

Special theme: ACCREDITATION, GOOD GOVERNANCE AND BEST PRACTICES

EDITORIAL by Glenn Griener, President of NCEHR

As the winter ends, the Council will be receiving the final report of the Task Force for the Development of an Accreditation System for Human Research Protections Program. This marks an important milestone in research ethics in Canada, and also a turning point in NCEHR's involvement. Over the past few years NCEHR has been an important catalyst for national discussions of accreditation, supporting two task forces. The work will now be carried forward by a Sponsors' Table composed of the principal stakeholders, including representatives from the federal and provincial governments, universities, research funding agencies and professional organisations. The valuable work done by the volunteers on NCEHR's Task Force will now inform the deliberations of an experts committee to be created and supported by the Sponsors' Table.

One important message NCEHR heard in public responses to the accreditation initiatives is that the research ethics community in Canada values the work we do in education, through the National Conference and educational site visits, and in the careful analysis of emerging ethical issues. With decision-making about accredi-

tation in others' hands, NCEHR can now reinvigorate our activities in these core areas.

February witnessed another highly successful National Conference. Kirsten Bauer movingly reminded conference participants of the human tragedies that can occur when the human research protections programs are inadequate to their task. (See below.)

Several presentations focused on recent developments in the international arena. One highlight was the presentation by Dr. Didier Sicard, President of France's *Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé*, on the European framework. Another was Michèle Jean's discussion of the UNESCO Universal Declaration on Bioethics and Human Rights.

National Conference was also an opportunity to hear about ongoing developments in the Canadian research ethics environment and about emerging ethical challenges.

Community-based research is increasingly common in Canada. In some instances the research is conducted as a partnership between university and community. This poses some distinct

challenges to the standard operating practices of university-based REBs. Community-based research involving children and adolescents raises complex issues of consent and confidentiality. (See Elizabeth Banister, et al. below.) When all members of the research team come from the community they may have great difficulty finding a REB able and willing to take on the responsibility for ethical review. NCEHR is currently planning to address this emerging area of concern through an initiative which would bring together existing community-based REBs and draw on their diverse expertise and experience to develop practical guidance.

NCEHR is continuously incorporating the insights from such advances as CIHR's privacy best practices and the evolving guidelines for research involving of Aboriginal communities into the education and training programs we offer.

This is an extremely busy time for research ethics in this country. NCEHR will continue its valued contributions to the development of field.

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List of Invited Organizations

Association of Canadian Medical Colleges (ACMC)
Association of Universities and Colleges of Canada (AUCC)
Canadian Association of Research Ethics Boards (CAREB)
Canadian Association of University Teachers (CAUT)
Canadian Council on Animal Care (CCAC)
Canadian Federation of Humanities and Social Sciences (CFHSS)
Canadian Institutes of Health Research (CIHR)
Health Canada (HC)
Interagency Advisory Panel on Research Ethics (IAPRE)
Office for Human Research Protections (OHRP)
The Royal College of Physicians and Surgeons of Canada (RCPSC)



**National
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national
d'éthique
en recherche
chez l'humain**

NCEHR

240 Catherine Street
Suite 208

Ottawa, ON K2P 2G8

Tel.: (613) 233-5445

Fax: (613) 2330658

Website: www.ncehr-cnerh.org

E-mail: office@ncehr-cnerh.org

Richard Carpentier, Ph.D.

Executive Director
rcarpentier@ncehr-cnerh.org

Christine MacRae

Office Coordinator/
Administration, Meetings & Events
cmacrae@ncehr-cnerh.org

Felicetta Celenza

Coordinator of Educational Visits
fcelenza@ncehr-cnerh.org

Chloe Bouza

Office Assistant
cbouza@ncehr-cnerh.org



A Message From Our Guest Editor

Accreditation, Good Governance and Best Practices

by Deborah Poff

As many readers will be aware and as noted in the message from our President on the first page of this newsletter, the NCEHR board will soon be receiving the final report of the Task Force for the Development of an Accreditation System for Human Research Protections Program. Given the priority of this report for NCEHR, the Communications committee of the board decided on the timely theme of “Accreditation, Good Governance and Best Practices” for this issue of Communiqué. This issue begins with an article by Henry Dinsdale which is a guide for those unfamiliar to accreditation in terms of its meaning and purpose. This is followed by a very personal view on why NCEHR took a leadership role in the Task force on Accreditation by one of the co-chairs of the taskforce, Dr. K. Davey. This is followed by an article from an expert in quality assurance in the private sector on the positive relationship between accreditation and total quality management.

Not all researchers agree that accreditation is necessarily a good fit for their type of research and consequently in this issue, we have tried to include different perspectives on issues of best practices and good governance. In an article by Mary Blackstone, she addresses the issue of best practices from the perspective of artists and their research participants. In this article, the author gives a brief history of the unique status and perhaps the unique issues with respect to at least some elements in the arts. Blackstone notes that research ethics boards “need to be open to legitimate and established discipline-specific distinctions between the nature of research and the researcher/research participant relationship in the Fine Arts and the medical sciences...[while]...artist-researchers need to embrace more broadly an emerging area of research concerning ethical practices...”

In another article, Nancy Janovicek argues that oral historians have unique moral issues not addressed by the Tri-council Policy Statement (TCPS) which she states is “based on the medical model”. In terms of best practices, Janovicek argues that “oral historians have developed practices that reduce harm for research participants”.

This issue also includes articles by two graduate students. Doctoral candidate, Joanna Kafarowski, speaks of the complexity of aboriginal and gender issues in her piece entitled, “The women/gender questions: Best practices of conducting research with Indigenous peoples in Canada.” Her work is informed by her own doctoral research with Inuit women. Master’s student, Jeremy Shragge addresses the issue of accreditation directly from the perspective of a graduate student and ponders the issue that

[a]ny Canadian system of PEERH accreditation must consider the advisability of a situation in which graduate students are morally, academically and legally responsible for the safety of their subjects but are inconsistently provided with the tools necessary to ensure that the appropriate safeguards are maintained.

Also, in this issue are two presentations on community-based research and ethical review. Both presentations were made in a panel discussion at this year’s NCEHR conference. In the first, Elizabeth Banister et al speak to the issues of community-based research with children and youth, particularly from the experience in Alberta. Deborah Poff describes the experience of the recently formed research ethics board of the British Columbia Medical Services Foundation.

In another conference presentation, Kristen Bauer spoke eloquently and tragically about her father’s death while he was a participant in a clinical drug trial. Ms. Bauer’s story brings home the personal cost of losing a family member in such a very sad and unexpected way.

Finally, we include a very interesting case vignette by Mark Goldberg on the recruitment of subjects from medical care facilities into observational epidemiological studies.

We hope you find this issue of Communiqué interesting. We want to provide timely and helpful information through our newsletter and would appreciate your feedback.



Accreditation and Research Involving Humans in Canada: Background and Prospects

by Henry B. Dinsdale

Accreditation of institutions responsible for research in humans in Canada was a goal identified by Dr. Pierre Bois, President of the Medical Research Council (MRC) when the National Council on Bioethics in Human Research (NCBHR) was established nearly two decades ago. Since then there has been a major expansion of research in humans involving many disciplines at increasingly diverse locations. Research no longer is conducted at a single institution by a single investigator or small team. Studies now involve scores of research centres and thousands of participants in biomedical, behavioural and social sciences research. Much research has shifted into the community, away from academic centres. Medical and social science research is undertaken by the private sector, NGOs and departments and agencies of government. Guidelines and policies such as the Tri-Council Policy Statement on Research in Humans (TCPS) have attempted to stay abreast of advances in the ethical aspects of research in humans. Yet few substantial changes have been implemented to ensure and evaluate their implementation.

What is accreditation?

Accreditation is a non-governmental, self-assessment and external peer assessment process designed to accurately assess levels of performance in relation to established standards and to implement ways to continuously improve (1)

Accreditation involves peers knowledgeable about research and safeguards for participants. It provides intelligent accountability - an understanding of what *ought* to be done. Other systems based on managerial conceptions centred on controlling performance lead to what has been described as unintelligent accountability (2).

Accreditation standards would be based on government regulations, relevant Canadian guidelines such as the TCPS and applicable international legislation and policies. Accreditation standards set the bar higher than basic regulations. Accreditation is a voluntary process but jurisdictions such as government may require accreditation as evidence of compliance with regulations.

How does legislation, regulations, certification or audit differ from accreditation?

Legislation is the responsibility and instrument of elected representatives to parliament who create laws that reflect the values of the country.

Regulations are the rules or directives made and maintained by an authority. They are a mechanism whereby government bureaucracy implements legislation. Regulations may cite guidelines produced by non-governmental organizations.

Certification is a procedure whereby a disinterested party gives written assurance that a product, process, individual or service conforms to specific requirements. It can testify to the level of achievement of an individual. For example, certification and maintenance of certification of physicians is a process of continuing education providing evidence of personal professional development and enabling the privilege to practice.

An audit is an inspection of an individual's or organization's accounts with a focus on financial management. Auditors are independent of the organizations they audit. Fundamental differences between audit and



accreditation are found in accreditation's involvement of peers and its educational impact. The adaptability and flexibility in creating and incorporating new and evolving accreditation standards are emphasized in the article in this issue by M. Vanderwel (3).

Why do we need accreditation?

Conducting research in humans is a privilege and brings with it responsibilities. A general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects (4). The cornerstone of research is trust between the individual participating in the research and the investigator, university, hospital or private company conducting the research. Accreditation is an important mechanism maintaining that trust (5).

Infrequent but well publicized examples of egregious events continue to occur including non-compliance with research protocols, financial conflicts of interest, inadequate procedures for ethical review and lack of understanding by investigators of ethical requirements related to risks such as breach of confidentiality, invasion of privacy and psychological trauma. Lack of consistency in the application of ethical principles and processes has been encountered in the site visits performed by NCEHR (6). All transgressions, from the obvious to the subtle, weaken public trust in the research enterprise.

Public polls reveal a wish for more oversight, especially of a non-governmental nature, of emerging health technologies (7, 8). The recent report of the Health Council of Canada emphasizes the importance of accreditation (9).

What would be accredited in a program concerned with research in humans?

An accreditation process designed to assess the protection for human participants in research would review the structure of the organization that assumes the responsibility for research. There may be considerable dissimilarities between organizations ranging from universities to biotechnology companies and from institutions reviewing many to those with few protocols.

Elements assessed would include: the process providing the ethical review of research; methods ensuring that all in the research team understood their responsibilities; policies dealing with such issues as institutional conflict of interest, publication and participants injured in research; and mechanisms enabling participants to be active and informed partners in research

How is accreditation conducted?

Accreditation begins with institutional self-assessment followed by on-site evaluation by a team of peers. The site visit team compiles a report with recommendations to the accrediting body. Customary categories are approval of accreditation, provisional approval or denial of approval (or withdrawal). Accreditation is given for a specific time period, e.g. 5 years. Provisional approval may require an interim report and be for a shorter period.

The list of accredited institutions would be available to the public. Institutions are proud to identify themselves when accredited by an established organization.

What are the benefits of accreditation?

The main objective of accreditation is to enhance the protection of participants in research. It helps ensure consistency and sound ethical research across the country with readily-accessible standards

Accrediting organizations influence education in ways unattainable through regulations or audits. Educational benefits of accreditation begin with institutional self assessment, an informative process identifying strengths and weaknesses. The site visit team, comprised of peers brings to the institution and investigators experience and understanding of what is required to meet accreditation standards. Visits are also educational for the site team thereby completing an educational cycle that informs the process of standard development. Individuals with accreditation experience and knowledgeable about standards are important resource members back at their own institution.

Accreditation is more flexible than mandatory government requirements. It adapts more easily to change and sets a higher bar than minimum standards. It provides Canada-wide standards while avoiding federal-provincial jurisdictional problems encountered by government programs. It provides confidence to government concerning compliance with regulations.

An important benefit of accreditation is the understanding and synergy that develops among representatives from diverse research disciplines as they work together developing standards and participating in site visits.

Accreditation provides a component of risk management for investigators, institutions and sponsors of research. Their protection is enhanced as well as that of the participants in research. The benchmark for human research protection will be raised each time an organization is accredited. Researchers will find more consistency in the review process.

By seeking accreditation, an institution signals that it is committed to high, contemporary standards.

Accreditation provides a vehicle for reciprocal recognition and interchange internationally. This will be increasingly important with the rapid increase in multinational based research in humans.

What are the challenges to establishing accreditation in Canada?

A number of factors have delayed the development of accreditation in Canada. Compared to some other countries, examples of serious lapses in the oversight of research in humans in Canada have not resulted in the sanctions and reactions of responsible organizations seen elsewhere. The American Association of Universities and the Association of American Medical Colleges provided leadership establishing AAHRPP whose founding members include the Consortium of Social Science Associations. They recognized that additional public accountability was needed in response to lax supervision and well-publicized egregious events in research with humans (10).

Accreditation should concern itself with all research in humans. Research is increasingly multidisciplinary in nature as exemplified by the four pillars of CIHR. However, differences in opinion about accreditation between the biomedical, behavioural and social sciences have created tensions that have threatened to derail developments. It remains to be seen how they will play out.

. The expenses of accreditation can be met by fee-for-service, government, consortium of stakeholders or a blend of those options. There is concern by some administrators that accreditation only adds financial costs. More importantly, they must also recognize that there are costs of continuing inaction by those responsible for the conduct of research in humans, with or without future egregious events. The major costs will be declining public trust in research and the professions and imposition by government of increased regulatory constraints.

What are the implications for Canada of developments in accreditation in other countries?

In the United States, nearly 80% of medical schools, as well as universities whose portfolios are primarily behavioural and social science, government agencies, clinical research organizations and independent REBs

have earned or begun the accreditation process with Association for the Accreditation of Human Research Protection Programs (AHRPP)(11). Sponsors of research will begin to look for AAHRPP accreditation. In the absence of a Canadian program (which would be based on Canadian regulations and applicable provincial requirements), it is probable that AAHRPP accreditation would be sought by Canadian institutions seeking to have an international presence.

The RESPECT project in Europe, accreditation in the United Kingdom and developments in New Zealand are other examples of international initiatives.

What remains to be done?

The NCEHR report of site visits to Canadian universities to review REB functions that was published in 1995 documented numerous weaknesses and made 20 recommendations for improvement (6). Subsequent NCEHR reports (12, 13) recommended an accreditation program for Canada. Diverse organizations concerned about research in humans in Canada have also recommended the establishment of accreditation including the Standing Committee on Health of the Government of Canada (14), the Canadian Biotechnology Advisory Committee (15) and task forces of the Royal College of Physicians and Surgeons of Canada (16). Nevertheless, Canada remains without an accreditation program designed to assess the protection of those volunteers who agree to participate in research.

Canada has a tradition of leadership in accreditation in professional programs such as medical specialty training and the protection of animals in research. Those in positions of responsibility should accept no less when it comes to the protection of human participants in research. It remains to be seen if the required will and commitment can be found in Canada...

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Why Did NCEHR Take the Lead? A personal view

by Ken Davey

In November of 2003, at the final Council meeting of my Presidency, I introduced the motion that led to the formation of the Task Force for the Development of an Accreditation System for Human Research Protection Programs, the final report of which will be issued early in April. This was an entirely personal initiative, arising from my own sense of frustration at the difficulties that I, together with many others, saw within the system and the stagnation characterizing attempts to ease those difficulties. I am not an expert in the field, but I have been an interested observer. My knowledge came from several site visits to a variety of organisations (universities of various sizes, with and without medical schools, community hospitals), from listening at workshops and national conferences and from many conversations with researchers, participants, REB members and administrators. There was much talk of governance (an over-worked and poorly understood term), but little action. Health Canada had established a Working Group, and there had been some fairly wide consultations, but little in the way of concrete action or proposals had resulted.

What were the difficulties that I saw, and why did I think that a system of accreditation would help? First, my personal experience on site visits demonstrated that none of the organisations was in compliance with the established policies such as TCPS. This is not to say that this left participants or research subjects in peril, because most REBs were generally doing a good job. Second, the system as a whole was very seriously under-funded and under-resourced by the organisations conducting the research. This problem has been partially eased recently at many universities by the funds made available through the infrastructure overheads program, but it has not in my view been solved. Third, in many organisations, the relationship between the REB and many of the researchers was at best fragile, usually traceable to a well-intentioned rigid over-interpretation of the guidelines. Fourth, researchers engaged in collaborative enterprises with colleagues at other institutions were frustrated by apparently differing requirements, and a lack of trust among institutions, that required full review by a number of REBs.

An observant person would conclude that education was the key to easing these difficulties. NCEHR and others had urged for some time the development of a national consensus on education, but that proposal had failed to attract any funding. Accreditation is fundamentally an educational process in which the national consensus is expressed in the development of standards. Accreditation has the added attraction of public validation of an organisation's Program of Ensuring Ethical Research with Humans, but at its core is education for all involved.

Will accreditation solve all of the system's problems? Probably not. I am convinced, however, that it will be a good start that will lead to improvements. It is this conviction that led me to make the proposal in 2003, that led NCEHR, with its expertise in, and history of commitment to, education to endorse the motion and establish the task Force, and that led the Task Force to do the work that underlies the report.



Accreditation: The Application of Quality Principles to the Protection of Human Research Subjects

by Marianne Vanderwel, M. Eng., M.Sc.

Introduction

The issuance of the Nuremburg Code (1) and subsequently the Declaration of Helsinki (2) brought about the routine implementation of informed consent and independent ethics review processes for research involving humans. While there has been improved understanding of the ethical considerations associated with consent or ethical review, until recently, there has been little innovation in developing additional protections for human research subjects. In the past decade, the implementation of accreditation of organizations conducting research involving humans (which may include a variety of entities, ranging from academic institutions, community hospitals to private practice clinics) has shown real potential to significantly improve the protections for subjects. An accreditation system for organizations that have human research protection programs (HRPPs) was put in place by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in the United States in 2001. To date, 33 organizations representing a total of 97 entities have been accredited while over 200 organizations are working toward achieving accreditation. In Canada, discussions with a variety of interested stakeholders is continuing and the National Council on Ethics in Human Research (NCEHR) has led the way by establishing a taskforce to evaluate how a system of accreditation of organizations that have programs for ensuring the ethical conduct of research in humans (PEERH) might be established.

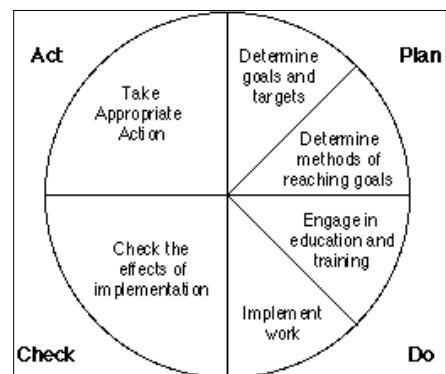
As a quality assurance professional, it was immediately evident to me that the accreditation process (as implemented in the United States by the AAHRPP or as envisioned by the NCEHR taskforce) is a direct application of quality principles to the area of protection of human research subjects. An organization that is successful in gaining accreditation status is one that has firmly embraced a total quality management (TQM) approach for protecting its research subjects. In this article, we will compare the accreditation process and the implications for organizations seeking accreditation with some aspects of the quality philosophies of several experts in TQM, W. Edwards Deming, Kaoru Ishikawa, and Philip B. Crosby. We will examine the three components of the TQM definition, namely, long-term success, company-wide participation and customer satisfaction, in the context of accreditation of HRPPs or PEERH. Ultimately, we will see that the benefits of accreditation are consistent with the benefits of a TQM approach.

Total Quality Management Definition

TQM is a management approach centered on quality, based on **company-wide participation**, and aimed at **long-term success** through **customer satisfaction**.

Long-term success – continuous improvement

Long-term success in the TQM definition means that the management of an organization must be committed to the continuous improvement of its processes and ultimately in the products and services that it provides. The Plan/Do/Check/Act (PDCA) Cycle was popularized in Japan in the 1950s by W. Edwards Deming and later expanded by Kaoru Ishikawa (4). The PDCA Cycle, shown in Figure 2 (5), is consistent with the process that an organization must follow to achieve accreditation and to remain accredited. It teaches organizations to think in terms of cycles or continuous quality improvement. First, the organization must make a decision to seek accreditation and identify how to go about getting there. In the planning phase, the organization should review the accreditation standards carefully to identify any gaps in its processes and make a plan to address these gaps. In the second step, the organization should implement its plan. Since this may involve the development of policies or procedures,



the organization should be realistic about the time needed to complete this step as well as the potential human or other resources that may be required in training all relevant personnel and implementing new work processes. When the organization submits its application for accreditation, it signals that it is ready for the third step – an independent evaluation of the organization which includes a site visit by knowledgeable peer reviewers to assess its systems against the standards. The fourth step is when the organization acts on what has been learned during the evaluation and implements any corrective actions that may have been identified during the site visit. This is not the final step since accreditation is granted for a specified term (e.g., three to five years) and the whole process must be repeated in order to maintain accreditation status.

Company-wide participation starts with management commitment

Another quality guru whose ideas are relevant to TQM is Philip B. Crosby, who coined the phrase “do it right the first time”. Crosby believes that management should take prime responsibility for quality and developed the four “absolutes of quality management” (6). In the first absolute, Crosby defines quality as conformance to requirements. It is the credibility and acceptance of accreditation standards at a national level that is the key to the senior management of organizations embracing the standards as the definitive norm for conducting research in humans. It is crucial that management endorse the standards, lead by example, and encourage all employees to adhere to them.

The Four Absolutes of Quality Management

1. Quality is **conformance** to requirements
2. Quality **prevention** is preferable to quality inspection
3. **Zero defects** is the quality performance standard
4. Quality is measured in **monetary** terms – the price of non-conformance

Prevention of errors means that all personnel involved in research must be appropriately trained in research ethics and understand the need to make the safety and well-being of human subjects a primary goal. For this reason, the HRPP or PEERH must include researchers, their staff, members and staff associated with the Institutional Review Board or Research Ethics Board as well as other personnel associated with the conduct and administration of research involving humans and their interactions with external parties, such as funders or sponsors, regulators, and the public. While accreditation standards must be flexible in order to be meaningful for all sizes of organizations and depend on the volume and nature of the research conducted at the organization, management must firmly embrace the standards and not propagate a feeling of “that’s close enough”. The accreditation site visit is done by knowledgeable peer reviewers who use an educational approach to encourage organizations to stretch their sights (or raise the bar) rather than merely complying with minimal requirements. Unlike audits or inspections, which verify the quality of specific research studies, accreditation takes a systems approach to ensure that processes are in place to prevent non-compliance and promote quality research.

In addition to the intangible costs to the reputation of the organization or the esteem of the researchers, it is possible to also think in terms of the monetary aspects of the price of quality. There are costs associated with prevention such as the cost of training personnel, developing policies and procedures, implementing an internal quality review process. These are balanced by the costs associated with a failed system which may include costs associated with conducting inconclusive, poorly designed research costs and the subsequent need to repeating research. In extreme cases, the cost of failure will include costs associated with the lack of research funding, litigation costs, penalties, and regulatory actions.

Customer Satisfaction – the benefits of accreditation

This brings me to the third part of the TQM definition, customer satisfaction. Who really are the customers for human research and how does an accreditation system benefit them?

- The employees of an organization that achieves accreditation will have a sense of satisfaction in doing a good job and a greater pride in the services provided.
- Various groups within the organization will be able to communicate more effectively by speaking the same language and following processes that make sense.
- Peer reviewers will learn from their experiences at a variety of institutions and be able to share positive practices during site visits and within their own organization.



- Funders or sponsors of research will have confidence that the organizations that they fund will meet the highest standards for the protection of research subjects.
- Subjects who participate in research will benefit by having a sense of satisfaction at being able to advance society's knowledge, while having greater confidence that their rights and safety are protected.
- Credibility of research outcomes will be enhanced, to the benefit of the academic community.
- Conducting effective clinical trials should impact clinical equipoise, hence improving medical practice.
- The public will benefit from access to new knowledge or new treatments as well as by being assured that adequate safeguards are in place should they choose to participate in research.

In summary, accreditation of organizations that conduct human research will ensure that they develop their management teams, researchers and staff, processes, and partners to better protect the rights and well-being of the subjects who participate in research, improve research outcomes, and reduce the non-valued expense of error and waste. Implementation of an accreditation system may significantly improve the trust that the public has in research by providing a transparent approach to the assessment of organizations that are involved in research in humans.

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Power Dynamics and Ethical Practices Governing Artists and their Research Participants

by Mary A. Blackstone

A concern with best practices in research involving human subjects is fundamentally a concern with the power dynamics of a human relationship encompassing the researcher and "the researched." Consequently, an understanding of such issues as they relate to researchers within the Fine and performing arts begins with recognition of the historical and current, perceived and actual, position of the artist within the power structure.

A common conception of the artist relative to society is that promoted in numerous 19th century works of art such as Giacomo Puccini's *La Boheme* and the novel from which it was derived, Henry Murger's *La vie de Boheme*. The starving artists cultivate a life outside the dominant culture. From that marginalized position, they can watch and comment on society although they ultimately succumb as victims. This characterization of the artist continues in postmodern culture as in the film *Moulin Rouge* where the relationship between the writer and the prostitute reminds us of the close association artists have traditionally had with the lowest echelons of society, who have also been the subjects of their work. Particularly with his backstage scenes featuring ballerinas, Edgar Degas further underscores the artist's voyeuristic position while simultaneously



highlighting the position of the performer as one who is formally separated from society on a stage which also sets them up as objects of voyeurism.

One of the reasons why the late 19th century dramatic work of Alfred Jarry was greeted with riots was that he consciously merged his fictional character Ubu Roi with his own publicly presented persona to represent the anti-artist in his own everyday life. An arbitrary, violent despot whose sole motivation is to seize and maintain power, Ubu's bourgeois greed leads him as king to invent a 'debraining machine' which will kill all of his subjects. This character paved the way for the evolution of the Theatre of Cruelty and related developments in other art forms during the 20th century in which some artists began to assert a degree of power from their marginal position to 'hold the audience's feet to the fire'—to literally reach out beyond the 'fourth wall' and break the division imposed by the stage in an effort to force the audience to experience painful, unpleasant, disruptive realities and thereby share the insights—if not occupy the position—of the marginalized artist. The tendency of postmodern theorists to see the margins as a position of strength and insights has to some degree perpetuated the conception of the artist as "other" and outside the dominant discourse. At the same time "breaking the fourth wall" in postmodern art practice has achieved a highly reflexive level such that it is common, particularly through the incorporation of new media and technology, for the audience and its response to become the overt subject and a key element in the work of art itself.

This highly simplified distillation of the perceived evolution and status of the modern artist relative to the dynamics of power helps us to understand some of the tensions surrounding the development of ethical principles governing the work of artists as well as the ethical complexities involved in the artist-subject relationship. A search for the word "ethics" on the websites for Canada's major research funding agencies yields numerous "hits": SSHRC (93), NSERC (121), CIHR (5969) and NRC (319).¹ A similar search on the Canada Council website yields 2 items—a 2004 conference in Montreal on aesthetics and ethics in community arts projects and an award-winning work of non-fiction concerned with an area of ethics unrelated to the Arts.² Similarly, a search on the Universities Art Association of Canada website yields no hits, at least on those pages publicly available, whereas a search on the Canadian Psychological Association website yields 174 hits many relating to the Canadian Code of Ethics for Psychologists.³ A simple quantitative survey of websites can certainly not be taken as a measure of the relative concern or care invested in ethical practices by professionals connected with these sites, but it does give us a sense of the extent to which ethics figures in the public face presented by each of these organizations. The website for the College Art Association in the United States provides further insight as to how many artists position themselves relative to ethics. This search brings up 52 hits many of which lead to codes of ethics for members of their constituency—eg. art historians, museum professionals and artists. The Code of Ethics delineating professional practices for artists, however, concerns itself almost exclusively with the protection of the artist: a responsibility for attention to factors affecting the artist's health and safety; a responsibility for organizations like universities and galleries to assure appropriate liability coverage; protocols for contracts involving galleries, public commissions, etc; assertions of the right of artists to place a notice of copyright on their work and cross listings to copyright laws and other laws governing the artists' control of their work.⁴

In a discipline where historically the role of the nude model continues to have a place of importance in both the training and practice of artists, the lack of attention to the artist's relationship with the human subject in such a code would seem to be surprising—perhaps all the more so because individual artists and institutions—particularly within the context of university art classes—have developed ethically informed, practical approaches to the use nude models. I would argue, however, that the orientation of the College Art Association Code of Ethics and the general absence of procedures to address the power dynamics involved in the relationship between artist and subject derives in part from the fact that artists have traditionally focused on their own social, economic, and political vulnerability. In positioning themselves as "others" on the margins of power, they have tended to see themselves as being acted upon, as opposed to participating in a Foucault-like network in which they are "simultaneously undergoing and exercising this power." (Foucault, 1980, p. 98).

The reality is that many Canadian artists, and particularly university-based artists (who have grown from small numbers in the 1950s to significant numbers within academe and considerable prominence within the Canadian arts community) operate very much within extensions of dominant power structures: eg. educational institutions; federal and provincial funding agencies; regional theatres; orchestras; art galleries;



national dance companies; cultural industries such as media production companies, film and television companies, sound recording studios and publishers; and wealthy public, corporate or private patrons. Of course, the artist's relationship to many of these organizations and individuals has tended to be comparatively dependent, but because of their relatively high salary and the practice of tenure, university-based artists, in particular, have enjoyed more independence and security than many in pursuing their art practice. Even in the academy, though, it has taken some time for the work of university-based artists to be seen as research within their institutions' core mandates of teaching and research. Until recently, though, the lack of significant federal research funding programs to which artists could apply has, in fact, limited the kind of work they could do and left them dependent on collaboration as poor cousins with researchers in the sciences or humanities, who could take the lead in securing major funding.

When SSHRC introduced its Research/Creation Grants in Fine Arts in 2003, however, artist-researchers in postsecondary institutions were recognized as being genuinely part of the research fabric of the country, as having a potentially transformative impact on the nature of that research and as playing an especially central role in humanities and interdisciplinary research.⁵ The facts that these arts disciplines routinely disseminated their research to a broad cross-section of the public in live or mediated formats and that the performative and representational nature of the completed work involved large numbers of human participants as objects and/or subjects of the research were assets from SSHRC's perspective. At the same time, though, SSHRC's recognition and funding of these practices raised artist-researchers above the radar screen of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, which had been in place since 1998.⁶ This group of researchers who had historically positioned themselves on the margins of power with few publicly articulated guidelines for interaction with human subjects were set on a collision course with REBs charged with the implementation of a policy statement which has been recognized as being dominated by the long established and well-documented area of medical ethics.⁷

An initial response by artist-researchers, at least within my own institution, was to invoke the position of outsider and demand exemption from TCPS review like that given journalism. More recently, though, a strong consensus to the contrary emerged at a discussion of ethics policies and the artist-researcher at the October 2005 meeting of the Canadian Association of Fine Arts Deans. The battle for the inclusion of the artist as a researcher and central to research mandates at the level of postsecondary institutions and national funding agencies had taken too long and been too hard fought to now argue for exclusion. Additionally several Faculties of Fine Arts or other related colleges or faculties had begun to establish their own REBs. The centrality of human participants in much of arts-based research is undeniable when one considers examples such as human models, candid photography or film shoots involving not only performers but also unsuspecting individuals, electronic recordings of audience members and gallery visitors,⁸ creative writing based on the life stories of living people (sometimes performed by those very people), the invitation of spectators to physically participate in dance or theatre performances, or the application of Stanislavsky Method by a stage director in rehearsal to encourage individual actors to make personal biographical and psychological material available in the collective development of dramatic characters.

Especially with few guidelines specific to arts disciplines to draw from, the challenge here is to determine exactly who is a human subject or research participant under the guidelines of the TCPS. The arts clearly involve a much broader and very different range of human participants than the more traditional research disciplines which influenced the development of those guidelines. The risks to human participants posed by most research engaged in by university-based artists are likely to be minimal, but clearly they do exist. Speaking from the perspective of a friend of a creative writer who suddenly and unexpectedly found herself and personal incidents in which she was involved depicted with less creative disguise than she would have liked in a widely published novel, I could say that any relationship with an artist may be transformed into a researcher/human subject relationship because artists must draw from the human experiences which feed their work.⁹ Where are the boundaries between artistic freedom, academic freedom and the rights of human subjects? What are the distinctions between artistic and academic freedom? Some artists would argue that the collective benefits of insights to be derived from artistically-based research trump any rights of individual human subjects beyond those stipulated by the law. If so, what are the criteria for evaluating such a case?

The current drift in many postmodern societies towards the dominance of non-verbal images and representations over the printed and spoken word draws our attention to the significance of insights to be



derived by artist-researchers. In a post 9/11 era the orchestration, deconstruction and interpretation of real-life events as if they were artistic constructions or performances makes it clear that the creative and analytical process of the artist offers tactics that have been embraced more broadly though often without accompanying ethical considerations. Film, television and new media have also raised the stakes with respect to the urgency for artist-researchers to take the lead in the development of ethical criteria governing relationships with human subjects and participants. Artists working in these media are no longer on the margins of power, but working at the centre of popular cultural negotiation. Such mediated formats have the potential to give the artist instantaneous, global and indiscriminate impact, but they also increase the potential impact of risk for individuals—and for collective “subjects” or audiences in specific cultures or societies.

The broadening recognition of the potential for artistic practice to make significant research contributions beyond the immediate discipline can be seen in the increasing number of researchers from outside the Fine Arts who are incorporating artistic practice into their research programs. For instance, humanities scholars are putting on plays to study repertory theatre practice in early modern England,¹⁰ anthropologists are undertaking ethnographies of artists’ models (Roe, 1995) and studying the performance of classical music as a form of social action (Ilean, 1999). Researchers concerned with education are using “ethnographic performance texts,” on occasion incorporating research participants to publicly perform themselves (Saldana, 1998; Mienczakowski, 1999; Nicholson, 1999). Health researchers are using “medical narratives” in the form of novels, plays and films to explore sensitive topics such as genetics research (Nisker and Daar, 2005; Young, 2005), while environmental scientists and geographers have released a documentary so controversial that their university sought to block its release (“Controversial Video,” 2005).

In the absence of widely accepted discipline-specific ethical criteria for Fine Arts research involving human subjects, it is understandable that these cross-over researchers have responded variously on ethical matters. Some have assumed that ethical concerns governing more traditional academic approaches need not be applied in non-traditional, “creative” formats such as video. Others have resorted to ethical frameworks with which they are familiar within their home disciplines or have introduced new ethical principles which seem foreign to the world of art and artists. For instance, in considering the absence of clear guidelines governing the treatment of “narrative research participants,” Jeff Nisker and Abdallah Daar observe that because “the public’s understanding of genetic science is derived largely from the media, but also from novels, plays, and films, . . . guidelines, consistent in all media, should be developed for the moral presentation of genetics-based narratives.” Although founded in a legitimate concern for the protection of genetics research participants and their families, the researchers’ insistence on the need for policies to ensure the presentation of such stories “in a balanced manner” (2005, p. 2) would lead many artists to interpret such suggestions as a call for censorship and resist the assumption that all narratives on any topic should have such singular objectives.

This example highlights the need for artist-researchers from the perspective of their particular disciplines to articulate the ethical assumptions governing their art practice, their definition of the human subject or research participant and guidelines governing the power dynamics encompassing the artist researcher and the research participant. A special 2005 issue of *Research in Drama Education* devoted to a consideration of ethical practices governing drama research in community and educational contexts is possibly a model for the type of debate and articulation which needs to take place. For Canadian artist-researchers this is a particularly pressing need given the fact that the TCPS seems to have been conceived without sufficient acknowledgement of artistic practice as research and the circumstances and assumptions governing the researcher and “the researched” in these disciplines. The Interagency Advisory Panel on Research Ethics and its Social Sciences and Humanities Research Ethics Special Working Committee (of which I am a member) are charged with introducing changes to the TCPS and its implementation at the REB level, and a survey of the arts community soon to be released by this Committee will provide an immediate mechanism for providing input towards such changes.

In the interim, REBs need to recognize that the absence of written, discipline-specific ethical codes in the Fine Arts does not mean that there are no traditional ethical practices. If they are to facilitate rather than impede an important field of research, they need to be open to legitimate and established discipline-specific distinctions between the nature of research and the researcher/research participant relationship in the Fine Arts and the medical sciences. REBs established within Faculties of Fine Arts have a particular leadership role to play in



this respect. At the same time, artist-researchers need to embrace more broadly an emerging area of research concerning ethical practices and see it as an opportunity to re-examine traditional assumptions regarding the relative position of artists in networks of power and question the nature of their roles as artists, educators, and researchers in relation to their research participants, their audiences and their communities.

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¹ www.sshrc-crsh.gc.ca, www.nserc.gc.ca, www.cihr-irsc.gc.ca, www.nrc-cnrc.gc.ca

² www.conseildesarts.ca; for a one-page summary of conference proceedings see www.engrenage.ca.

³ www.uaac-aauc.com, www.cpa.ca

⁴ www.collegeart.org/guidelines/

⁵ www.sshrc.ca/web/apply/program_descriptions/fine_arts_e.asp

⁶ It should be noted that neither the SSHRC Research/Creation grant nor the TCPS are applicable simply to artistic practice for art's sake. Just as SSHRC would not fund a scholar who simply proposed to "write a book," so too it would not fund an artist who simply proposed to "paint a picture." SSHRC funds research involving creative practice so that artist-researchers are expected to present a research program based on areas of investigation, hypotheses, research questions and a methodology or approach. They must demonstrate that their research will result in significant intellectual and artistic insights and contribute to the development of their art form. It is only creative practice within such a research framework that currently falls under TCPS review, but the creative practice of most university-based artists tends to exist within such a framework.

⁷ The establishment of the Social Sciences and Humanities Research Ethics Special Working Committee by the Interagency Advisory Panel on Research Ethics was, in fact, a response to this concern. It was further confirmed in the results of a survey conducted by this Committee within the Social Sciences and Humanities disciplines and a report based on the survey which was published by PRE in 2004 under the title of *Giving Voice to the Spectrum*. It is currently available at <http://pre.ethics.gc.ca/english/workgroups/sshwc/reporttopre.cfm>.

⁸ This particular aspect of human subject research in the Fine Arts has already generated queries to PRE regarding its ethical interpretation under the TCPS. See *Interpreting the TCPS* (2004) which was published by PRE. These and other responses to interpretation queries are also available at www.pre.ethics.gc.ca.

⁹ This concern with the definition of "human subject" or "research participant" within the context of arts-based research is one of the most important considerations for ethical review. In artistic practice a paid performer or an audience member would generally not be regarded as "subjects" or "research participants" in the social sciences sense despite the fact that they participate in the realization of a creative project. However, in creative practice and especially within research programs which involve creative practice, the potential fluidity of roles makes it difficult to anticipate and address developments that would be of concern under the current TCPS expectations and procedures governing matters such as consent or privacy. Fine Arts researchers have much in common with colleagues in the humanities and social sciences who are finding these expectations and procedures unworkable or contrary to established practice. As described

in the previous paragraph, in rehearsal, performers can be transformed into “human subjects” and through public performance and audience response, spectators can unexpectedly transform themselves into “research participants.”

¹⁰ This project based at the University of Toronto and connected with the Records of Early English Drama project was recently funded by SSHRC. See www.reed.utoronto.ca/QueensMen/index.html.

Ethics and Oral History

by Nancy Janovicek

Since oral history methodology gained credibility in the 1970s, historians who use oral interviews in their research have been engaged in a lively discussion about ethics. Developing practices that address the power imbalance between the researcher and the informant and that protect the privacy and interests of informants have been key themes in this discussion. Since the adoption of national statements on ethics practice, such as the *Tri-Council Policy Statement: Ethical Statement on Research Involving Humans* (1998) (*TCPS*) and the development of Research Ethics Boards (REBs), historians have been obliged to address ethical concerns that many historians feel do not reflect the moral issues they face in the field. Because the *TCPS* is based on the medical model, many of the practices that REBs prefer do not accord with methods developed by oral historians to ensure that they balance the reputations of their informants with their professional requirements as historians. Moreover, historians are becoming concerned that ethics policy is increasingly becoming an issue of legislative concern.

One of the unfortunate ramifications of the current ethics regime is that rather than talking about serious moral and ethical issues, historians swap strategies to by-pass ethics policies that do not accord with historical methodologies. One creative solution has been the American Historical Association’s argument that oral history should be excluded from federal regulation guiding research with human subjects because oral history does not produce generalizable knowledge. The Canadian Historical Association (CHA) has not pursued this route. It has recently struck an ethics committee to monitor national ethics policies, to develop its own statement on research ethics, and to address new ethical issues as they arise. Key areas of concern for the CHA Ethics Committee are the REBs’ interpretation of the *TCPS* guidelines for privacy and confidentiality, informed consent and minimal risk, and research topics relating to Aboriginal peoples.

Privacy and Confidentiality

National policies and REBs emphasize privacy and confidentiality, arguing that it is the best method to protect the dignity of research participants. The *TCPS* recommends that released data should mask personal information such as culture, age, religion, social status, and educational, medical, or employment histories. This methodology is suitable for qualitative research that seeks out general trends from large data sets, but not for history because the purpose of oral history is to better understand the relationship between culture and individuals. Examining how social background influences personal decisions and choices is important. Concealing the identity of research participants is often undesirable since social historians seek to include the voices of people who have been “hidden from history.” While REBs do allow historians give research participants the option to release their identity, they expect researchers to provide extensive rationale for their decision. Explaining these issues to an REB can be a valuable process because it forces historians, and particularly graduate students, to think through the impact that their research may have on individuals. However, in some institutions this can be a long process since members of REBs are usually trained in other fields and do not understand the nature and purpose of oral history.

Emphasis on privacy and confidentiality raises debates about preserving data and the secondary use of material. National policies recommend that data be stored in locked filing cabinets and destroyed once the project is complete. These requirements are undesirable for oral historians who value historical records and make every effort to protect them. Professional standards also require historians to make oral evidence available for verification. More recently, oral historians have recognized the value of the elements of oral interviews that



cannot be transcribed such as silences and intonations of voice. As new ways of sharing research results that include audio excerpts become more widely available, such as publishing on the web, it will be important to keep tapes. The *TCPS* requires researchers to identify anticipated secondary use of data. Oral historians rarely use all of the information from interviews. They expect that it will be useful to other historians, but cannot anticipate how other researchers will use the data.

Informed Consent and Minimal Risk

Ethics policy has bureaucratized the relationship between oral historians and research participants. REBs require historians to use consent forms that outline the potential for risks and harm associated with the project. Overly cautious REBs tend to equate harm with upsetting research participants, making it difficult for historians to conduct research on sensitive issues. Dealing with consent forms can break down the friendly rapport established prior to the interview. Describing the harms and benefits in the consent form can also be a superficial exercise because historians cannot predict what people will discuss in interviews. REBs often review interview questionnaires to try to determine potential risk, but following a research schedule approved by an REB does not work in the field. Since research participants often raise issues that take the interview in a different direction, oral historians include statements explaining why it is important to be flexible during interviews in their applications for ethics review.

Oral historians have developed practices that reduce harm for research participants. In some cases, historians contact informants after the interview and allow them to review the transcripts to make corrections or to delete portions of the interview. Personal ethics guide decisions about what to publish, and most historians are careful to leave out information that will embarrass people who are not used to being in the public eye. Historians who do not work in institutions that are bound by the *TCPS* should also follow procedures established in ethics policy. The CHA Ethics Committee is currently drafting a statement on ethics policy that will disseminate common values and practices to historians working in academic institutions, museums, governments, and as independent researchers.

Research with Aboriginal Peoples

National ethics statements and REBs recommend that researchers exploring topics relating to Aboriginal peoples work in collaboration with those communities. Working with Aboriginal communities is a sound research practice that enables historians to question the contemporary impact of historical research. National statements on ethics do not problematize “community,” and the expectations of REBs raise important questions for historians. Who speaks for the best interests of the community? Who is excluded from these decisions? Protocols that are currently in place may restrict research on controversial subjects and may limit access to those who are marginalized in Aboriginal communities or who do not have a close connection to their communities.

The guidelines for research with Aboriginal peoples are under revision, and it is crucial that the new policy does not exacerbate tensions within communities. The *TCPS* guides researchers and REBs to determine when an Aboriginal person is speaking as an individual and when they are speaking on behalf of their communities. This policy posits a dichotomous identity for indigenous peoples. It also echoes arguments within Aboriginal communities against pursuing individual rights because they undermine the collective goals of the community. The CHA plans to play a role in the development of guidelines for doing research with Aboriginal peoples in dialogue with the individuals and communities affected by the research, researchers in other disciplines who have established good ethics protocols, and the organizations that are responsible for developing ethics policy.

The ethical practices of oral historians have evolved to address new methodologies and questions. While it is important to develop guidelines for research involving humans, it is as important that policies are amenable to change. We should not accept current ethics policies as the last word on ethics. New ethical dilemmas will arise as historians develop new methodologies and ways of disseminating information. Good ethics policy will anticipate these changes and will foster discussions about these issues.



The women/gender questions: Best practices of conducting research with Indigenous peoples in Canada

by Joanna Kafarowski

Over the last decade, Indigenous communities and national organizations including the Council of Yukon First Nations and the Arctic Athabaskan Council have assumed a leading role in initiating partnerships between the community and the researcher. This is due in part to the evolving politicization of the Indigenous research agenda¹ linked closely in Canada to a menu of contentious issues including land claims and self-government, and rights and access to natural resources (Flaherty, 1995; Association of Canadian Universities for Northern Studies, 1997). The exploitative nature of many studies conducted by Western scientists on Indigenous peoples in the mid to late twentieth century in which the scientist benefited at the expense of the “subject”, heralded alarm both within Indigenous communities and the academy (Association of Canadian Universities for Northern Studies, 1997; Fondahl, 2001; Castellano, 2004). In response, ethical protocols were developed to ensure that future research was relevant to Indigenous needs, local residents were engaged in all stages of the research and that Indigenous communities would be protected from harm (Flaherty, 1995; Weijer *et al.*, 1999). While the establishment of these protocols represents a critical first step in ensuring accountability, at least theoretically, it is questionable whether these guidelines are adequate in addressing issues on an empirical basis, particularly as they relate to sub-sets of the community population, for example, women. Based on the author’s experience in conducting research with Inuit women in Nunavik, Nunavut and the Northwest Territories, this article will investigate to what degree current research practices including ethical guidelines are equally applicable to Indigenous women and men.

Ethical guidelines or protocols have been devised by the Tri-Council and by disciplinary bodies including the Canadian Sociology and Anthropology Association and the Canadian Archaeological Association as well as by Indigenous organizations and communities². While the impetus behind the development of these guidelines is commendable, it is evident that significant shortcomings exist. Many guidelines such as those developed by the Royal Commission on Aboriginal Peoples have been established by external bodies with Indigenous input (the “top-down” approach). These guidelines have been rejected by Martha Flaherty, former President

of Pauktuutit Inuit Women’s Association (1995): “The very name of the Commission provides a hint of where it might locate itself with respect to my assumptions. This is a Commission “on” Aboriginal Peoples, not “for” or “of” them... I do think it is safe to assume that the Commission does not share my assumptions since their own ethical guidelines for research directly challenge them” (p. 3). Additionally, guidelines established by research ethics boards within the academy are usually developed with minimal Indigenous involvement (if at all) and “may not be in the best interests of Aboriginal communities” (Schnarch, 2004, p. 84). Increasingly, Indigenous communities are developing their own ethical guidelines (the “bottom-up” approach) based on OCAP³ principles. These guidelines provide Indigenous communities with greater autonomy over research foci and methodology. However, few guidelines, whether generated by Western-based scientists or Indigenous communities, articulate a clear vision of how gender should be addressed by researchers.

As stated by McPherson *et al.* (2004), there has been a rising interest expressed in conducting research with Indigenous peoples that deals with emerging issues and with working with sectors of the community poorly represented in the literature. “The inclusion of women in research is essential if men and women are equally to benefit from research. It advances both the commitment to justice and to rigorous scholarly or scientific analysis” (Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, 1998). According to the Tri-Council Policy Statement (1998) and Meadows *et al.* (2003), Indigenous women have been both excluded from taking part in research and subsumed into the research population. Accurate data on Indigenous peoples is often difficult to obtain and is rarely disaggregated by gender. According to Kafarowski (p. 201):

“Using disaggregated data means carefully examining data to ensure that analysts and policymakers understand the impact of any measure on various groups. This is particularly critical in the Arctic where the experiences of individuals and the impacts of policies and programs may vary dramatically according to whether one is female or male, old or young, claims kinship to one group or another and lives/works in the northern or southern region of a circumpolar nation”.



Conducting research with Indigenous women and adopting a gender-based analysis means that researchers recognize the differing social roles and responsibilities of women and men, the socio-cultural context in which these roles are constructed and the dynamics of relationships between women and men. However, a flexible definition of gender that is subject to interpretation coupled with a lack of knowledge about how a gendered lens may be applied when carrying out research, results in gender being left out of the equation. As stated, in Canada, some guidelines make a passing nod at gender but this is usually interpreted to mean that women *and* men are included as research participants or as board members advising a project. Rarely is gender explicitly identified as a factor within the research design itself. For example, regarding a wildlife study conducted in Nunavut, Tyrrell writes:

“The preliminary report of the Nunavut Wildlife Harvest Study makes no distinction between male and female hunters and therefore, it is impossible to know whether those reporting char catches are male or female... This lack of information points to a need to collect wildlife harvest data disaggregated by gender, particularly with relation to fish where there are varied perceptions as to which gender is the predominant harvester and in relation to whether harvesting is for commercial or subsistence purposes” (2007, forthcoming).

This failure to grapple with gender may be due to several reasons. Some researchers impose Western-based gender stereotypes onto the community while others, working within narrow disciplinary boundaries, may not deem gender to be of relevance to the study’s outcome as in the above-mentioned example. This results in the conflation of women’s and men’s unique views and the privileging of the male perspective. Situating gender within the appropriate cultural context affects the relevance of the research to the community. Indeed, Gilchrist (1997) contends that the “interpretation of Aboriginal cultural phenomena from a non-Aboriginal worldview produces distorted and incorrect results” (p. 76). As pointed out by Tuhiwai Smith (2001) and others, Indigenous and Western views of gender and the roles of women and men differs dramatically.

“One of the more significant challenges to white feminism has come from women variously described as ‘women of colour’, ‘Third World women’, ‘black women’ and ‘indigenous women’. These groups of women challenged the assumptions of the Western/white women’s movement that all women shared some universal characteristics and suffered from universal oppressions which could be understood and described by a group of predominantly white, Western-trained women academics” (Tuhiwai Smith, p. 166).

Western-based researchers working with Indigenous women must be conscious of their own biases regarding the roles and responsibilities of women and men and declare them openly. A more extensive discussion about what gender means and how gender-based analysis will be integrated into the research design will assist in ensuring that the research will truly be reflective of community needs.

One of the most glaring shortcomings of many ethical guidelines is the failure to recognize the pre-eminent status held by the *community* rather than the *individual* within Indigenous cultures (McPherson *et al.*, 2004). For example, Weijer *et al.* (1999) state: “The Belmont Report⁴ has been criticized for overemphasizing individual rights and failing to take into account important human relationships found in the family and the community” (p. 275). This presents a conundrum. Although research into Indigenous women’s issues is conducted infrequently (compared to men or children), how can studies on women alone that seemingly flout the collective rights of the community be justified? From a Western liberal perspective, these studies can be justified in that work with women addresses a serious gap in Indigenous research. From an Indigenous viewpoint, it is apparent that research that addresses *gender* – focusing on the interconnectedness and dynamic nature of relationships- will be valued more highly than research that examines women or men as *separate* from the whole. As an example, the work of organizations such as Pauktuutit Inuit Women’s Association promote “the betterment of individual, family and community health conditions through advocacy and program action” *as well as* (author’s emphasis) “better social, economic and political conditions for Inuit women” (Pauktuutit Inuit Women’s Association, 2006). Therefore, researchers committed to gender-based analysis are tasked with the dual responsibility of identifying women’s unique needs and contributions *and* linking them to the specific needs and contributions of men, children and elders.

Future research with and among Indigenous peoples in Canada will continue to be directed by Indigenous leaders and academics. In steering the course of scholarly and/or community inquiry, it is hoped that Indigenous leaders will demand increased control over the research agenda and acknowledge gender as a critical variable when developing or revising ethical guidelines. Indigenous communities must assume the lead in defining gender and gender-based analysis within an Indigenous context as well as ensuring that collected data is disaggregated by gender and that the primacy of the community (with all of its components) rather than the individual is respected. While ethical protocols only guide research practices, introducing gender to the dialogue would send a powerful and decisive message to researchers that women play a pivotal role in the complex set of relationships that make up an Indigenous community.

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¹ This term is broadly used to refer to issues of concern to Indigenous peoples but does not imply that the same issues are of importance to all groups or communities.

² For example, see A Participatory Research Process for Dene/Métis Communities: Exploring Community-Based Research Concerns for Aboriginal Northerners Used by Dene and Métis Communities (1993), Tl'azt'en Nation Guidelines for Research in Tl'atz'en Territory (1998 and currently under review) and the Principles and Guidelines for Conducting Research With and/or Among Mi'kmaq People (2000).

³ OCAP refers to the ownership, control, access and possession of the research process or, "self-determination applied to research" as termed by Schnarch (2004). While OCAP is situated within a post-colonialist framework, it does not adopt a gender-based analysis.

⁴ Published by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, The Belmont Report is identified by Weijer *et al.* (1999) as: "the predominant framework for analysing ethical issues in clinical research" (p. 280).



A Graduate Student Perspective on the Accreditation of Programs Ensuring Ethical Research with Humans

by Jeremy E. Shragge

The purpose of this brief report is to provide a graduate student perspective on the accreditation of Programs Ensuring Ethical Research with Humans (PEERH). Several months ago, as the chairman of a national graduate students' representative organisation, I was asked to present such a viewpoint at NCHER's Annual General Meeting in Alymer, Quebec. I was honoured that NCHER felt that my musings were sufficiently meritorious to warrant further exposition.

According to Statistics Canada, in 2003-2004, there were 142,800 graduate students enrolled in Canadian universities. Of these, an unknown minority would have worked on a study that involved human subjects. Even with the latest enrolment figures, as well as the data contained in Statscan's 2005 *Study of Earned Doctorates*, the assumptions that would be required to even hazard a guess are so tenuous as to effectively prohibit such an estimate. My organisation (the Graduate Students' Association of Canada) recently polled a number of Canadian university research ethics boards (REB) to determine, *inter alia*, what proportion of applications were received from graduate students. One administrator averred that answering this question would have been "an impossible feat".

It is probably fair to say that, even for those students who work with human subjects (and in this group I include myself), participant protection is not especially high on the priority list. One reason for this is that the dissemination of basic research ethics principles, let alone their philosophical underpinnings, is generally quite poor in Canadian graduate programmes. When one considers that graduate students compose the vanguard of researchers working with human participants in Canadian universities (with the exception of clinical, medical research), this educational state of affairs represents an impediment to the implementation of optimal ethical standards – which, surely, is meant to be a key outcome of the accreditation process.

It is also a major problem for students insofar as we are generally responsible for the ethical conduct of our work. As the University of Toronto's *Student Guide on Ethical Conduct* states, "It is vital that both parties [students and supervisors] are aware of what these responsibilities entail." Although I believe that most graduate students would gladly accept a leading role in ensuring the protection of their subjects, such an assumption is contingent upon adequate **ethics training**; furthermore, if we are to effectively contribute to the protection of human research participants, an appropriate mechanism must be in place for **dispute resolution** between students and supervisors (e.g., disputes about ethical research design or adverse event reporting). I shall discuss both these – what I believe are *sine qua non* of PEERH accreditation – in turn.

For students who undertake research projects involving humans, the opportunities to become sufficiently knowledgeable on how to sufficiently protect research participants are inconsistent from university to university, and at times from department to department, in terms of necessity, variety, content and duration. For example, our research has indicated that some of universities (e.g., Toronto, Saskatchewan, Queens) encourage/suggest/advise graduate students to take the online introductory tutorial for the Tri-Council Policy Statement. Others, such as Memorial and Windsor, require proof of the tutorial's successful completion before an application for ethical approval can even be submitted. A number of universities have recently established mandatory ethics training for graduate students; however, the human research participant protection component of these – typically short – courses is minor if it is present at all. These findings resonate with – and indeed help to explain – the observation by Dr. Bernard Schwetz, director of the Office for Human Research Protections (USA), that "Investigators generally have very little training in research ethics..." (*Communiqué*, 13:1, p. 16, 2005). Which is to say, if this training does not occur in graduate schools, when should academic be expected to have taken it?

Although I should hate to be accused of advocating for an increased work load for master's and doctoral students, I do believe that the current system is neither fair nor tenable. Any Canadian system of PEERH accreditation must consider the advisability of a situation in which graduate students are morally, academically and legally responsible for the safety of their subjects but are inconsistently provided with the tools necessary to ensure that the appropriate safeguards are maintained. A normalised education programme in human research participant



protection, whether provided separately or within the ambit of general “research ethics” training, would help post-graduate scholars empower themselves to effectively live up to their ethical responsibilities. I should respectfully suggest, however, that such a programme must be developed with graduate student input.

As well as training the next generation of academics to have a greater understanding and respect for human research participant protection, education should aid in the removal of an obstacle currently facing PEERH: an institutional culture of disrespect for the ethical review process. I am not suggesting that this culture is ingrained in most or even many university research groups. But it most certainly exists. And it is a problem. I offer as evidence the persistence of ethical regulatory compliance (or the lack thereof) as a concern in research involving humans; furthermore, there can be little doubt that a great number of academics/supervisors cling to the belief that the ethical review process is but one more obstacle standing in the way of the efficient execution of their – often industry funded – research programmes. As one REB administrator noted to me, one is forced to wonder how many fewer ethics applications would be submitted if the release of Tri-Council funding were not dependent on approval. What sort of attitude towards human research participant protection might be expected to be cultivated in a graduate student working in such an – admittedly, probably rare, but never the less extant – environment?

I submit that proper education of post-graduate trainees is a basic first step that will reduce the number of ethically suspect research protocols submitted for review, and, perhaps more important, break the cycle of in which disdain for the review process is passed from mentor to protégé.

Education, however, is not enough to ensure improved vigilance by graduate students. We must also be protected from reprisals should reports of adverse events or other activities inimical to the ethical conduct of human research be viewed as antagonistic to the agendas of our supervisors – or those of their benefactors. One particular concern is the danger that the interests of research subjects will take a back seat to those of commercial funders of research. Like it or not, the provision of human research participant protection as well as the research ethics review process in general are not immune to conflicts of interest. As Prof. Jocelyn Downie, Director of Dalhousie University’s Health Law Institute noted on an Australian radio in 2003, “The conflicts of interest that are contaminating the ethics review process and the research process have not yet been managed, we don’t yet have a handle on how to control the conflicts and make sure that the integrity of research is not contaminated by the interests of industry.”

No graduate student working with human subjects should have their academic future be dependent on the execution of a research project in which the health and safety of the participants is not given supremacy; in which a transparent and independently monitored mechanism of adverse event reporting is not clearly elucidated. Thesis projects must not be contingent upon a student entering into a confidentiality agreement with a corporate sponsor, a supervisor’s start-up or the university itself, if such a contract were prejudicial to the protection of research participants. I freely concede that conflict resolution between students and supervisors a major issue that requires its own management and is not strictly within the purview of PEERH. The accreditation enterprise, however, must in some way ensure that students are not hung out to dry should they choose, in good faith, to reveal publicly or refuse to abet unethical research designs, coercive recruitment procedures or experimental conduct.

In closing, I should like to applaud the work done by the Task Force for the Development of an Accreditation System for Human Research Protection Programs. In particular, I was encouraged by the inclusion “education” and “conflict of interest” as rationale for the establishment of PEERH accreditation as outlined in the Task Force’s *Draft Final Report*. As a proportion of our numbers, only a minority of graduate students undertake research with humans – albeit, I cannot help but note that we do represent a large body of willing volunteers subjects for our peer’s work. Nevertheless, as the ‘of most university research programmes and as tomorrow’s academic leaders, I feel that graduate students have much to gain from and even more to offer to PEERH accreditation.

The author is Chairman of the Graduate Students’ Association of Canada, an all volunteer student organisation based in Edmonton, which represents over 20,000 graduate students from sea to sea. He has just finished defending his master’s thesis at the University of Alberta, in the field of oncological nutrition. He is also the graduate student member of the Faculty of Agriculture, Forestry and Home Economics Research Ethics Board.



Ethical Issues in Community-Based Research with Children and Youth

by Elizabeth Banister
and Bonnie Leadbeater, Cecilia Benoit,
Michael Jansson, Anne Marshall
& Ted Riecken

Community-university alliances have brought new methods for investigating social problems and innovative practices for preventing or treating them. These alliances or partnerships typically join teams of university-based researchers from different disciplines with targeted members of the non-university community (e.g. policy makers, non-for-profit groups, health service providers, parents and children, or youth themselves). Community-based research alliances often deal with high profile sensitive social issues such as bullying and sexual exploitation. Such alliances create new roles and responsibilities for investigators and participants in research and uncharted ethics questions.

Ethics guidelines for research seek to: minimize risks, burdens or harms; increase the benefits of research for individual participants; ensure that the consent given by participants or their guardians is freely offered and informed by knowledge of what participants are being asked to do; and maintain participants' privacy and confidentiality. These ethics concerns are also central in community-based research alliances. However, in part because of the newness of these research partnerships, precedents for applying established ethics guidelines, organizational policies, and even child protection laws are not widely available to guide research practices or the decisions of university or community ethics review boards.

A fundamental requirement for involvement of people in research is informed consent. Generally, there are three elements to informed consent: 1) the person needs to be capable of making the decision about research participation (competent); 2) the person must be acting voluntarily; and 3) the person needs sufficient information (in an understandable form) to enable him/her to make an informed decision. The prevailing belief is that minors are not competent to adequately comprehend the risks and benefits of participating in research. Some studies have shown that school-age children age seven and older can understand the informed consent process and are capable of making a decision on their own behalf (Kanner, Langerman & Grey, 2004). To complicate matters, there is considerable variability and conflict, particularly in Canada, concerning the age at which youth are deemed legally competent to give informed consent.

In community-based research, the competence of individuals giving consent for research participation is a concern especially for vulnerable populations such as youth. Youth need to understand the limits of confidentiality before they agree to participate; informing youth of reporting requirements may not be sufficient. This may necessitate asking for feedback from children and youth about their understanding of the risks and benefits of the research in order to increase confidence that they have the knowledge needed to make an informed choice about participation. Reassessing consent and understanding of the research in the course of a research project can provide more protection and freedom of choice for vulnerable participants (see Munall, 1988). Multiple methods can be used for explaining the study such as videotapes, written materials, diagrams, discussion, and mini-tutorials.

Furthermore, specific research data collection methods challenge the competence of youth to give informed consent. Despite well-documented advantages (Morgan, 1997), group interviews create risks for participants regarding over-disclosure (Banister & Daly, 2006). Young people may lack experience to anticipate the consequences of revealing their private thoughts in a group setting, particularly as they believe they can talk safely in an ongoing group. Confidentiality cannot be guaranteed when using group interviews. Early group sessions need to devote time to developing group rules about safety and trust and need to be revisited in subsequent sessions. Participants need the opportunity to discuss the possible risks related to confidentiality and need to be reminded that they have choices about what they disclose. While disclosing highly personal information is not necessarily harmful, and may have a therapeutic effect for some participants if handled sensitively, facilitators need special training to minimize participants' inappropriate over-disclosure in the data collection process (Marshall & Shepard, 2006).



Ethical care in community-based research should strive for transparency and openness with participants in the research process. Research alliances must provide opportunities for community and university dialogue on potential research benefits and harms, and must engage representatives of key stakeholders (youth, parents, schools, researchers, and graduate students) in ongoing processes for assessment of research protocols, development interventions, and creation of plans for dissemination of findings. Research Ethics Boards and research advisory groups could formally involve relevant community members such as school principals, parent representatives, and school board officials and authorities responsible for enforcing reporting laws.

Discussion of the values and beliefs about the benefits and harms of research must become public and transparent with more opportunities to increase dialogue through community-based research, community forums, and media. Without such dialogue, research will continue to exclude vulnerable populations and avoid focusing on socially sensitive issues.

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Community-Based REBS: The Experience of the British Columbia Medical Services Foundation

by Deborah Poff

I want to begin my discussion today but outlining the purpose and goals of the BC Medical Foundation. These are to support health-related research in both academic and community settings that can be expected to have a direct impact on health and health care in British Columbia. It encourages interdisciplinary and collaborative research. It actively promotes the increase of research capacity, explores solutions to health care issues, and advances study in the health sciences.

These purposes are met through funding the following:

- Applied Clinical Health Care and Population Health Research Projects: Studies/projects/investigations that apply research methodology to health, the provision of health care and current practical clinical problems. Population health research applications are also encouraged from non-medical disciplines such as sociology, psychology, education etc.
- Community Based Health Research Projects: Studies/projects/investigations that address community based health issues (including social determinants of health) identified by the community and conducted in partnership between community members, researchers and health providers using qualitative methods.



- Activities which build research capacity in health professionals and educational institutions that lack opportunities and funding for research. (Eg. Nurses, family physicians, community colleges, aboriginal communities).
- In addition, BCMSF provides student assistance in the form of Health Sciences and Nursing Bursaries, Summer Research Scholarships and Pre-Doctoral Fellowships.
- Current emphasis on projects related to rural and remote health.

The move toward funding community research started in 2002 and was intended to extend necessary resources and engage community ngos, particularly in rural and remote communities in capacity-building around applied research questions where there was no established community of researchers such as exists where there are universities in place. The intention was to empower community organizations and agencies in relevant community-based human participant research on issues of critical importance for those communities. The research has thus all fallen into aspects of the social and economic determinants of health and well-being. In September 2002, the foundation contracted with two leaders in community-based research to provide a ethical review framework for the establishment of an REB for the BC Medical Services Foundation. In 2004, that REB was appointed. I am the chair and among other things the foundation adopted the TCPS as the basis of its ethical guidelines.

What I wanted to share with you is some comments about the complex and messy nature of the proposals that we review, the consequent relationship that the committee has with researchers and why I think we are serving an important role in supporting this type of research although that support comes with some level of discomfort sometimes given the nature of the work.

I would suggest that most of the proposals we receive are strongly advocacy-based. These are people who are actively engaged in types of social service delivery or are engaged with communities who face issues related to poverty, or food security or violence or marginalization because of race, ethnicity, socio-economic status, or issues of addiction, etc. Consequently, a number of issues arise and I'll identify some key ones here:

- The research may involve leading questions or pre-determined expectations about what is to be found through the study
- There may be perceived or actual conflicts of interest because the findings are intended to be used as vehicles for lobbying activities
- The Principal Investigators may be members of the group which wishes to see re-dress as a consequence of the findings
- The Principal Investigator may be a service provider and is requesting participation from clients so that there may perceived coercion or less than meaningful free choice in participating
- The research may be being conducted by volunteers who change over time raising issues of previous commitments (e.g., to keep records confidential and under lock and key for a specified duration) and issues of stability and sustainability over the life of the project (food security - high unemployment)
- The communities may be so small and insular that everyone knows everyone with some high risk consequences if confidential material is leaked (underground economy, relatives)

If these are the issues, what has that meant for our REB? We think that much of the research is really important and would not otherwise be done. So we have developed an iterative relationship with many of the projects. We do discuss methodology with researchers particularly where the methodology has potentially troubling ethical consequences. Although this might seem like mission-creep, we do wish to assist in the mandate of BCMSF of capacity-building, so I think we sometimes do comment on methodology solely to help improve the project which I know is a no-no for university REBs but we are dealing in many cases with novices in the research arena and I think that most of our comments are welcomed because the intention is facilitative and constructive. We try to point out some of the inherent difficulties that I referred to and propose methods to mediate some of the potential or real conflicts of interest or biases in questions and design. I think the committee is extremely rewarding for its members. At least, many committee members express this precisely because this is such immediate and real stuff compared to the more rarified experience of reviewing some of the university-based research.



A Preventable Death - A Contribution to Research

by Kirsten Bauer

My father died while a participant in the Antihypertensive and Lipid Lowering to Prevent Heart Attack Trial (ALLHAT) with all FDA-approved medication. I accepted an invitation to speak at the NCEHR 2006 Conference because my father's case of two serious drug-induced conditions illustrates how proper informed consent and reporting adverse reactions could have protected him. My father can still contribute to research if his case serves to strengthen the belief in these important elements of the clinical trial process. Although my family and I are saddened by his loss, my mother is benefiting from well-designed, ethical research. She is receiving valuable treatment for her breast cancer with the new drug Herceptin, and she is indebted to all who participated in trials of that medication.

When my father entered the ALLHAT study at Lankenau Hospital in Wynnewood, PA, he rated a health a 90 on a scale of 100 on the ALLHAT questionnaire. He died with drug-induced lupus and rapidly progressing kidney failure (glomerulonephritis) from the direct vasodilator, hydralazine. Although these conditions were documented on autopsy, lab, and pathology reports, the FDA has no record of my father's adverse reactions caused by hydralazine.

After my father's death, I was dismayed by the lack of oversight represented in his ALLHAT medical file. The research team did not provide the FDA recommended lab tests (CBC, ANA) every six months to monitor for the early stages of drug-induced lupus and renal dysfunction. Without this monitoring, the investigators allowed the conditions of drug-induced lupus and glomerulonephritis to progress to the end stage.

When my father reported a petechial rash—an indicator of an autoimmune response, and reason to discontinue study medication according to the study's Manual of Operations—the Research Coordinator sent more medication by express mail. The research team failed to report other conditions my father developed, despite the fact that they were listed in the Physician's Desk Reference as adverse reactions for one or more of the study drugs: peripheral edema (+2), tachycardia, anemia, and elevated lab values (BUN and Creatinine). I was concerned that postcards or phone calls were used as substitutes for clinic visits; the nurse was allowed to increase the dosage of study medication; and she crossed out the word abnormal on one of two abnormal electrocardiograms.

Violations of protocol included:

- Failing to monitor blood pressure every 4 months;
- Failing to follow the stepped care process for add-on medication;
- Failing to order indicated lab tests regarding muscle cramps/statin drug;
- Failing to discontinue study drugs when labs indicated renal dysfunction.

After the researchers did not self-acknowledge serious lapses in clinical trial oversight, I contacted the Office of Human Research Protection. In December 2002, the OHRP determined that "...certain unanticipated problems involving risks to subjects or others were not promptly reported to appropriate institutional officials, the IRB, OHRP, or the head of the sponsoring Federal department or agency..."

The OHRP also determined that the informed consent documents failed to adequately describe adverse reactions and foreseeable risks.

- The documents did not provide an adequate list of side effects/adverse reactions, listing only 8 total side effects to cover 9 possible study drugs.
- The documents did not name the Step 2 drugs and the Step 3 (hydralazine), or their side effects because the ALLHAT doctor was to explain them.

ALLHAT had over 42,000 subjects enrolled at over 500 sites throughout the USA and Canada. I don't know how many of the sites used the inadequate consent documents, but anyone taking hydralazine should have been



informed that lab tests were available to monitor for drug-induced lupus and renal dysfunction. Just knowing how to recognize the symptoms could have saved my dad's life.

The new antihypertensive medication BiDil, the first drug developed specifically for African Americans, contains the ingredient hydralazine. The clinical trial for BiDil had at least one confirmed case of drug-induced lupus. When BiDil was released in July 2005, the product literature did not caution doctors to test patients for lupus biannually, although such information accompanies the generic form of hydralazine

I do not know if proper reporting of my father's hydralazine-induced lupus and glomerulonephritis would have made a difference to the FDA or to the manufacturers of BiDil; however, I still believe that the investigators should report it.

I am discouraged by the lack of responsibility and accountability in my father's case, but I applaud all who are working with principle concern for the welfare of human research subjects.

(Kirsten Bauer can be contacted at ASPRE@comcast.net)

Case Vignette

by Mark Goldberg

THE RECRUITMENT OF SUBJECTS FROM MEDICAL CARE FACILITIES INTO OBSERVATIONAL EPIDEMIOLOGICAL STUDIES

Epidemiological studies of health are used to relate health-related outcomes with characteristics of subjects or exposures that they may have been subjected to. The purpose of most of these studies is to shed light on etiology, such as in the Framingham cohort study where levels of myeloperoxidase were related to the risk of coronary artery disease(1), in a case-control study of breast cancer and the consumption of alcohol(2), or in a cross-sectional health survey from Santé Québec to estimate prevalence rates of psychiatric disorders. These studies do not involve medical interventions that may alter a subject's health status, but rather are based upon the collection of different types of data that are required to answer the research question(s). The modes of data collection may include questionnaires of subjects or surrogate respondents, obtaining biological specimens, linkage to administrative data (e.g., health insurance claims), measurements of ambient air pollution, etc...

In epidemiology, it is important to obtain high response rates and the method of approaching subjects is thus critical to the validity of the study. There is wide variation among research ethics boards (hereafter referred to as REBs) in the types of procedures that they approve for approaching potential subjects. This variation reflects to some degree the idiosyncratic nature of the review process and institutional policies. In some instances, the procedures advocated by the REB may be consistent with accepted epidemiological procedures that are known to yield valid data but in other instances these policies may lead to procedures that may render a study invalid.

The purpose of this vignette is to inform REBs which methods of contacting potential subjects in observational epidemiological studies are valid epidemiologically and are consistent with present ethical guidelines.

What is an epidemiological study?

Epidemiology is the primary tool used in medicine and public health to gain insights into the etiology of disease, and its roots trace back to John Snow's efforts in the mid-1800s to rid England of the cholera. A central distinction in epidemiological designs are whether studies are observational or experimental. In the former type of study, although subjects may be contacted directly to obtain information, there is no medical intervention that may alter their health status, although some invasive procedures may be used to obtain data (e.g., blood samples for



genotyping). In the latter type of study, interventions are made on subjects, usually within the context of randomizing participants to different arms of an intervention, and their health status may thus be modified.

Observational epidemiology covers a broad spectrum of activities, including studies of the natural history of diseases, monitoring health effects from medical treatment, post-surveillance monitoring of adverse drug reactions, evaluation of medicare and health insurance plans, evaluation of medical technologies, familial aggregation and genetics, psycho-social effects on health, clusters of environmentally-caused disease, correlations between biochemical markers, self-reported health, establishment of normal values and diagnostic errors, quality of care, and economic consequences of disease.

Epidemiologists use a variety of designs to answer questions about health in human populations. Cohort studies comprise a set of designs in which groups of individuals having some element in common are followed through time to identify occurrences of health events or to measure states of health. The essential concept is to estimate incidence rates and compare these rates between subgroups representing different levels of "exposure". Cohort studies can be based on a common characteristic of subjects, such as army conscripts, women who availed themselves to family planning centers, siblings entered in a twin registry, and individuals with atrial fibrillation. Alternatively, cohorts may represent samples from the general population, such as the Honolulu Heart Program(3) and the American Cancer Society Cancer Prevention Study(4).

The case-control design also yields valid inferences about associations on incidence rates, but it uses a different scheme to sample subjects from a population. In case-control studies, case subjects are selected as having newly developed a disease and control subjects are those who do not have the disease at that time. It is common that case subjects are identified from hospital records (e.g., new cases of invasive breast cancer) and control subjects are either drawn from the general population (e.g., through electoral lists) or are selected from a pool of subjects who are hospitalized for other conditions.

The other major design used in epidemiology is the cross-sectional study (a synonym for a survey) in which subjects are selected independent of exposure status and disease status. These studies can be nested within a well-defined cohort or can be a sample from the general population. Surveys provide estimates of the prevalence of attributes of a population, such as percentages of persons who smoke, who vote in an election for a particular candidate, who have some health condition, etc... In some cross-sectional studies, there is interest in correlating the prevalence of a health state to concurrent or antecedent exposures in an attempt to identify etiological factors, but its use as a tool to infer causality is limited.

Selection Bias in Observational Epidemiology

As indicated above, epidemiological studies make use of samples of populations, and so the statistical aspects of a study are crucial. One important bias that may occur is when the results of the study deviate from that which would be obtained if the entire population had been studied. In other terms, this means that the procedures for selecting subjects into the study were such that the joint distribution of disease and exposure among selected subjects was different from that of the population of which they are members (referred to as the target population). For example, if the interest is in determining whether hormonal replacement therapy is associated with the subsequent onset of invasive breast cancer among postmenopausal women living in Montreal, then a case-control study would generally be used. The target population would be all postmenopausal women living in Montreal during the study period. The study procedures should guarantee that 1) all newly diagnosed breast cancer cases from the target population would have an equal probability of being enrolled in the study and that 2) all women without breast cancer (controls) would also have an equal probability of selection (e.g., voter registration lists).

A well-validated method for the identification of new cases that ensures complete coverage is the perusal of hospital pathology reports. An alternative but biased procedure would be if women with breast cancer were identified in offices of obstetricians and gynaecologists; because women not receiving hormonal therapy would be less likely to be referred to a specialist, it is likely that this procedure may lead to inflated estimates of the use of hormonal replacement therapy and, consequently, to an overestimate of risk.

Once the method for identifying potential case subjects has been developed, the next issue is to find a valid and ethical approach to contact and enrol these subjects into the study. The procedures developed by the epidemiologist will account for how information is to be gathered. In the study described above, a typical source of information is the subject herself or next-of-kin, and the epidemiologist will usually use a questionnaire to obtain this information. Personal information may be obtained through mailed self-administered



questionnaires, telephone interviews, direct interviews in-hospital or in-clinic, or a combination of these. In addition, ecological data may also be collected (e.g., obtaining median income from census data), ancillary information from provincial and other drug plans may be used, subject to provincial laws and consent from the subject, and genetic or other biological material may also be obtained.

Once there is a guarantee that the entire study population can be identified without bias, the procedure to contact subjects should maximize response rates. For example, in a telephone interview study in breast cancer, a procedure that leads to high response rates is to send by mail a description of the study, the consent form, and the questionnaire. The subject is then contacted by telephone, requested to participate, and the interview is conducted at that time or at a later date, either in-person or by other means.

One procedure that is known to lead to low response rates is when care providers are made the gatekeepers; for example, some cancer case-control studies have resulted in response rates of about 50% when active approval to contact patients from treating physicians is required, and the results from these studies are questionable. If the study is population-based (namely, cases are recruited from all institutions covering a geographic area), it is infeasible to contact and obtain permission from the care providers. In addition, medical treatment is for the most part multidisciplinary and in many instances there is a team of clinicians treating patients. This is particularly evident in breast cancer, for which treatment may comprise surgery, chemotherapy, and radiotherapy. In these situations, it can be argued that because there is often not one treating clinician, the *de facto* "treating physician" becomes the institution.

I believe that in such studies, it is unethical for a care provider to grant consent for a patient to be approached for a study, as it violates the right of the patient to participate freely. Consider the case of a patient who may wish to participate in a study but is denied that because the care provider did not have the time to respond to the study's request or assumed that the patient would not want to participate. In addition, there is also the potential for an inherent conflict of interest among treating physicians who also conduct their own research. For example, a clinician may want to have his patients enrolled in a clinical trial and may think that participating in an observational study would limit their interest or eligibility. Such circumstances would make some forms of research impossible to carry out.

On the other hand, there may be instances in which subjects have told physicians that they do not want to be in a study. I suggest below another mechanism by which patients' wishes can be maintained without the need to obtain approval directly from physicians.

Suggested Procedures for Identifying and Contacting Subjects in Hospital-Based Studies

There is a precedent in Canada for conducting case-control studies in which cases are identified from hospital records and then contacted without the explicit consent of physicians. These procedures, developed initially by Jack Siemiatycki about 20 years ago, have been used in four population-based case-control cancer studies conducted across Montreal hospitals. The studies have involved thousands of subjects and response rates have been above 80%.

The following suggested procedures are based on this experience and refer to observational studies in which there needs to be direct contact with subjects so that additional information not present on the hospital chart is obtained.

- 1) Identification of potential subjects is through hospital records. It can be carried out by study and/or hospital personnel, at the discretion of the Director of Professional Services or other authorized administrator. The justification for the use of study personnel is that there are usually no resources available at the institution to conduct the work. Of course, appropriate procedures are required to protect the integrity of the information.
- 2) In population-based studies, the control population may derive from patients with other conditions, in which point 1) above applies, or it may come from a random sample of the general population (e.g., electoral lists), in which other methods for identification and contact would apply.
- 3) Appropriate methods are required to correctly identify potentially eligible subjects; e.g., in cancer, the pathology report should be unequivocal.
- 4) There is an assumption that the patient knows about his/her condition before being contacted. Patients are usually told of their diagnosis and there is no need to have any additional processes to ascertain this. In some instances in which a patient may not be informed, and this itself has dubious ethics, possible strategies

- include: i) waiting until treatment is underway or has been completed or ii) identification of these patients from the treatment team.
- 5) There is no general or necessary requirement to delay contact until treatment is completed, although there may be instances in which delays are appropriate.
 - 6) The issue of subjects indicating to a clinician that they do not want to participate in studies may be dealt with in a number of ways. For example:
 - a. All patients are informed in writing at time of admission that they may be approached by accredited researchers for all manner of health studies, and they are free to participate or not without their decision affecting their care. This implies that researchers may still contact the subject.
 - b. Patients are informed that they may be contacted for participation in research projects and they can opt-out by filling out a form or telephoning the hospital (e.g., ombudsman). Precise procedures would likely vary from hospital to hospital, and databases may have to be established for non-participating subjects, but information about non-participation must be kept confidential from clinicians (but obviously available to researchers).
- Option 1) requires no maintenance or costs on the part of the institution.
- 7) Contact is then made with potential subjects by the research team. A covering letter from the administration and/or head of the relevant clinical departments should be included to assure the potential subject that the study is legitimate and it would also have the effect of mitigating individuals' belief that their privacy has been violated. Methods for contacting subjects can vary according to the study design (e.g., in-hospital, in-person, by phone, by mail).
 - 8) Appropriate consent forms and letters of introduction are, of course, required. In some instances, waivers of signing a consent form may be used and in some instances, such as in telephone interviews, verbal consent may be sufficient in lieu of signed consent.

Conclusion

It is important to understand the main scientific argument for these procedures is the need to achieve high response rates so that the results will be valid and generalizable (i.e., study subjects have to be representative of the base population). The above procedures increase the scientific validity of the study, as the highest possible participation rates can be obtained from the overall pool of eligible patients (i.e., no intermediary to reduce the pool (e.g., through explicit physician consent)), without interfering with the rights of patients to privacy. These procedures recognize that patients should have the opportunity to participate in research projects that they may have some interest in and that it is the patient, in the end, who should be agreeing or not to participate in a study, subject to appropriate privacy conditions, and acknowledging that their treatment will not be modified if they participate or not. In addition, these procedures will result in reduced study costs, as the step of tracing physicians and obtaining their consent is eliminated.

The above procedures also satisfy CIHR's recent guidelines(5). Element 4, points 1 and 2 (minimal invasion of privacy, potential subjects unaware of research) (see Appendix) by ensuring that the patient has been informed of their condition, through the letter from the hospital's administration, the ability to opt-out in advance, and the second covering letter from the head of the department or from the hospital. In addition, they are fully consistent with Element 4, points 2 and 3 (separation of research activity between subject and institution, no coercion of subjects).

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Appendix. GUIDELINES FOR PROTECTING PRIVACY AND CONFIDENTIALITY IN THE DESIGN, CONDUCT AND EVALUATION OF HEALTH RESEARCH" (CIHR, April 2004) (5)

ELEMENT #4: Recruiting prospective research participants.

A proposed recruitment procedure should normally ensure that initial contact with an individual about a research project is made by someone whom the individual would expect to have relevant information about them, or by other non-invasive means. The recruitment procedure should not inappropriately interfere in the lives of potential research participants, nor exert any undue pressure on eligible individuals to agree to participation in research.

1. To minimize potential invasion of privacy, by having the initial contact about the research conducted by someone whom prospective participants can reasonably expect already has personal contact information and any other personal health-related information.
2. To separate, to the extent possible and appropriate, the from the nature of the existing relationship between data holder and research participant.
3. To eliminate or reduce any undue pressure on participants and enhance the voluntary nature of their consent.

To avoid situations where prospective participants are not aware, prior to being contacted by researchers, of health information about them.

