provide advise on issues relating to the delivery of health and disability services” (p.1). The Ministry of Health recognizes that ethical review cannot be mandated via a document. In fact the Operational Standard states, “The application and weighting given to each of the guiding principles are not absolute and will vary depending on the nature of the research or innovative practice”. Good ethical reasoning requires thought, insight and sensitivity to the context of each proposal. The Operational Standards that guide New Zealand REBs appear to allow flexibility and a high level of consistency in ethical review throughout the country due to the common training received by members and the accreditation process each board participates in.

A brief listing of some of the more important features of the New Zealand system follows. This should not be considered exhaustive, but rather a summary of the characteristics of oversight that are unique to North American REB systems and relevant to the dissertation topic. For a full understanding of the New Zealand system of oversight, please see the 2002 Operational Standards for Ethics Committees and the related documents referred to within the Standards. With regard to the current topic, the most important unique characteristics of the New Zealand system are:

1. The New Zealand system does not focus on the issue of research vs. non-research. Rather the system has integrated other relevant documents into the oversight system by indicating that any or all of the following source documents may indicate that a project requires ethical review. These include:
    i. The Code of Health and Disability Services Consumer Rights;
    ii. Internationally recognized conventions and statements (such as the Declaration of Helsinki);
    iii. Professional codes of conduct and registration requirements of health and disability professional bodies;
    iv. The approval requirements of research funding organizations;
    v. Requirements in the Health Research Council Act 1990 regarding ethical review of health research applications for funding grants from the Health Research Council;
    vi. The Injury, Prevention, Rehabilitation and Compensation Act 2001;

   vii. The Health Information Privacy Code 1994;
   viii. The requirements of a researcher's employer;
   ix. Purchase agreements with health and disability providers;
   x. The requirements of peer-reviewed publishers of research reports.

2. Some projects do not require review. The Operational Standard is clear on this point. The section that deals with exempt projects is quite specific, and is apparently based on an assessment of risk to the individual or community (p. 26). However, community members are invited to ask their ethics committee for advice on any project and any issue, including whether the study in question should be submitted for ethical review.
3. The Minister of Health is directly responsible for all ethics committees.
4. All ethics committees reviewing health and disability research in New Zealand are encouraged to be approved (accredited) to the requirements of the Operational Standard, and there are substantial incentives via liability insurance to do so.
5. The Operational Standards have been developed specifically to be in harmony with both internationally recognized guidelines for ethics such as the Declaration of Helsinki and the guidelines set forth for ethical behavior by professional associations.
6. All applications to ethics committees must be made on a single form…the National Application form.
7. In the case of multi-centre studies, a single Principal Investigator is selected by the research group. The ethics committee functioning in the

area in which the Principal Investigator works is considered the primary ethics committee. This is the committee that makes the final decision regarding whether the research may proceed in ***all*** jurisdictions applied for. It is the responsibility of the primary ethics committee to seek out the advice of all secondary ethics committees, and to incorporate the results of such consultation into a succinct report back to the Principal Investigator. If this policy works well in practice it should save considerably on resources and speed the approval process.

8. Relevant legal provisions have been made to support the operation of ethics committees.

The New Zealand system directly addresses the issue of liability arising from injury that results from participating in research. If medical treatment is part of the research (i.e. if a clinical trial of a new medicine is the focus of the research), the individual participant may be compensated under section 32 of the Injury Prevention, Rehabilitation and Compensation Act 2001, as long as the ethics committee is approved by the Director-General of Health or the Health Research Council, and the individual providing the medical treatment is a registered health practitioner (New Zealand Ministry of Health, 2002). Liability for student research is covered by the individual educational institutions when the potential harm of the research is considered to be minimal. In those cases where student research is considered to pose a risk of harm more than that which might be experienced in everyday life, the student's proposal goes through the same level of review as any other research proposal.

Also noticeable throughout the New Zealand system is an underlying emphasis that research, research ethics and the results of research belong in the community where the research takes place. The philosophy appears to be one of openness, helpfulness and inclusiveness.

In summary, the New Zealand system takes a pluralistic perspective on "truth" and purposefully incorporates indigenous knowledge and community values into deliberating and determining what matters with regard to creating new knowledge while protecting participants. Rather than placing "science" or "research" at the top of the values pyramid and then comparing all other perspectives to this standard, the New Zealand system appears to place equal value on the varied views of their multicultural population. Consequently, the question facing New Zealand REBs is not "what is research", but rather "what is worth knowing." As a result, the pursuit of truth, "is never under the sole proprietorship of any single domain of knowledge – not even science" (Cobern & Loving, 2001). This is an important consideration, particularly given the seriousness of the decisions that must soon be made in a number of critical areas such the, "emerging issues of the human genome, cloning and stem-cell research, privacy of medical records, reproductive technologies, bioengineered foods and professional relations with the pharmaceutical industry" (Borsellino, 2002). Many of these areas could fit neatly into the "natural science" pinnacle described by Corbern & Loving, (Cobern & Loving, 2001) and which is so intimately linked with experimental biomedical research that was the intended purview of the Nuremberg Code. Consequently, these are the types of studies that would likely come under REB review as it currently exists in the western world. The current REB process clearly leaves these critical decisions in the hands of scientists rather than in the communities where the impact of the research carried out and decisions made will clearly be felt. This is not to say that one system is better than the other, only that there is much to be learned from both with a view to ensuring that good decisions are made with regard to resources, protecting human participants and allowing community and professional voices to be heard.

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