A QUALITATIVE STUDY OF INFORMED CONSENT: MOVING THE DISCUSSION BEYOND THE CONSENT FORM

By:

Lisa LaBine

A Thesis submitted to the Faculty of Graduate Studies of

The University of Manitoba

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A Qualitative Study of Informed Consent: Moving the Discussion Beyond the Consent Form

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THESIS ABSTRACT

Informed decision-making, resulting in either consent or refusal to participate in research, is an essential prerequisite for ethical research involving human subjects; however, a preoccupation with documentation and the consent *form* has largely dominated the process of informed decision-making. To date, most of the scholarly discourse has focused on the consent form, addressing issues of content, readability, or assessing the competency of specific populations to provide consent. While such studies have been effective in highlighting some of the limitations associated with traditional consent forms, this narrow focus fails to engage some of the wider contextual issues, practicalities and relationships that impact the process of negotiating meaningful consent. This study utilizes a comprehensive approach, incorporating the perspectives of researchers, front-line research workers, research ethics board members and other 'experts' including policy-makers and scholars, who all play important yet varying roles in the consent process. Drawing on the thoughts and comments of these key players, this research project explores some of these wider dimensions and will contribute to a better understanding of the real-life challenges and priorities for reform, not just with respect to the consent form, but for the consent process overall.

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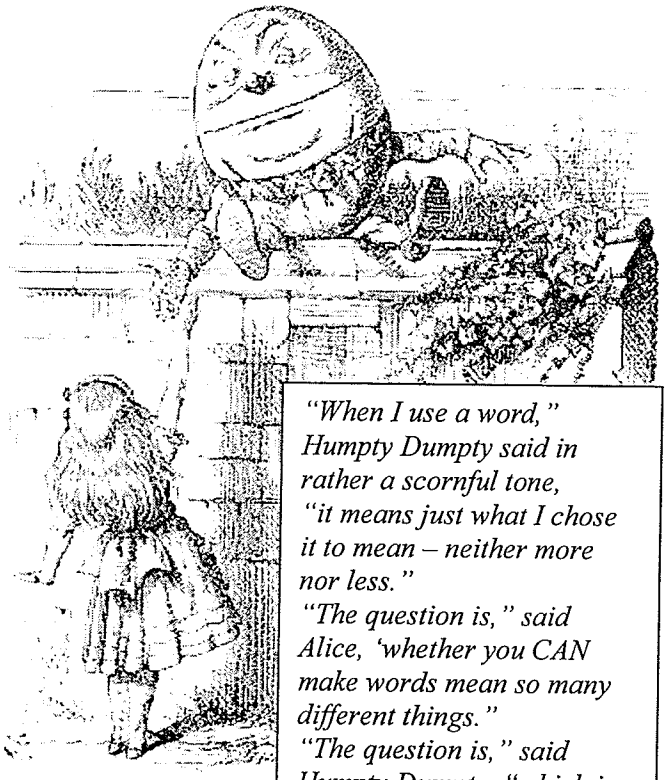

"When I use a word," Humpty Dumpty said in rather a scornful tone, "it means just what I chose it to mean – neither more nor less."
"The question is," said Alice, 'whether you CAN make words mean so many different things."
"The question is," said Humpty Dumpty, "which is to be master – that's all."

1

[1]The inspiration to use this caption originates from Greely HT (2007). The Uneasy Ethical and Legal Underpinings of Large-Scale Genomic Biobanks. *Annual Review of Genomics & Human Genetics*, 8, p.344. The illustration and prose from Carroll L (Dodgson CL) (1871). *Through the Looking Glass and What Alice Found There*. New York: Macmillan.

Introduction

Informed decision-making, resulting in either consent or refusal to participate in research, is an essential prerequisite for ethical research involving human subjects; however, a preoccupation with documentation that focuses on the consent form has largely dominated the process of informed decision-making. To date, empirical research has primarily examined the consent form, addressing issues of content, readability, or assessing the competency of specific populations to provide consent (Flory & Emanuel, 2004; Sugarman, 2004). While such studies have been effective in highlighting some of the limitations associated with traditional consent forms, this narrow focus fails to engage some of the wider contextual issues, practicalities and relationships that impact negotiating meaningful consent. Researchers, front-line research workers, research ethics board [REB] members and other 'experts' including policy-makers and scholars, all play important roles in the consent process, yet most of the scholarly discourse has focused on the printed consent form document rather than on a more comprehensive approach that explores their perception of the current issues, priorities and concerns with respect to the whole process of informed consent, meaning the wider social aspects, such as the dialogue and information sharing that also occurs during this process (Davis, Hull, Grady, Wilfond & Henderson, 2002; Il-Wakeel, Taylor & Tate, 2006).

Despite the recognized limitations, as evidenced by the existing body of scholarly literature, the requirement for informed consent remains a cornerstone of ethical research practice. The research community has become increasingly dependent on the consent form as a formal document, and critics assert concerns over the growing disconnect

between those who regulate the process of informed consent, and those who are responsible for obtaining and ensuring informed consent. Moreover, there is disconnect across oversight systems and policies for ethical research amongst multiple institutions and research ethics boards, which further creates tensions between those who oversee and those who are involved – both directly and indirectly in research (Dawson & Kass, 2005; DuBois, 2004). There is an urgent need to improve evaluation and feedback practices between stakeholder groups to facilitate constructive relationships and communication amongst: **1)** Researchers; **2)** Research Ethics Board [REB] members; **3)** Policy-makers and/or scholars with expertise in research ethics, and **4)** Front-line research workers and others who contribute to the research process including research coordinators, nurses and other health care professionals, interviewers, translators, interpreters, research assistants, graduate and post-graduate students.

This research project, as part of a wider study[2], investigates this gap via in-depth, semi-structured interviews from a geo-graphic sub-set[3] of key stakeholders, and a review of published and 'grey' literature[4], which includes reports, guidelines and regulations, across social sciences, epidemiology, legal and ethical disciplines. Individual narratives from interviews engage historical context, changes in health research over time, structural

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[2]Research Team: Susan Cox (Principal Investigator), Michael McDonald (Co-Principal Investigator), Patricia Kaufert (Co-Investigator), Joseph Kaufert (Co-Investigator), Anne Townsend (Co-Investigator), Lisa LaBine, Toni Morris-Oswald, Darquise Lafreniere, Natasha Damiano-Paterson, Sara Hancock, Nina Preto, Cathy Schuppli and Kim Taylor. The overall project, entitled "*Centring the Human Subject in Health Research: Understanding the Meaning and Experience of Research Participation*", is sponsored by the Canadian Institutes of Health Research [CIHR] and is based at the University of British Columbia [UBC] and the University of Manitoba [UMan]. The Western Regional Training Centre [WRTC] also supports partial funding of this student initiative.

[3] This student thesis project only utilizes interview data collected by the University of Manitoba Research Team, and the most of key stakeholders interviewed live and work within the province of Manitoba.

[4] This term refers to papers, reports, technical notes or other documents produced and published by governmental agencies, academic institutions and other groups that are not distributed or indexed by commercial publishers, and as a result, these documents may be more difficult for the general public to locate and/or obtain.

determinants of informed consent policies, and explore the nuanced relationships of relevant stakeholders at all levels and their role in human subject protection, but always with an emphasis on the process of informed consent.

Conceptually, this student research project explores the key themes and salient differences that emerged from each stakeholder group, focusing on the perceived objective of the consent process, and the barriers and facilitators of implementation. The resultant findings form the basis of recommendations to promote a much more meaningful process of informed consent for human subjects, and a much more effective one for others also involved in health research at all levels, and is based on areas for improvement and change within existing frameworks as identified from key informant narratives. This project links conceptual issues that emerged from the interview data analysis to a descriptive summary of current and burgeoning issues in informed consent, and a brief chronology of events and changes that have occurred over time, including the ethical and other impacts on the process of informed consent for research involving human subjects. Thus, the objectives specific to this student research program are:

1) Explore the roles and relationships of multiple stakeholders involved within the processes of health research and the impact of alternative perspectives on informed consent;

2) Compare/contrast perspectives of various actors, and their perception of the issues, problems and identify priority areas for improvement to reform the current process of informed consent;

3) Summarize and contextualize some of the changes that have occurred over time with respect to guidelines and policies for informed consent, including a review of the current literature.

1.0 CHAPTER 1: Historical Background

Informed decision-making, resulting in either consent or refusal to participate in research, is an important prerequisite for research involving human subjects. Generally, research is thought to be ethically permissible only if each individual research subject gives his/her voluntary and informed consent prior to participation. At least, the research is then permissible given that certain other conditions are also met – conditions such as the scientific validity of the research design, the importance of the study, limited risk to research subjects, and the proportionality between the risk of harm and the likelihood of benefit (Interagency Advisory Panel on Research Ethics, 2008; Levine, 1986). So, while recognition of the value of informed consent is significant, the processes that govern informed consent have noticeably changed. In the past, there was much more liberty with respect to how consent should be initiated, while today there is perhaps more consensus, or at least current notions of what is expected of researchers is now much more prescribed than it was in the past.

Varied influences and key events have shaped practices and guide our understanding of what constitutes ethical research ultimately leading to a much greater emphasis on the rights and protections of human subjects, increased responsibilities for researchers and institutions supporting research, the regulation of ethical codes and the development of the Research Ethics Board [REB] (Institutional Review Board [IRB] in the U.S.) to both oversee and adjudicate research involving human subjects (Whittaker, 2005). Events and changes that have occurred over time have influenced relationships – both at a theoretical and practical level – between human subjects and other stakeholders

involved in research, and perhaps most notably, this is reflected in the history and development of informed consent agreements. There is important knowledge to be gained by exploring these relationships; however, this aspect of consent has rarely been the focus of research. This research project will add to the body of literature by examining these and other relevant issues, which includes a review of the important changes that have occurred over time with respect to guidelines and policies for informed consent.

1.1 *The Nuremberg Code*

Current policies that guide ethical research address the principle of 'respect for persons', or 'respect for the equal moral status of all humans' via informed consent requirements. Within moral and political philosophy literature, respect for persons refers to the notion that all people, irrespective of social position, individual characteristics, achievements, or moral merit, should be accorded the same level of respect and concern simply because they are persons (Interagency Advisory Panel on Research Ethics, 2008). Thus, persons share a distinct moral status and therefore merit special categorical obligations to both regard and treat others in ways that are constrained by certain inviolable limits. These 'limits' are sometimes expressed in terms of rights, and persons are thought to have a fundamental moral right to respect others, but equally they also have the right to garner respect, simply because they are persons (Stanford Encyclopedia of Philosophy, 2009).

In research, 'respect for persons' incorporates two key ethical tenets; first, that individuals should be treated as autonomous agents, which reflects the primacy of the competent individual's self-determination, and decision to consent or refuse participation in research. Secondly, the principle acknowledges that persons with diminished autonomy are also entitled to protection, and therefore, this moral requirement provides protection for vulnerable persons with respect to their involvement in research undertaking as well. Generally, an autonomous person is considered to be an individual capable of deliberation about personal goals, and acting in response to such deliberation. To respect autonomy, others must defer to the considered opinions and choices of an autonomous person; while to show lack of respect is to refuse to acknowledge the considered judgment, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so. However, not every human being is capable of self-determination, and children, individuals with illnesses such as Alzheimer's disease, mental disability, or other circumstances that severely compromise self-determination – whether temporary or long-term – are generally considered to have diminished autonomy. Therefore, such individuals may require protections as they mature or while they are incapacitated, etc. and this will likely vary in different situations. Thus, the principle of 'respect for persons' is more than simply respect for autonomy, and it necessarily includes protection of vulnerable persons, or those with diminished autonomy, which encompasses a broader expression of respect for them as persons as well (Levine, 1986; National Institutes of Health [NIH], 2009; Nuremburg Code, 1949).

The principle of 'respect for persons', although for the most part widely accepted, is still debated and particularly with respect to the scope, the grounds for respect, and the justification for the obligation; however, a detailed overview of these debates will not be discussed here at length. It is worth noting that in most cases of research involving human subjects, 'respect for persons' requires that human subjects enter into the research voluntarily and with adequate information, but in some situations, application of the principle is not always obvious or simple (NIH, 2009; Nuremburg Code, 1949).

Formally integrating ethical principles such as 'respect for persons' into research processes may have been a gradual process, but an important attempt to embed ethical principles in research practice occurred following the events of Nazi Germany during the Second World War. As a result of the human experiment atrocities that occurred, the Nuremberg Code became one of the first recognized documents to outline a professional ethic to guide medical researchers. The Code was intended to formally acknowledge these horrific events and prevent any further violations of rights from occurring in research involving human subjects (Levine, 1986).

Central to the Nuremberg Code is the notion of voluntary informed consent in which the "responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment" (Nuremberg Code, 1949, p.181). This requirement for informed consent advises that all human subjects who are competent to give consent, should be given the opportunity to exercise free power of choice without force, fraud, deceit, duress, coercion or any other constraint, and have a sufficient knowledge and comprehension of the research including their own involvement, in order to make an informed decision (Doyal & Tobias, 2000; Marshall,

2007; Nuremberg Code, 1949). The Nuremberg Code set precedence by establishing a formal recognition of human rights for subjects involved in research; but despite its significance, it had only minimal impact in North American and Internationally. The ethical standards received little attention because, although most researchers agreed that the standards seemed appropriate, the majority tended to dissociate their own research intentions and practice from that of the convicted Nazi investigators. Thus, the general sentiment amongst researchers was that strict adherence to the articulated codes was not applicable to them or their work and as a consequence, unethical research continued to occur (Bhutta 2004; Blustein 2007; Haack 2006; Moreno 2001; Weindling 2001; Yoder 2006). Bird (1996, p.85) characterizes such attitudes as "moral blindness", or when individuals fail to recognize moral concerns and expectations that have direct implications for their activities and involvements. Within this context, while many researchers understood the moral issues associated with Nazi investigators, they failed to anticipate the ways in which their own research activities could give rise to unanticipated or undesirable developments (Bird, 1996). Furthermore, at this time there was a much more indirect governance of professional groups, which was based mostly on collegiality and trust. Researchers were given broad discretion with respect to research conduct and interpretation of ethical guidelines (Tuohy, 2003). So, while these ethical standards attempted to provide guidelines to promote fair and equitable research practice, as Bird & Smucker (2007) note, without proper understanding of the circumstances in which they should be interpreted or applied, such standards are reduced to mere statements of intent or means to burnish reputation.

In addition to concerns about compliance, the Nuremberg Code was also criticized for being too limited in scope. In light of medical progress and the development of new techniques and methodologies, the principles no longer seemed relevant to a wide spectrum of health research or even the study populations involved. Many researchers, although agreeing with the overall concepts emphasized in the Code, were hesitant to endorse a single set of rules for all disciplines and types of research. There was a particular sense of discomfort with the notion that voluntary consent was absolutely essential under all conditions (U.S. Government, 1994). This clause left no room for exception, and this was particularly troublesome for research involving individuals who were not capable of providing consent, or required other consent options, such as verbal consent or authorization by a third party or appointed proxy to provide consent on the behalf of another. As a result, much of the research community felt that the codes were extreme and discrepancies between what actually occurred in research and the ideals set out in the Nuremberg Code began to widen (U.S. Government, 1994; Weindling, 2001). Beecher, commenting on some of the concerns raised by the research community, noted that more needed to be done than simply creating a set of principles to provide moral guidance for researchers without knowledge transfer, or checks to ensure these codes were followed in an appropriate manner:

> [I]t is not my view that many rules can be laid down to govern experimentation in man. In most cases, these are more likely to do harm than good. Rules are not going to curb the unscrupulous. Such abuses as have occurred are usually due to ignorance and inexperience. The most effective protection for all concerned depends upon recognition and an understanding of the various aspects of the problem. (Beecher, 1959, p.119)

There was a growing sense that a set of prescribed guidelines, created in consultation with the research community, was needed in order to facilitate real change in the way health research was conducted, and to understand why the ideals described in the Nuremberg Code were neither effective nor practical. Such measures were important because if rigorously implemented, the Nuremberg Code would effectively preclude much important research from ever taking place.

1.2 *The Declaration of Helsinki*

In 1964, the World Medical Association prompted by the demands for a stricter formalization of research standards and policies, developed the Declaration of Helsinki, which has been revised several times, most recently in October 2008 in Seoul, Korea ("Editorial", 2003; McDonald, 2000; World Medical Association [WMA], 1964). Essentially, this international agreement was an interpretation of the Nuremberg Code, with a much greater focus on medical research directed at improving therapeutic intervention and outcomes. This iteration of the Declaration reflected some of the changes occurring in research practice and populations involved, most notably, adopting a much more accommodating view of informed consent, which recognized that research occurs within different settings and with different populations under unique circumstances. Instead of an absolute requirement analogous to that put forth in the Nuremberg Code, the Declaration of Helsinki advised that informed consent should be sought "if at all possible", but also recognized that other forms of consent were also

acceptable in some circumstances. Situations arise in which consent is impossible or impractical to obtain, particularly for subjects who are physically or mentally incapable of giving consent, for example, unconscious patients. In such circumstances, rather than foregoing research altogether, it would be permissible to seek informed consent from a proxy or legally authorized representative as long as the conditions of research participation were still identified and understood (WMA, 1964, p.177).

The Declaration of Helsinki was an important development because it helped facilitate the expansion of ethical discourse beyond researchers' assertions simply at the beginning of a study. Researchers were now expected to formally articulate all research methods and interventions, and ensure accordance with the Declaration throughout the duration of a research project. With the introduction of this agreement came other conditional responsibilities as well; journal editors began to insist that all published research followed the ethical principles set out in the Declaration (Bayer & Fairchild, 2004; Corrigan 2003; Delgado & Leskovac, 1986). So, while the Declaration as a formal document did not have any legal force, adherence to the guidelines was important if one wished to publish in scholarly journals. Ethical guidelines on authorship or methodology, for example, required certain processes such as informed consent prior to research participation, to be followed. If such research protocols were not followed, leading journals could refuse to publish the work. Thus, when faced with the threat of this consequence as a result of unacceptable research methodology, researchers were more inclined – if they had not been previously – to ensure study protocols followed the codes set out in the Declaration (Shamoo, 2001;Whittaker, 2005).

Both the Nuremberg Code and the Declaration of Helsinki represented significant advances in protections for human subjects involved in health research, but still unethical research occurred. Despite minimal publication requirements, little effort was made to prohibit unethical occurrences, or even to ensure that research was conducted in accordance with such guidelines. The Declaration of Helsinki lacked influence as a document, drawing its authority only from the degree to which it was codified in and influenced national or regional legislation and regulations (Fluss, 1999; Human & Fluss, 2001). In fact, it took a series of highly publicized critical events – the Thalidomide study which caused significant harm to the unborn children of the pregnant women who participated, the Willowbrook study wherein many children were purposefully infected with the hepatitis virus, and perhaps the most well known, the Tuskegee Syphilis Study – to elicit true change. This moment for change would begin to transform the relationship between human subjects and other stakeholders involved in research, and eventually lead to greater protections for human subjects involved in research against exploitation, abuse and undisclosed harm.

1.3 *Tuskegee Syphilis Study*

The Tuskegee Syphilis Study funded by the U.S. Department of Health was perhaps one of the most influential studies to change public perceptions of research (Corrigan, 2003; National Institute of Environmental Health Sciences [NIEHS], 2007; Whittaker, 2005). This particular study spanned a total of 40 years, ending quite recently

in 1972. It carried on throughout the duration of the Nuremberg Trials, well past the Declaration of Helsinki in 1964, and even continued through 1942 when penicillin became available as a cure for syphilis (Canadians for Health Research [CHR], 2006).

Essentially, the intent of the Tuskegee Syphilis study was to examine the progression of untreated syphilis. Investigators knowingly recruited an impoverished group of black men in Tuskegee, Alabama to participate in this study in exchange for enticements such as free meals, medical services and payment of burial and funeral expenses (Haack, 2006; NIEHS, 2007; University of Virginia Health Sciences Library [UV], 2006). Frequent and serious violations of ethical standards occurred throughout the study's progression and at many different stages in the research, the most profound of which was the complete disregard for the process of informed consent. The human subjects in this study were not adequately informed about their illness, study purpose and procedures, or even the non-therapeutic nature of the study. They were also not informed about standard care and available therapies that could improve their illness and were even mislead and denied treatment when penicillin, a cure for syphilis, finally became available (Haack, 2006; NIEHS, 2007; UV, 2006). As a result of untreated syphilis, most of the research subjects developed serious complications and also passed the disease onto their spouse and children, many who later developed congenital syphilis (UV, 2006; White, 2000).

One piece of the Tuskegee Syphilis study that is rarely discussed is the importance of the role of the research nurse, Ms. Eunice Rivers throughout the study. As one of the only people to work the total duration of the study, Ms. Rivers was a perennial fixture and actively participated in negotiations to keep human subjects enrolled in the

study. The role of Ms. Rivers, as with research workers more broadly, is complex, with multiple relationships that can extend in more than one direction and to more than one individual. While some of these wider relationships may not be formally recognized, research workers often undertake much of the social interactions that occur – both socially and in direct context to research procedures – at pivotal points throughout research participation (Davis et al. 2002; Kaufert, Kaufert & LaBine, forthcoming; McDonald, Townsend, Cox, Damiano-Paterson & Lafreniere, 2008; White, 2000). Essentially, Ms. Rivers was the "face" of the research study to the group of research subjects who took part in the Tuskegee research study, acting as liaison between the men involved and the study doctors conducting the research. In fact, she was a key player from the beginning of the study right through to the end, and was thought to have played a key role in sustaining subjects' continued participation the 40 years the study spanned. Over time, Ms. Rivers developed a rapport with the subject population and their families. In turn, the relationships she developed were very important to the researchers who relied on her, and particularly her trusted status within the community, as well as her intimate knowledge of the subjects and their families, to help recruit, consent and retain study participants and maintain compliance with research procedures (Smith, 1996).

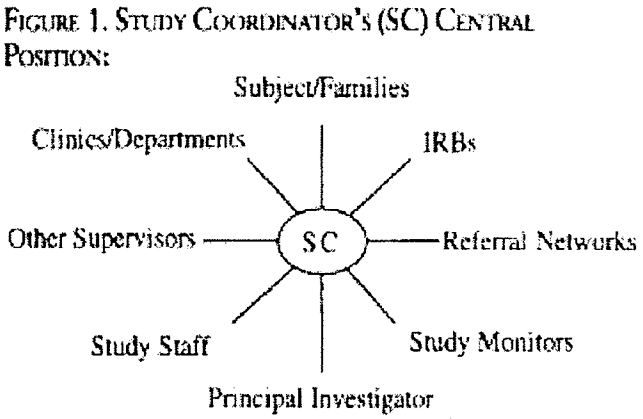
To be fair, the situation of Ms. Rivers was that of an African American women working in the 1930s under the direction of white male doctors and researchers. Thus, her working conditions and relationship to her employers were subject to prevailing inequalities, power disparities and politics of the time. So, while Ms. Rivers could not have been expected to either alter or influence the study in any substantial way, her situation does call attention to the important role of research workers, and the ways in

which they shape the ethical conduct of research through interactions and encounters with human subjects. Additionally, this example draws parallels to the power differentials that still endure even today between research workers and others situated in the research milieu, including researchers, doctors, REB members and even policy-makers, and the ways in which such relationships can impose on the actions of research workers (Cantini & Ells, 2007; Hill & MacArthur, 2006; Priest, Segrott, Green & Rout, 2007; Schafer 2004). Although a discussion of the motivations and conditions of Ms. Rivers' involvement in the Tuskegee Syphilis study will not be discussed at length here, an important issue, which relates to this research project, is that the role of Ms. Rivers, as with others involved in research at many different levels, is complex (McDonald et al., 2008; Kaufert et al., forthcoming). The complexity of the position, and focus on the centrality of the research worker particularly at the time of consent, is depicted in a 2002 publication illustrating how multiple relationships can often extend or pull from more than one direction (see Figure 1); however, it is important to note that all individuals, not just the study coordinator or research nurse, play an important role in human subject protections for research and have a unique perspective to contribute.

Despite the fact that research workers are central to research as it happens in practice, there is relatively little scholarly literature that focuses on the role of various health research workers including, research coordinators, nurses, interviewers, translators and interpreters, particularly as it relates to the process of informed consent, which is the first point of contact between research workers and human subjects. In fact, their role and subsequent impact on the process of informed consent is one that is often over-looked or underestimated by regulators, the REB and others at the institutional level

(Davis et al., 2002; Hill et al., 2006; Huntington & Robinson, 2007; Kaufert et al., forthcoming). Given their centrality and varying degree of visibility to the principal investigator(s) and human subjects within the research study, research workers are ideally situated to provide some interesting insight into some of the ethical, contextual and other practicalities of negotiating informed consent. An integrated approach that elicits varied perspectives of all individuals involved in human subject research to explore their relationships, dynamics and unique perspective is relevant as a means to more fully understand its impact on the real-life practicalities and limitations associated with human subject protections, and specifically, the process of informed consent. Thus, this research project, which will explore this and the way in which the roles of various players influence and coalesce within the context of the consent process, makes a valuable contribution to the literature.

Figure 1: Key Location of the Research Professional[5]



[5] Davis et al. (2002). The Invisible Hand in Clinical Research: The Study Coordinator's Critical Role in Human Subject Protection. *Journal of Law, Medicine and Ethics*, 30(3), 411-419

The Tuskegee syphilis study had many serious consequences for participants as well as their families; yet, much of the ethical misconduct remained undisclosed. This all changed in 1966 when Henry Beecher published an article in the *New England Journal of Medicine*[6] describing the Syphilis study along with at least 22 other examples of ethical impropriety in research. These examples became the first public admonition that such behavior, whether intentional or not, was frequently occurring and furthermore, reputable researchers were not free from conduct that placed social interests, and/or professional ambitions ahead of the interests of the human subjects (Moreno, 2001)

In the wake of these and other media disclosures, attitudes towards research participation and even researchers themselves began to shift; it became evident that something needed to be done at the policy level. Since most of the funding for biomedical research, as well as social sciences research came from the federal government, "it was clear that federal action was needed, if only for the protection of the government agencies involved in research" (Whittaker, 2005, p.518).

1.4 *The U.S.A. and the Belmont Report*

The U.S. federal government responded to the Beecher exposé with a series of congressional inquiries to investigate the Tuskegee study along with other questionable research, and as a result, the Tuskegee Syphilis study closed in 1972 (Doyal & Tobias, 2000). Despite this response, there still was a genuine reluctance on the part of

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[6] Beech HK (1966). Ethics and Clinical Research. *New England Journal of Medicine*, 274 (24), 1354-60.

government to take action and develop a more active role in research governance and ethical regulation. For the most part, governments did not want to "take on the task of interfering in the activities of the medical and academic communities" (Whittaker, 2005, p.518) because the conventions that guided professionals had long been left to the professional licensing bodies to sort out. Development of stricter mandates to govern research involving human subjects was initially viewed as a challenge to professional control over the creation of medical knowledge and academic freedom. And as Whittaker (2005) notes, past "certitude about knowledge and the sacred dictums of academic freedom have permitted the belief that every scholar has the right to pursue individually chosen projects, unfettered, uninterrupted and uncriticized" (Whittaker, 2005, p.521); however, pressure from the public, media and groups of concerned academics helped force the issue. So, in 1974 the U.S. Congress passed the National Research Act [NRA], which essentially allowed federal agencies to develop and enforce human research regulations (Blustein, 2007).

The U.S. government put together a Commission for the protection of human subjects in biomedical and behavioral research with the task of identifying key ethical principles considered essential for research involving human subjects. The Commission sought to develop ethical standards that could be used to guide researchers, funding agencies and other key players, but perhaps more importantly, assure that human subjects involved in research would be treated in a manner that was in accordance with these ethical principles (Bayer et al., 2004; Haack, 2006; Whittaker, 2005). This last point was particularly important given that surfacing reports of ethical misconduct in health research had started to take its toll. The general public was growing increasingly hesitant

to participate in research, and without study participants, research is unable to advance. "That 'medical progress is based on research which ultimately must rest in part on experimentation with human subjects' is an a priori" (Corrigan, 2003, p.85). Currently as it stands, African Americans tend to be under-represented in research, which is undoubtedly influenced by the events of Tuskegee and sentiments of distrust and betrayal that still linger today (Fouad "et al.", 2000; Halpern, 2004; Wailoo, 2004). In time, it became evident that a reliance on professional codes, or self-regulated processes that had been employed in the past was no longer appropriate (Bayer et al., 2004; Burgess, Brunger, Asch & McDonald, 2000; Dresser, 1999).

In 1979, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research released a compilation of ethical principles, which came to be known as the Belmont report. This Report identified three major principles including, autonomy, beneficence and justice, and consequently, all future research would be assessed ethically in terms of these prescribed principles (Blustein, 2007; Doyal & Tobias, 2000; Gillon, 1994; Oakes, 2002). In particular, respect for persons, which acknowledges persons as self-governing, is the moral obligation to respect the attitudes and decisions of autonomous agents, who are capable of deliberation. For research involving human subjects, this principle requires that human subjects enter into research voluntarily and with adequate information. That is, prior to research participation, potential subjects are to be provided with information, which is intended to help them understand the purpose of the research, what it entails and its foreseeable risks and benefits so that they can make an informed decision to either refuse or consent to research participation. Respect for persons requires that subjects, to the degree that they

are capable, be given the opportunity to choose what shall or shall not happen to them, and generally this is thought to be fulfilled when adequate standards for informed consent are satisfied (Levine, 1986; Macklin, 1999; NIH, 2009).

Informed consent for research is a formal process that requires researchers to develop a comprehensive account of the "elements of informed consent" for presentation to prospective research subjects (Interagency Advisory Panel on Research Ethics, 2008; Levine, 1983). The process of securing informed consent is characterized by three key elements: information, comprehension and voluntariness. In order to be considered appropriate and valid, consent for research, should be fully informed, voluntary, and given by a person with an adequate ability to make the decision at hand (however special allowances may be permitted wherein decision-making capacity is compromised[7]). The last element, perhaps the most controversial, has typically been referred to as decision-making, decisional capacity, or competence, and the nature and possibility of an informed consent for some populations and under certain circumstances is still debated. Nonetheless, it is essential that the process of informed consent insures that research subjects receive enough information on which to base their initial decision to participate as well as their continued decision to participate in a study, that the consent is completely voluntary and has not been forced in any way (Dresser, 2001; Interagency Advisory Panel on Research Ethics, 2008; Gillon, 1994; Levine, 1986; Macklin, 1999; NIH, 2009).

The development of the ethical principles set out in the Belmont report also set the stage for the implementation of the Research Ethics Board [REB], since standards

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[7] For those individuals who are legally incompetent, cognitively impaired, those who once were capable but now have diminished capacity (e.g., individuals with Alzheimer's disease) or compromised (e.g., individuals who are unconscious), a proxy or authorized third party may be permitted to give permission or authorize participation on behalf of the incapable individual; however, only competent and capable persons can provide informed consent for research participation.

upon which to assess a study's ethical adherence were now available and compliance was expected (Oakes, 2002). "The principal mandate of these committees was and continues to be the review of proposals to carry out research on patients or healthy volunteer subjects within the medical environment" (Corrigan, 2003, p.81). Additionally, ethical approval by the REB became a requirement of any research study that took place within a government institution, or received government funds in the form of grants (Buchanan, 2006; McDonald, 2000; Resnik, 2001; Whittaker, 2005). In this way, the ethical principles sanctioned in the Belmont report garnered more attention from the research community, and carried more weight than some of the policies that had come before. Even today, these ethical principles are influential and continue to guide ethical research, not only in the U.S., but also in Canada and internationally.

1.5 *Canada and the Tri-Council Policy Statement*

In Canada, the development of ethical regulations has been somewhat different; however, instances of misconduct that occurred in research were very similar to the U.S. experience. Perhaps one of the more prominent examples of research misconduct that involved a breakdown at the level of informed consent was that of *Halushka v. University of Saskatchewan et al.*[8] This particular example was important because it was one of the few cases that set legal precedence and established that the standard for consent in research is much stricter than that for clinical therapy (Pullman, 2001). As a student at

[8] *Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) [hereinafter *Halushka*].

the University of Saskatchewan, Walter Halushka signed a consent form authorizing his participation in a clinical research trial to test a new drug; however, the information conveyed to Halushka both in the consent form and by the research team failed to inform him that little information was known about this new drug, and therefore the resultant probability and nature of any of unknown risks, as well of the exact procedures that participation in the study would entail. As a direct consequence of his participation in research, Halushka suffered a complete cardiac arrest and some long-term brain damage, which resulted in permanent diminished mental capacity (Pullman, 2001, p.115). From the ruling in this case, the 'reasonable persons' standard became the standard for informed consent, wherein full and frank disclosure of information about the study must be given in such a way that human subjects have an "informed understanding of, and appreciation for, that to which he or she is asked to consent" (Pullman, 2001, p.117).

A second, and more recent example involved the case of Weiss v. Solomon[9] (Freedman & Glass, 1990). In this particular case, the family of a research subject successfully sued the principal investigator and the university-affiliated hospital, when their family member suffered a cardiac arrest and died taking part in a non-therapeutic research study. The court ultimately found the principal investigator and the university-affiliated hospital liable, attributing some of the liability to the fact that the Research Ethics Board [REB] failed to ensure that the consent form used was appropriate. In fact, the consent form approved by the REB for this research study was determined by the Court to be deficient because it did not disclose a rare but fatal complication. Thus, similar to *Halushka*, the Weiss case again supported a higher standard of informed

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[9] *Weiss v. Solomon* (1989), 48 C.C.L.T. 280, A.Q. no. 312 (QL) (Que. S.C.)

consent for research involving human subjects, which entails disclosure of all known risks including those that are rare or remote, and especially if they may entail grave consequences (Freedman & Glass, 1990; Glass & Freedman, 1991; Shaul, Birenbaum & Evans, 2005).

Another and perhaps one of the most infamous examples of research misconduct within the Canadian context is that of Dr. Ewen Cameron, a psychiatrist at the Allan Memorial Institute in Montreal. Between 1950-1964 Cameron enrolled many individuals – without their consent or knowledge – in a research program subsidized by the Central Intelligence Agency [CIA] along with the Canadian federal government, which subjected human subjects to electroshock therapy, sensory and sleep deprivation, drug-induced comas, LSD dosing and other experimental drugs (Johnson, 2009; Raymont, 2008). Essentially, Cameron's research focused on methods labeled 'de-patterning' or 'psychic-driving', wherein the objective was to erase portions of the human subjects' personality and replace or 'program' it with other character traits and/or attitudes. As a result of involvement in this research, nearly all the human subjects suffered long-term, harmful effects, and many were reduced to a 'childlike state' (Raymont, 2008). It wasn't until 1988 that the CIA provided compensation to those who suffered abuse as a result of Cameron's research. The Canadian government, however, did not provide reparation until 1994, and even then, only 77 individuals (or those believed to be the most affected by their involvement in Cameron's study) received compensation; approximately 250 others did not receive anything despite the long-term consequences and impact this study had on many unsuspecting human subjects (Raymont, 2008). So as evidenced by the

preceding examples, while Cameron's work was perhaps the most notorious case of research misconduct in Canada, he was hardly alone.

Canada's first attempt to introduce formal controls with respect to research ethics occurred in 1978 when the Medical Research Council of Canada [MRC], now known as the Canadian Institutes of Health Research [CIHR], Natural Sciences and Engineering Research Council [NSERC] and Social Science and Humanities Research Council [SSHRC] each issued separate guidelines, which were based on the Belmont Report and other international codes of ethics (Boulton & Parker, 2007; CHR, 2006; Government of Canada [GC], 2008). The motivation to introduce formal guidelines for research involving human subjects was precipitated as a result of the errors in judgment and research practice that occurred, even when support for the research was provided by one of the three major funding bodies. So while the introduction of formal guidelines may not have directly evolved from the specific research improprieties outlined previously, there was, nonetheless, an overall concern about research misconduct in Canada that precipitated this move.

Regulation of ethical research was initiated at the federal level, which set up the Tri-Council Working Group in 1995 as part of a larger initiative aimed at transforming research in Canada. In 1998, the three major federal granting agencies, "each originally created by an Act of Parliament and therefore, responsible to that body" (Whittaker, 2005, p.518), jointly published the Tri-Council Policy Statement [TCPS] on Ethical Research Involving Humans, as a single standard document to be used by REBs to assess the ethical feasibility of research across Canada (Boulton & Parker, 2007; CHR, 2006; Doyal & Tobias, 2000; GC, 2008). The document, published in 1998, was the final

version of a four-year collaborative process that produced three draft versions in the interim. When CIHR, NSERC and SSHRC adopted the Tri-Council Policy Statement, they committed to keeping it a living document, which meant that it would be subject to continued re-evaluation and revision in order to respond to new developments and identified or emerging gaps (GC, 2008).

As a living document, the principles emphasized in the TCPS reflect varying shifts in social structures at both the political and contextual levels of society at a given time. Indeed, the implementation and requirement of REB approval was an integral part of the emergence of a new research culture in Canada and elsewhere. Essentially, the REB became a gatekeeper and thereby responsible for taking the generally accepted views of society, reflected in the ethical principles of the TCPS, and turning them into workable canons to which research should adhere (Corrigan, 2003; Lunstroth, 2007; Whittaker, 2005). This process is, for the most part, subjective and researchers, REBs and even the public at large interpret the guidelines set out in the TCPS. As such, the application of these principles is subject to changes in ethical discourse within disciplines and society in general (Halpern, 2004; Loh, Butow, Brown & Boyle, 2002; Lunstroth, 2007; Whittaker, 2005).

In addition to articulating ethical norms, the TCPS outlines standards and procedures for research, and is applicable to those conducting, reviewing and participating in research of any kind. Whereas previously, all three major funding agencies of Canada had their own codes of ethics, the goal in creating the TCPS was to generate over-arching ethical codes that would be applicable across all disciplines. Therefore the move to create the TCPS, as a single set of standard ethical guidelines was

threefold: 1) to advance the protection of human subjects; 2) to enhance accountability; and 3) to restore and improve public trust in research and oversight procedures.

Development of the TCPS as a single set of ethical guidelines was not a simple task and initially, it met much resistance. One of the most challenging undertakings involved reconciling differences between biomedical and social sciences and humanities interpretations of ethics in research. Qualitative research approaches, often favored by those in social sciences and humanities, are grounded in different assumptions than those that shape biomedical models of research (Interagency Advisory Panel on Research Ethics, 2008). So, while biomedical interpretations tended to focus on rigid procedures related to confidentiality, privacy and informed consent for each individual study participant, the social sciences and humanities tended to take a much broader approach to the timing and scope of consent, incorporating notions of community consent and/or emphasizing consultation with groups, the development of relationships and participation and/or input of study populations. Further adding to the complexity of reconciling the two approaches was the recognition that the issues relevant to public health and social sciences research were not always equivalent to the issues that present in biomedical research. There was a lack of congruence between the set of codes that were intended to guide all three major funding agencies. Consequently, the first draft of the guidelines, which circulated in 1996, generated much criticism from the research community who felt that numerous methodological concerns were neither fully understood nor properly acknowledged. Thus, between 1996 and 1998, two more drafts of the TCPS were circulated but several sections including those related to research involving group, community or First Nations consent, or assent for research with children, still were not

yet well defined (Beauchamp, Faden, Wallace & Walters, 1982; Interagency Advisory Panel on Research Ethics, 2008; Kaufert, Glass, Freeman & LaBine, 2004; Miller & Boulton, 2007; Murphy & Dingwall, 2007).

Suggestions for revisions to the TCPS not only came from the research community, but the public, and more specifically advocacy groups for people living with HIV/AIDS and women with breast cancer, also expressed their concerns. These groups pressed for consumer and marginalized group rights, and wanted a greater say in how research dollars were spent and how research was conducted. First Nations groups also began to demand greater control over the content, process and outcomes of research, particularly when an identifiable group or community was the primary focus of the research question (Kaufert et al. 2004; Halpern, 2004). Currently, the Interagency Advisory Panel on Research Ethics [PRE] is undergoing consultations for revisions to the 2nd Edition Draft of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans published December 2008 (GC, 2008). This draft is the first attempt at a much more comprehensive set of revisions to the TCPS since its adoption in 1998. The revisions try to address some of the previously identified concerns and gaps, and include new chapters specific to research involving Aboriginal Peoples, qualitative research, as well as updated guidelines pertaining to newer issues for research with human tissue, genetics and stem cell research (Interagency Advisory Panel on Research Ethic, 2008).

As it now stands, there are several key components central to the TCPS that all research is expected to meet, including the core principles of respect for autonomy, respect for the equal moral status of all humans and concern for welfare. As such,

research must take into account issues related to justice and inclusiveness of subjects, and find ways to balance harms and benefits – minimizing harms and maximizing benefits – but above all, respect for human dignity should be the moral and ethical foundation (Doyal & Tobias, 2000; Interagency Advisory Panel on Research Ethics, 2008). The key principles outlined in the TCPS are not novel, and in fact comply with international standards already established by the Nuremberg Code, Declaration of Helsinki and the Belmont report. This however, was done intentionally to impart a sense of relevance and universal applicability (Brewster-Smith, 2000; Corrigan, 2003; Levine, 1986). Thus, the TCPS is intended to be universal both across disciplines and in function; nevertheless, the guidelines are based on Western liberal conceptions, in which individual informed consent figures prominently.

2.0 CHAPTER 2: Informed Consent in Current Research Practice & Ethical Oversight

Perhaps the most familiar of all ethical requirements, informed consent "has become the sine qua non of ethical practice in medical research involving human participants" (Boulton & Parker, 2007, p.2187). Historically grounded in beliefs about the dignity and worth of every individual and out of respect for the freedom of choice following the horrific events of Nazi Germany, this requirement was established as a right of all people who were to participate in research of any kind (Corrigan, 2003). The process of informed consent, which begins prior to research participation, is often the research subjects' first introduction to the research, study procedures as well as the first point of contact with investigator(s) and/or research workers. An important piece of the process is the consent form, which is ideally intended to clearly define the relationship, mutual expectations and the limits specific to the researcher/research team as well as that of the prospective research subject (Levine, 1986). While, currently there has been much attention given to the notion of securing the written consent of a potential research subject, the revised draft of the TCPS (December 2008), similar to earlier versions, emphasizes that free and informed consent involves more than simply documentation of the agreement, or a signed consent form.

> Consent encompasses a process that begins with the initial contact and carries through to the end of – and sometimes beyond – the involvement of research participants in the project… the process of informed consent refers to the dialogue, information sharing and general process through which prospective participants choose to participate in research (Interagency Advisory Panel on Research Ethics, 2008, p.26-27)

Formally, a valid informed consent process must incorporate four essential elements. "It must be competent (legally), voluntary, informed, and comprehending (or

understanding)" (Levine, 1986, p.98); however, more recent depictions typically characterize the process as giving prospective participants the facts they need to make an informed choice about study enrollment (Dresser, 2001; 1999; 1996).

The importance of the requirement for informed consent in health research cannot be overstated. Protection of human subjects is an essential aspect of research conduct and undoubtedly, informed consent plays a central and important role in that process; yet, as Ferreira Bento et al. (2008) note, obtaining informed consent should not be restricted to an act that occurs at one specific point in time, for example, the signing of the consent form. Rather, this process demands substantial time and effort on the part of the investigators, research workers and potential human subjects. Although current standard practice and ethical review has been "front-end" and paper-based (McDonald, 2000), placing much emphasis on signing of a consent form and the document itself, consent can be evidenced in many legitimate ways. In fact, it is a more complex consideration wherein "the primary focus of ethical concern should be on the quality of consent, and not how it is documented" (Interagency Advisory Panel on Research Ethics, 2008, p.21).

There is almost universal agreement about the significance of consent in research today; however, critics assert that a single set of guidelines cannot adequately reflect the breadth and depth of issues that arise from diverse research paradigms, designs and/or target populations (Boulton & Parker, 2007; Corrigan, 2003; Glass & Kaufert 2007; Tu "et al.", 2004). While researchers may not have trouble addressing some of the more general risks of research participation and addressing some of the broad or more common concerns regarding the goals of research in the consent form, it can be much more difficult to predict the concerns of each particular research subject in order to address

such concerns adequately (Wendler & Grady, 2008). Furthermore, consent agreements describe increasingly complex methodologies and interventions, which challenge even the most educated individuals to fully understand what is being asked of them, and what they are agreeing to by giving their consent for research participation (Ferreira Bento, Hardy & Duarte Osis, 2008; Koski, 1999). Ethical guidelines list the elements that potential participants should be informed about; yet, there is still a great deal of room for interpretation about the information that should be disclosed in this regard (Wendler & Grady, 2008). Moreover, research developments and advances in emergency medicine, genetic research and tissue banking, community and/or participatory research have sparked a renewed critical focus on informed consent guidelines and requirements (Boulton & Parker, 2007). There are numerous unresolved issues and limitations associated with conventional informed consent requirements in many areas of health research, yet there is still an expectation of compliance.

In an annotated bibliography of empirical research on informed consent for research and clinical practice, in which a total of 377 articles, incorporating 3,173 hypotheses were included in the review, Sugarman et al. (1999) found that most studies focused on disclosure and understanding; so, the type of information provided, the way it was conveyed as well as human subjects' comprehension and recall of information presented. Relatively few studies examined issues related to how informed consent is obtained, or who obtains consent. Of those empirical studies specific to health research that did focus on this issue, most centered on documentation or the consent form – whether consent forms were presented and signed by potential participants – and not on the process of informed consent or the quality of this process. Two notable exclusions to

this generalization include one study that found that the task of obtaining consent was not ascribed to the Principal Investigator [PI] but rather was delegated to research worker(s). Perhaps more interestingly, this study went on to further conclude that the PI(s) had little knowledge of the interactions that occurred between potential participants and research workers or the practicalities of this encounter (Appelbaum & Roth, 1983). The second was a landmark study conducted by the National Commission for the Protection of Human Subjects, wherein extensive interviews were conducted with REB members, researchers and human subjects. At its conclusion, the study found that consent forms were the focus of REB scrutiny and review; however, such scrutiny was contained to the preliminary stages of research since the REB had virtually no influence over the way consent was obtained in practice, who obtained it, or the setting and circumstances in which informed consent was obtained (Gray, Cooke & Tannenbaum, 1978). As a result of this systematic review, the authors conclude that there was still much "uncertainty about how or whether meaningful consent is achieved in practice, and what practices help enhance... meaningful consent to participation in research" (Sugarman "et al.", 1999).

More recent literature has been similarly varied and reflects many of the same issues identified in the annotated bibliography by Sugarman et al. (1999). Concern over the limits of informed consent, and the ability of human subjects to take in and recall information provided in consent forms, have incited interest in defining, measuring and enhancing consent-related decision-making; however most studies, confirming earlier conclusions by Sugarman et al. (1999), reveal gaps in knowledge about the process of informed consent, or even how understanding can be improved (Beardsley, Jefford & Mileshkin, 2007; Eyler & Jeste, 2006; Flory & Emmanuel 2004; Sudore "et al.", 2006;

Wade, Donovan, Athene Lane, Neal & Hamdy, 2009). Yet at the same time, the discourse around the process of informed consent has also expanded to respond to new developments and emerging gaps. For example, new technologies and rapidly expanding areas in the field of biobanking have rendered it difficult to anticipate the risks and benefits of long-term research in an area where new research questions emerge frequently. As a consequence, consent for such research may be both competent and voluntary, but human subjects (and even those conducting the research) cannot gain a complete understanding of all, and particularly future, aspects of the research project because most "biobanks do not know what [research] risks or benefits may be; they do not even know what the research topics will be" (Greely, 2007, p.357). While this may seem a common dilemma for research more generally, the issue with biobanks has been that of "blanket consent" wherein human subjects receive only the broadest descriptions and/or minimal information about the specific research that will be done with their samples, and they do not have any real control of how their materials will be used, or for what projects (Clayton, 2002; Greely, 2007; 2001). Thus, the notion of informing and the extent to which consent is *informed* is challenged in such circumstances. While at the same time, there is also recognition that requiring full understanding in such cases would effectively preclude the use of biobank samples for valuable research purposes.

Research in the field of biomedicine and genetics in particular, further challenge traditional notions of consent, given that such research can, in many cases, have implications for individuals, families, groups and/or communities beyond those who give their consent for research. That is, discovery of genetic predispositions or disease markers could potentially bring substantial financial harm or social stigmatization, for

example, not only to the particular individual who consents but also to any unsuspecting but genetically similar family member(s) (Greenbaum, Du & Gerstein, 2008). Such dilemma's draw attention to the theoretical underpinnings of the principle of informed consent, and an emphasis on autonomy, which reflects the increasing centrality of individualism within Western liberalism (Corrigan, 2003).

Similarly, community-based research involving Aboriginal Peoples, including First Nations, Inuit and Métis have helped to expand notions of informed consent beyond the individual. So, although research with Aboriginal Peoples must adhere to the provisions for free and informed consent set out in the TCPS, there are additional provisions for group and community engagement. The newly revised draft of the TCPS acknowledges that protections for communities are both legitimate and necessary in addition to the protections granted to individual research subjects, based on the dilemmas presented in the following example. Suppose a research study proposes to identify an infectious but not particularly contagious disease amongst an identifiable and perhaps even marginalized community. The community may even welcome such research, particularly if the disease burden amongst community members seems high and the research results and/or subsequent therapies would be accessible to community members. Such a study may pose little if any risk of harm to *individual* participants, particularly if individual identifiers are removed and individuals themselves cannot be linked directly to the disease; nonetheless, the *community* that is the target of the research may be exposed to substantial risk of harm. For example, depending on numerous factors such as the nature of the disease to be identified or prevented, how the disease is contracted, and the nature of the targeted community, research results may harm the community abetting

prejudice towards the community and/or exacerbating discrimination and stigmatization, perhaps even rendering it harder for individuals associated with the community to marry, get insurance, find work, and so on (Clayton, 2002; Freeman & Romero, 2002; Greely 2001; Kaufert et al. 2004).

The above account highlights one of the central concerns with ethical paradigms that stress individualism; namely, in addition to individuals, communities may be the subject of harm and accordingly, such communities may have unique interests that are distinct from those of the individual that also require ethical consideration. Moreover, even when the rights and entitlements of each individual research participant are respected, Weijer et al. (2004) notes "...protections for individual subjects do little in and of themselves to protect or show respect for the community" (Weijer & Miller, 2004, p.11). Ostensibly some research has risks and benefits that impact the whole community in ways that may interact with, but are not necessarily identical to, the impact on each individual who consents to participate in research (Greely, 2001). Yet in light of this recognition, under no circumstances should community consent constitute individual informed consent to participate in research, and the TCPS goes on to note that "researchers should be sensitive to the possibility that an individual's decision to participate or withhold participation in research may be constrained by group influence" (Interagency Advisory Panel on Research Ethics, 2008, p.98-99). So, while individual informed consent remains important, slowly recognition of other paradigms is becoming more acceptable.

In addition to research involving Aboriginal Peoples of Canada, researchers are undertaking more research internationally, which can involve balancing ethical policies

and procedures required for research in Canada with rules applicable in the host country or institution. Differences in worldviews, interpretations of concepts and understandings of health and illness can all play an important role in how individuals interpret consent and view participation in health research (Jegede, 2008; McDonald, 2001). Although in some countries or even some types of research, formal frameworks or requirements for ethical research do not exist, there is a growing awareness that the principle of informed consent, which emphasizes written consent by means of a signed consent form, may not be universally applicable across all jurisdictions. Accordingly, the TCPS acknowledges that other means of consent, such as verbal agreement or a handshake (Interagency Advisory Panel on Research Ethics, 2008, p.36) are appropriate in cultural settings where written documentation is contrary to prevailing norms (Bolhm & Simon, 2008; Interagency Advisory Panel on Research Ethics, 2008). Thus, there seems to be a gradual shift towards consent as a process, which focuses on communication, understanding and relationships, and a slight relinquishing of the focus on the signed consent form as the only legitimate source of formal documentation.

The role of written information within the process of informed consent has been raised in other contexts as well. In a recent article published in *Social Science & Medicine*, Dixon-Woods et al. (2007) comment on the complexity of the relationship between "informed" consent for research participation and the role of consent forms, and argue that human subjects make sense of information given to them about research, and specifically the content of written information in the consent form, in complex and unexpected ways (Dixon-Woods "et al.", 2007, p.2219). Within the article, it is suggested that the failure of human subjects to correctly interpret information provided in

consent forms should not necessarily be attributed to poor readability of the printed materials or (reading) incompetence, but perhaps, "the process of meaning creation occurs when the text interacts with people's own meaning systems" (Dixon-Woods et al., 2007, p.2219). That is to say, human subjects' understanding of research may not be defined solely by the information that is contained in the consent form. There may in fact be other values, such as informal reasoning about trust, participation and relationships that may also influences informed decision-making and the process of negotiating meaningful consent. So for example, as a result of their study Dixon et al. (2007) discovered that human subjects absorb and interpret more information than simply that which is described in the consent form. The authors note that perceived professionalism of research workers during the consent process and the presence of institutional logos on the consent form both factored into human subjects' decision to participate, and contributed to feelings of confidence in the study. Thus, consent procedures do have an impact on the decision to participate in research; however, such decisions are not always as dependent solely on the information given in the consent form, as is commonly thought. In conclusion, the authors call for further research that explores the ways in which human subjects interpret information given to them during the process of informed consent, and the other factors or values that contribute to their understanding of this process.

Claims highlighting the social aspect of decision-making, the importance of interpersonal relationships and its influence on choice are not new. In fact, critics have argued that a primary focus on autonomy and individual rights, strip away context and as a result, have left little room to explore some of the wider social aspects that might also

influence decision-making (Corrigan, 2003; Jegede, 2008; Kim, 2005; Miller & Boulton, 2007). In particular, Corrigan (2003) has argued that such traditional approaches ignore "...the cultural context within which the process of informed consent takes place" (Corrigan, 2003, p.770). In a qualitative study looking at how the process of informed consent is experienced by participants in a clinical drug trial, Corrigan concludes that there is an increased need for more socially nuanced concepts of autonomy and consent. And while she does not go so far as to claim that perhaps extenuating circumstances, such as interactions with research workers obtaining consent for example, play a role in human subjects' decision to participate in research, she does admit that "decisions do not take place in isolation" (Corrigan, 2003, p.777). Relational ethics shifts the focus away from the rights and responsibilities of the autonomous individual to a more relational approach wherein "decisions are made in the context of their environment" (Larkin, 2008, p.235). Similarly, Felt et al. (2009) advocate for a more relational approach to autonomy, which centers on social contexts and understanding the ways that varied contexts impact both potential participants' ways of knowing and the decisions that they make. The authors here criticize an emphasis on the provision of information via the consent form, and the importance placed on this practice within the context of informed decision-making. Likewise, such criticisms also extend to the REB and the process of ethical review, which to date, has centered on the formal consent document. Such an emphasis, it is argued, leads to bureaucratic reductionism and trivializes the process of informed consent.

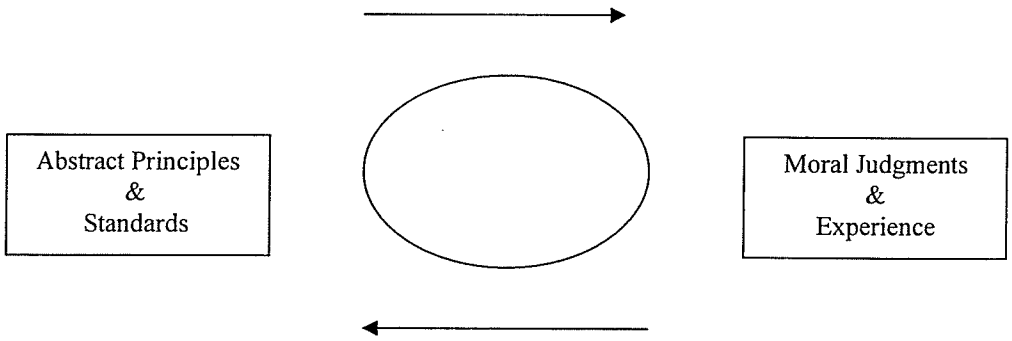
In *The Governance of Health Research Involving Human Subjects* prepared for the Law Commission of Canada, McDonald (2000) and his co-authors provide a comprehensive description and analysis of Canadian oversight for health research

involving human subjects. The report uncovered several unsettling trends, of which the REBs overemphasis on consent and focus on the review of the consent forms, figured prominently. Although McDonald (2000; 2001) recognizes that this focus is understandable given time and workload constraints of the REB, it still remains problematic that "informed consent is all too often reified into a paper form" (McDonald, 2001, p.11). Such a narrow focus on the consent form fails to recognize consent as a process, or one, as the TCPS indicates, that "begins with the initial contact and carries through to the end of – and sometimes beyond – the involvement of research participants in the project" (Interagency Advisory Panel on Research Ethics, 2008, p.26-27). Equally troubling, there are few 'checks and balances' to ensure that research projects approved by the REB proceed according to the conditions under which they were approved. That is, REB review currently relies on "a single-shot, front-end review of research protocols", which may "bear little resemblance to the actual conduct of research and its results" (McDonald, 2000, p.297). Essentially, once a project has been approved, the REB has little knowledge of the research as it happens in practice. There are obvious gaps in research governance, and McDonald (2000) and colleagues conclude that good governance "involves the translation of collective moral intentions into effective and accountable institutional actions" (McDonald, 2001, p.5). Attempts to bridge these gaps must include "virtuous learning loops" (McDonald, 2000, p.301), or information exchange, learning and accountability processes so that those involved in research at all levels can learn from each other.

Tensions between the theoretical aspects of ethical standards and the particulars of research as it happens in practices are the focus of the discussion in a 2006 article by

Peter. The proliferation of ethical standards for research involving human subjects has renewed interest in how and whether guidelines are utilized, practiced and understood by those involved in health research. Using Rawls' conception of reflective equilibrium, Peter suggests that an appropriate equilibrium between standards and practice is achieved when "abstract theoretical principles or norms coincide with particular moral judgments" (Peter, 2006, p.20). However Peter goes on to add that theoretical principles should also be tested "against the practical world of actual moral life" (Peter, 2006, p.21). This places Rawls' concept into the practical or 'real-time' to acknowledge some of the political and social nuances that also influence actions. So, whereas guidelines for research practice are representative of the theoretical, the actual consideration and application of these principles in practice are representative of moral life. The complexity of the relationship is depicted in a 2006 publication (see Figure 2), where Peter represents this as a dialectical relationship.

Figure 2: The Relationship Between Moral Judgments & Abstract Principles[10]



[10] Peter E (2006). The Interplay Between the Abstract and the Particular: Research Ethics Standards and the Practice of Research as Symbolic. *Nursing Science Quarterly*, 19(1), 20-24.

The TCPS outlines an ethical framework, and provides guidelines with respect to research review, practice and education. It also offers guidance to interpret the principles of ethical research; however, it does not provide steadfast rules that are to be rigidly applied. The particulars, or rather how guidelines inform research practice, effectively represent the other side of the equilibrium. In addition, many of the real-life practicalities and ethical concerns of those involved in the day-to-day work of a project, and specifically research workers who are responsible for important aspects such as obtaining consent for research participation, are often not adequately addressed. As a result, Peter (2006) acknowledges the lack of published and scholarly information available about other individuals' behaviors and practice in research conduct, and identifies the need for the input of those engaged in research practice, such as research workers, in the development of ethical guidelines for research practice.

Surprisingly, very little is known about the actual ways in which research workers explain and relay information provided in consent forms to human subjects during the consent process (Albrecht, Franks &Ruskdeschel, 2005; Kaufert et al., forthcoming). Indeed, the extent to which problems with informed consent are identified and consequently, how research workers act to rectify such issues is also largely unknown (Murff "et al.", 2006). The role of research workers, which includes engaging potential human subjects during the process of informed consent, involves real-time interactions that in turn, can influence human subjects in their decision to either accept or decline research participation in research. Within this role, Huntington & Robinson (2007) argue that research workers must make "countless practical decisions that shape the recruitment encounter and the informed consent process" (Huntington & Robinson, 2007, p.6).

However, despite the seemingly central role that research workers play, as Davis et al., (2002) note, research workers "still tend to be the invisible players in much of the general …research and ethics literature" (Davis et al., 2000, p.417). Increasingly, attention is being paid to the role of the research worker, which acknowledges their current "invisibility" within the research enterprise (Kaufert et al., forthcoming). Otherwise, failing to examine the process of informed consent at the level of the encounter between research workers and potential human subjects "ensures that the process is invisible to those who regulate it" (Huntington & Robinson, 2007, p.9). This scenario leaves little room to more fully define and understand the challenges of the process of informed consent in order to learn from and assess the quality of this encounter in hopes to improve on it (Davis et al., 2002).

Recognizing the gaps that exist within current ethical review and governance structures (McDonald 2001; 2000), protections for human subjects involved in health research cannot rely solely on REB review and the provision of consent forms. Rather, it must also include explicit recognition of all individuals involved in research practice at all levels, and their expertise of the issues, problems and priorities for reform. Currently, although many individuals have moral concerns with respect to research conduct, and specifically informed consent, many do not report or even voice their concerns (Bird, 1996; "Solutions, Not Scapegoats", 2008). Bird (1996) argues that individuals are "morally silent", or fail to act on their moral convictions as a result of underlying factors at both the individual and organizational level. Factors such as fears of implication, or that they will seem ethically inarticulate, are examples of individual level factors, while the various ways that organizations block both bottom-up and horizontal communication

are institutional level factors. The problem, as Bird suggests, "is interactive" (Bird, 1996, p.191) and calls for approaches that are both far-reaching and communicative. Researchers, research workers, REB member and policy-makers need to view the process of consent as collaborative and on-going, rather than just a point in time when a decision to accept or decline research participation is made (Burke, 2005; Corrigan, 2003). Eliciting feedback from all key players could help to establish more outlets for common dialogue and perhaps, improve the way in which the needs of human subjects are met during the process of informed consent, improving the quality of consent, and thereby moving the primary focus away from formal documentation.

In light of recent and emerging issues, the research community has gained a renewed sense of interest in examining the limitations associated with informed consent. To date, very little of this interest has extended beyond the consent form. Empirical research has focused almost exclusively on the effectiveness and success of information transfer, assessing the reading level, format, and language of the consent form; however, there is a need to address some of the wider contextual issues and relationships that impact the complete process of informed consent (Bhutta, 2004; Eyler & Jeste, 2006; Flory & Emmanuel, 2004). Furthermore, this narrow focus does not engage the interactions and active negotiation of relationships that occur amongst front-line research workers, such as research coordinators, interviewers, translators and interpreters, who are directly involved in obtaining consent and facilitating understanding of the information provided to potential human subjects during the consent process. Equally as important are the alternative perspectives and role of key stakeholders involved in other important areas of the consent process including those responsible for writing and reviewing

consent forms, or creating informed consent guidelines for researchers and the REB to follow. This qualitative research initiative addresses some of the gaps and identifies key stakeholder group perceptions of the issues, problems and priorities to reform the current process of informed consent.

3.0 CHAPTER 3: Research Design & Methods

3.1 *Rationale*

Informed consent is now an inherent part of health research involving human subjects. And while recognition of its value is significant, the limitations are well documented. The literature is replete with studies that confirm human subjects rarely understand or recall information disclosed on consent forms (Albrecht et al., 2005; Bhutta 2004; Boulton & Parker, 2007; Doyal & Tobias, 2000; Eyler & Jeste, 2006; Fisher, 2006; Flory & Emmanuel, 2004; Il-Wakeel et al., 2006; Loh et al., 2002; Marshall, 2007; Sugarman et al., 1999). Consistently, ambiguity and laborious documentation are sited as the source of the problem. Comprehension is a key component of the informed consent process and repeatedly emphasized in the TCPS but notwithstanding broad agreement about the need to obtain informed consent, Sugarman et al. (1999) note:

> [T]here is still uncertainty, about how or whether meaningful consent is achieved in practice, whether theoretical understandings of informed consent are useful or practical, and what practices help enhance the possibility that patients and subjects in fact meaningfully consent to treatment or participation. These are important empirical questions. (Sugarman et al., 1999, p.S1)

The issues that encumber informed consent requirements are not exclusive to health research, and in fact, have been debated across many different disciplines ranging from bioethics to law, medicine, and the social sciences and beyond (Boulton & Parker, 2007). To date, empirical research exploring this issue has focused almost exclusively on the consent form, examining the type of information provided, the way in which it is conveyed, as well as the potential subjects' comprehension and recall of information

presented. Most of the interest has centered around defining, measuring and enhancing consent-related decision-making, and developing ways to improve the delivery of information on consent *forms*, or increasing the subject's ability to take in or manipulate data provided on consent *forms* (Eyler & Jeste, 2006).

Despite the widespread attention, attempts to improve the informed consent process and enhance understanding have been both limited and ineffective. Boulton & Parker (2007) suggest that such attempts have actually "...had the effect of both problematising traditional notions of informed consent and of leading to calls for its tighter regulation" (Boulton & Parker, 2007, p.2187). Disconcertingly, measures aimed at improvement –longer and much more descriptive consent forms, detailed standards and guidelines for researchers, the addition of legal terms, formal agreements and templates – have all been criticized as "inappropriate and ill-considered bureaucratic requirements" (Boulton & Parker, 2007, p.2188) wherein little attention has been given to the accessibility of the information, or the impact on the research and/or research subject prior to its implementation (Corrigan, 2003; Miller & Boulton, 2007; Boulton & Parker, 2007). More often then not, time and effort is afforded to the creation of guidelines and requirements. Much less effort, beyond alerting those accountable, is made to ensure there is proper understanding, support or even an adequate awareness of the changes (Kirby & Simpson, 2007). Thus, the gap between those who regulate the process of consent, and those responsible for its 'real world' application, appears to be widening.

Almost counter-intuitively, this overall sense of the limitations associated with informed consent has not impacted its central role in health research. In fact, the research community has become progressively more reliant on this process, and in particular the

consent form, as the primary measure to protect human subjects from harm that could incur as a result of research participation (McDonald, 2001; Koski, 1999; Boulton & Parker, 2007). Corrigan (2003) comments on this unsettling trend:

> Informed consent has gained increasing salience within the health care field. The need to secure a patient's fully informed consent prior to medical intervention for treatment or research purposes is increasingly heralded as an ethical panacea counteracting the potential danger of paternalistic and autocratic practices (Corrigan, 2003, p.768).

Not surprisingly, this narrow focus on the consent form has left very little room to examine some of the wider contextual issues and relationships that may also impact the process of negotiating meaningful consent. Researchers, front-line research workers, research ethics board [REB] members, scholars and policy-makers all play central yet varying roles in the consent process. Currently, there is limited literature that describes their perceptions about the key issues and priorities, or even their opinions about how to make the process of consent more meaningful overall. Given the importance and varying degree of visibility of these actors in their role, which might include (but is not limited to) regulating, obtaining and/or ensuring adequate informed consent practices, it would seem that the inclusion of these alternative stakeholders could prove a valuable contribution to the literature. New understandings of the relationships and contexts that influence the process of informed consent will help reveal the underlying logic of those involved, account for the context and the inter-play between processes, people and events as well as attempt to explain the relations between organizations, individuals and other extenuating factors. Such insights will be helpful in identifying organizational barriers and facilitators, such as perceived support and resources, as well as the real-life practicalities

faced by these varied actors involved in human subject protections, but always with an emphasis on informed consent.

In addition to new understandings, there are also unrealized possibilities for exchange amongst key players. A further strength of this project is that it engages varied actors to foster inclusion of a broad range of experiences and reflection on the relevant issues at hand. Researchers, REB members, policy-makers, scholars and front-line research workers all have expertise in different areas, but their combined knowledge could yield practical suggestions for ethical governance and improvement within existing policies and frameworks relevant to informed consent for research more broadly. Properly translated, this knowledge could prove valuable in promoting and facilitating communication, establishing methods to improve human subject protections and ensuring appropriate policies for informed consent procedures are implemented. This research project includes the perspectives of a variety of stakeholders, as a means to gain feedback and understand how to facilitate productive dialogue amongst those directly involved with potential participants as they sign consent forms, or those who are responsible for creating templates or policies that guide informed consent procedures.

An integrated approach, which incorporates the perspectives of varied stakeholders, is ideally positioned to make a contribution given that these are the individuals most likely to be charged with the task of putting policies into practice. The key is to build communication and constructive relationships amongst stakeholders in order to gain support and awareness of the ethical standards necessary to achieve a truly meaningful process of informed consent (Albrecht et al., 2005). This approach helps to identify concerns that are not always evident using a conventional top-down policy

approach, as well as ensures the voices of those who are not typically included in policy formation, are heard. Thus, this research focuses on the perceptions of those most affected by guidelines or requirements for informed consent, and could lead to a much more meaningful process of informed consent for human subjects, and a much more effective one for others also involved in health research at all levels. It could also enhance 'buy-in' of informed consent guidelines by various stakeholders involved in health research. This study looks across disciplines, sectors, and institutions, in order to respond to issues that concern individuals from a wide range of perspectives; not just those traditionally included in health-care policy creation and reform.

This research project explores the key themes and salient differences that emerged from each stakeholder group, focusing on the perceived objective of the consent process, and the barriers and facilitators of implementation. The resultant findings form the basis of recommendations to promote a much more meaningful process of informed consent for human subjects, and a much more effective one for others also involved in health research at all levels, and is based on areas for improvement and change within existing frameworks as identified from key informant narratives. This project links conceptual issues emerging from the interview data analysis to a descriptive summary of current and burgeoning issues in informed consent, and a brief chronology of events and changes that have occurred over time, including the ethical and other impacts on the process of informed consent for research involving human subjects. Overall, this research makes a valuable contribution to the literature by exploring an aspect of the consent process that is rarely discussed; namely, the impact of varied contexts and relationships on negotiating meaningful consent.

3.2 *Study Design and Sample*

This student research initiative is an exploratory study that seeks to identify, understand and reconstruct a variety of perspectives and insights about the important issues raised by human subject protection and ethical governance for research involving human subjects, but always with an emphasis on informed consent. This thesis utilizes data from in-depth, semi-structured interviews with key stakeholders and a review of published and grey literature – reports, guidelines and regulations – across disciplines.

A preliminary document search and literature review identified key issues across the social science, epidemiological, legal, ethical and health research literature. The literature review provided background and sensitivity to the issues, which in turn, helped focus data collection and subsequent analysis (McCann & Clarke, 2003). This review includes a brief chronology of major events and changes over time, as well as the ethical and other impacts on the process of informed consent for research involving human subjects.

This student research project falls within the scope of a larger Canadian Institutes of Health Research [CIHR]-funded (2005-2010) initiative between the University of British Columbia and the University of Manitoba entitled, *Centring the Human Subject in Health Research: Understanding the Meaning and Experience of Research Participation*[11] [CHSIHR] (University of Manitoba, Bannatyne Campus, Health Research Ethics Board reference number: H2006:083, linked to H2008:121; University of British

[11] Research Team: Susan Cox (Principal Investigator), Michael McDonald (Co-Principal Investigator), Patricia Kaufert (Co-Investigator), Joseph Kaufert (Co-Investigator), Anne Townsend (Co-Investigator), Sara Hancock, Lisa LaBine, Darquise Lafreniere, Toni Morris-Oswald, Natasha Damiano-Paterson, Nina Preto, Cathy Schuppli and Kim Taylor.

Columbia, Behavioral Research Ethics Board reference number: B06-0213). The overall project seeks to understand the experience of being a research subject. The goals of research are to:

a) Explore the meanings and experiences of being a human subject from the standpoint of subjects;

b) Compare and contrast the perspectives of human subjects with the perspectives and practices of researchers, REB members, policy-makers and scholars;

c) Assess the ethical and other implications of recent and emerging changes in the context and design of health research; and,

d) Pilot new methods for implementing new understandings of the experience of being a human subject in research design, the process of ethical review and governance of research ethics.

This larger project involves three distinct phases. Phase I includes an intensive literature review and in-depth interviews with human subjects, members of Research Ethics Boards [REBs], health researchers, scholars, policy-makers and other key informants in health research. Phase II involves the selection of two to three health research projects in order to assess the ethical and other implications of recent and emerging changes in the context and design of health research identified during the literature review and analysis of Phase I interviews. And lastly in Phase III, the findings will be presented to experts in ethics, human subjects, and/or the general public in order to elicit feedback, which will inform a series of focus groups, consultation workshops and public forums. Currently, phase one of this three-phase study is nearly complete and

analysis is ongoing at both sites; phase two is underway at the University of British Columbia. Additionally, arts-based methods are being piloted at the University of British Columbia as a method to provide feedback and information to several stakeholder groups, including human subjects.

This student research project focused on a sub-sample of key informants located primarily in the province of Manitoba, who shared a cluster of REBs and therefore, provided a geographically centered, and institutionally-based sample. Thus, this research uses a geographic sub-set[12] of the data collected by the student and the Manitoba-based research team members within the larger CHSIHR study. My role has primarily involved coding and data analysis; however I was also involved in interviewing[13], theoretical analysis and compilation of research results and preliminary findings for the overall CHSIHR project. Narrative data from semi-structured, in-depth interviews was collected as part of the wider CHSIHR project from a broad spectrum of stakeholders including: **1)** Researchers; **2)** REB Members; **3)** Policy-Makers and Scholars with an expertise in research ethics; and **4)** Front-line Research Workers, or those who are responsible for many of the front-line research activities and others who contribute to the research process including research coordinators, nurses, interviewers, translators and interpreters. All participants gave their consent prior to participation, and agreed to allow their data and access to narratives from in-depth interviews resulting from their participation to be kept for the purpose of ongoing research as a part of this larger study. Participants were also given the option to agree to be contacted in the future for studies related to, but separate from, the CHSIHR project.

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[12] This student thesis project only utilizes interview data collected by the University of Manitoba Research Team.

[13] Interviews conducted were within the 'Human Subject' informant category.

Initial interviews with stakeholders as part of the larger CHSIHR project were drawn from purposive sampling techniques in order to elicit a range of divergent perspectives on topics relevant to health research. A matrix of various types of participants with research experience within a wide range of research methods including qualitative, quantitative, participatory, and experimental, as well as a range of disciplines from the social sciences, medical and clinical sciences, bioethics, epidemiology, and health services research was constructed to ensure a broad spectrum of key informants were selected from each stakeholder group. Participants were recruited using an opportunistic sampling approach by means of social, professional and networking connections. There was relatively equal distribution across stakeholder groups in order to yield maximal variance in attitudes and perceptions. Inclusion of multiple informants from each stakeholder group ensured depth and rigour, as well as enhanced credibility and consistency, and provided a means of triangulating emergent conceptual themes from various informant perspectives (Creswell, 2003). This thesis project, under the umbrella of the larger CHSIHR project, utilized a geographic sub-sample of key informant interviews (N=29) that were conducted by the University of Manitoba research team. A comprehensive approach, incorporating the perspectives of Researchers, REB Members, Policy-Makers, Scholars and Front-line Research Workers was drawn to reflect: *A)* Informant's role; *B)* Research involvement; and, *C)* Consent theme. Of the interviews conducted, the breakdown across key stakeholder groups was the following: **1)** Researchers, N = 8; **2)** REB Members, N = 4[14]; **3)** Policy-Makers and Scholars with an expertise in research ethics, N = 6; and **4)** Front-line Research Workers, N = 11.

[14] The REB interviews conducted in Manitoba involved informants selected to reflect the diversity of REBs across various academic departments, health delivery and universities to get a better sense of some of

Although key informants were interviewed and categorized into one of the four major stakeholder groups, in some cases they wore multiple hats. That is, some informants were interviewed primarily for their expertise as a researcher in a particular field, but may have had experiences as research worker or REB member as well. As a result, some informants moved across roles throughout the interview and spoke about these multiple or varied experiences, rather than simply conceptualizing their experiences within their primary role, which they currently occupy. Accordingly, this notion of multiple roles was acknowledged throughout coding and analysis due to the potential for alternative constructions and meanings given to key words or concepts, which is dependent on the perspective or "hat" the informant wears when describing the cultural scene and recounting his/her perspective.

Interviews followed an open-structure, and touched on some of the issues that emerged from the literature search. This format allowed both informants and Investigators to raise issues they perceived to be particularly relevant and current in the context of health research. The semi-structured interview guide was based on open questions, and organized around five broad areas: current research involvement and role, history of involvement in research and/or changes over time, experiences conducting, reviewing, or participating in research, broad views about human subject participation in research, the role of others involved in the research process and its impact on relationships, governance and research practice and/or methodology. Interview schedules were developed in relation to the informant's primary role and specific research

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the overlapping jurisdictional issues and alternative review criteria utilized or practiced amongst REBs.

expertise[15]. Prompts and probes were also listed on the interview guide, and used only as necessary (e.g. depending on the research expertise and background of the informant, probes might be specific to certain types of research, such as the impact of corporate sponsorship on pharmaceutical research, or the requirements for community consent). Sample interview guides were reviewed and approved by the University of Manitoba, Bannatyne Campus, Health Research Ethics Board (reference number: H2006:083, linked to H2008:121) and the University of British Columbia, Behavioral Research Ethics Board (reference number: B06-0213). Face to face interviews explored experiences of key stakeholders and their perceptions about a variety of experiences, while still allowing for clarification and further explanation if required.

An open structure approach to interviews was selected in order to avoid a priori assumptions about which issues or questions are most important, and to allow discovery and documentation of aspects of reality that may not necessarily be anticipated in the current literature or prior to fieldwork (Eakin & Mykhalovskiy, 2003). In addition, open-ended, in-depth interviews permit reflection and the opportunity to revise research questions, which enhances the use of effective methods for eliciting relevant informant accounts and allows for maximum response variance amongst participants (Bauman & Adair, 1992). All interviews were audio taped and transcribed, and transcripts were checked against tapes for accuracy. Following interviews, detailed field notes documenting impressions, research ideas, research observations and general thoughts, were written at the earliest opportunity.

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[15] Although key informants were interviewed and categorized into one of the four major stakeholder groups, in some cases they wore multiple hats. That is, some informants were interviewed primarily for their expertise as a researcher in a particular field, but may have had experiences as research worker or REB member as well.

3.3 *Data Collection and Analysis*

There were three main objectives specific to this student research initiative:

1) Explore the roles and relationships of multiple stakeholders involved in health research and the impact of alternative perspectives on informed consent;
2) Compare/contrast perspectives of various actors, and their perception of the issues, barriers and identify priority areas for improvement to reform the current process of informed consent;
3) Summarize some of the changes that have occurred over time with respect to guidelines and policies for informed consent, including a review of the current literature.

Some of the more specific questions that this project addresses from a wide spectrum of perspectives and experiences include the following:

- What are key informants' perceptions of the informed consent process?
- What is their perception of their role in the process?
- What is their relationship to other key stakeholders in that role?
- What is their knowledge and/or comfort level with current informed consent guidelines?
- What are their perceptions about the key issues, problems, and priorities for change?

These questions were important in exploring some of the strategic perspectives of stakeholders with respect to issues of consent and the process of obtaining consent from

human subjects, identifying structure and/or process barriers, and exploring expert stakeholder perspectives as to how to improve meaning-centered outcomes and improve overall understanding of the informed consent process.

Within the wider CHSIHR project, analysis of interview data is ongoing, and is based on constant comparative analysis, informed by a combined grounded theory and a literature-based theory approach (Strauss & Corbin, 1998). Similarly, this student research project utilizes a grounded theory model of analysis as emphasized by Strauss & Corbin (1998; 1990), in which the researcher assumes a role that is both dialectic and active, and the emphasis is on verification and validity of the theory hypothesis. This approach is perhaps more structured than traditional models by Glasser & Strauss (1967); however, Strauss & Corbin's model was selected because it allows for a more in-depth look at some of the outside influences that impact circumstances and environments. The focus of this grounded theory model of analysis recognizes that structural, contextual, symbolic and interactional influences are important in understanding the complete picture, and emphasize the significance of these factors in describing the cultural scene (macro) and socially constructed world of the participant (micro) (McCann & Clarke, 2003a; 2003b; 2003c). This student thesis explores some of the wider contextual issues and relationships that might also impact the process of negotiating meaningful consent. The hypothesis is that those who are responsible for regulating, obtaining and assuring informed consent are subject to various moderating influences and this approach allows further exploration of such dimensions.

A constant comparative analysis approach was used to identify key categories, concepts and themes that emerged from the data. Open coding was employed as a way to

categorize themes within informant narratives, identify patterns of events, and initialize the process of theory development. Within the context of this conceptual framework, narratives were compared across individual interviews, across key stakeholder categories, and with concepts noted in the literature review. Regularities and patterns that emerged from the data have been recorded, and deviant cases were acknowledged to increase rigour. Key concepts were identified and grouped into themes, which provided the structure for the conclusion and recommendations. Each theme comprised a series of concepts that were supported by narratives from interviews. Themes were also cross-referenced with those in the literature to further aid discussion and presentation (Creswell, 2003; Frankfort-Nachmias & Nachmias, 2007).

Analysis using grounded theory was first indexed by hand in order to achieve a greater visualization of the complete dataset. Later, interviews were entered into and managed via the qualitative data program software NVivo8, which allowed for basic 'code retrieval', as well as more sophisticated analysis using algorithms to identify co-occurring codes in a range of logically over-lapping or nesting possibilities. In addition, the program allowed quick and easy annotation of text and data, and permitted both the creation and amalgamation of codes (Bazeley, 2007; Richards, 1999). Conceptually, this thesis project documented key themes and important differences that emerged from each stakeholder group, focusing on the perceived objective of the consent process, and the barriers and facilitators of implementation. The resultant findings formed the basis of recommendations, and were based on areas for improvement and change within existing frameworks as identified from key informant narratives. This project links conceptual issues that emerged from interview data analysis to a descriptive account of some of the

current issues with informed consent and a brief chronology of relevant events and changes that have occurred over time, including the ethical and other impacts on the process of informed consent for research involving human subjects. To reiterate, for this specific student thesis project, analysis was conducted by the student, and it utilized interview data from the wider CHSIHR project. The members of the larger CHSIHR study, and for this related student thesis project, share access to the data. The larger CHSIHR research team supports access to the data for this student thesis project and overall objectives.

Relevant themes that emerged are highlighted in the chapters that follow, and associated meanings and implications are also discussed. The participants that have been quoted are identified with an extraneous study number, and general job titles or descriptions are made available only where needed to provide some clarity without revealing participant's identity.

3.4 *Limitations*

A limitation of the study was that participants had to be English-speaking. Skilled interpreters were not provided and therefore, it was not possible to include individuals from other ethno-cultural and language groups in interviews who may have very different views about informed consent and the process for obtaining it.

Given the limited resources of this graduate student project, feasibility entered into the sampling process. Such constraints did not invalidate the research findings or

fulfillment of the overall objectives and this project offers a solid account of the relevant issues, although practical constraints limited the size of the sample feasible for analysis. Similarly, due to the small sample size, the level of conceptual generalizability of the data is a concern. In response to this limitation, every effort was made to link interview data and emergent themes with relevant events and issues from national and international literatures, thereby placing local perspectives within much larger and widely applicable context. In addition, consistency between the issues that emerged from the data and those established in the literature further supported the generalizability of the data, and to the overall issues within the field at large.

The majority of the interviews for this student thesis project were conducted with individuals who live and work within the province of Manitoba. Although many of these individuals have been involved in a wide variety of projects, including national and international research projects, there is still a concern that the data will be regionally biased. In order to limit this effect, the source of the information as well as the informant's background, position, basis for selection and some of the biases that may have influenced his/her perception was noted and properly acknowledged in analysis. So, while regional bias is a significant issue, it is felt that the core issues presented at the conclusion of this project are common amongst those outside the province as well. As an advantage, this research project provides a geographically centered and institutionally-based sample.

Informants were selected to reflect the diversity of research across disciplines, methodologies and organizations, and accordingly there is some variability amongst individuals grouped within the same category (e.g., researcher category). Thus, some

experiences revealed alternative constructions and meanings given to key words or concepts, which is dependent on the perspective or professional and/or academic foundations of the informant. Accordingly, this issue was acknowledged throughout coding and analysis and general job titles or descriptions have been provided without revealing participant's identity, to add clarity to most narratives. Alternatively, this can also been viewed as an advantage, given the cross-role experiences and wide range of perceptions of informants.

As part of a larger study, the Co-Investigators from the University of Manitoba site, not the student, conducted interviews. However, the student worked closely with the Co-Investigators at all stages of coding and data analysis to ensure accurate interpretation and representation of emergent themes. In addition, following interviews the student was present during discussions as detailed field notes documenting impressions, research ideas, research observations and general thoughts about the interview, were compiled.

Lastly, grounded theory methodologies informed by Strauss & Corbin (1998; 1990) emphasize a more structured approach to data collection. While this feature is not necessarily problematic, critics assert that this approach is vulnerable to data 'forcing', or influencing the development and analysis of emerging data as a result of preconceived notions. This concern is valid, however; the methods of analysis for the described research initiative were structured such that the interviews were open-ended so as not to impose too much structure or impact the quality of the data. As an extra measure of precaution, informants were encouraged to speak freely, raise issues that were important to them and support their responses with examples wherever possible (Mishler, 1991).

Attempts were made to clarify any biases that are inevitably present, through self-reflection and identification of personal values, assumptions and biases at the outset of the study (Creswell, 2003).

3.5 *Ethical Considerations*

As part of a much larger CIHR-funded joint initiative between the University of British Columbia and The University of Manitoba (see 3.2 *Study Design and Sample*), this research study utilized a geographic sub-sample (N=29) of narrative data collected from open-ended, in-depth interviews with a broad spectrum of stakeholders. Ethical approval to conduct this larger study was obtained from both the University of Manitoba, Bannatyne Campus, Health Research Ethics Board (reference number: H2006:083, linked to H2008:121) and the University of British Columbia, Behavioral Research Ethics Board (reference number: B06-0213). All participants were asked to sign a consent form outlining the purpose of the study, the procedures, potential risks and/or discomforts, and provisions for anonymity and confidentiality. All participants, from the sub-sample and data that was drawn, gave their consent prior to participation. There was also agreement to allow data and research narratives resulting from their participation in in-depth interviews to be kept for the purpose of ongoing research as a part of this larger study. Participants also had the option to agree to be contacted in the future for studies related to, but separate from, the CHSIHR project.

As and active member of the larger CHSIHR research team, I have undertaken co-interviewing and data analysis of the larger project dataset. Under the supervision of Dr. Joseph Kaufert (Co-Investigator, UMan), and with the support of the other Investigators of the research team (Cox, S [Principal Investigator, UBC]; McDonald, M [Co-Principal Investigator, UBC]; Kaufert, P [Co-Investigator, UMan]; Townsend, A [Co-Investigator, UBC]), I utilized a sub-set of the interview data collected from the Manitoba research site. Participation in this study was completely voluntary, and no remuneration was provided. All participants were required to read and complete a consent form, which was approved by the appropriate REB, which in this case was both the University of British Columbia Research Ethics Board, and the University of Manitoba, Bannatyne Campus Health Research Ethics Board (reference number: H2006:083, linked to H2008:121).

Individual participants will not be identified in research publications. Due to the small sample size of this thesis project, particular measures were taken to ensure confidentiality was maintained, and that individual identity was masked. So for example, an extraneous study number was assigned to participants[16] and only very general job titles or descriptions are provided when necessary for clarity. Transcripts were first de-identified and then offered to participants. Each informant had the opportunity to read and highlight information that was particularly sensitive and/or potentially identifiable, ensuring that specific passages would not be used in publication[17]. Thus, the final decision regarding anonymity rested with the informant to ensure that individual

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[16] Although all study participants were assigned a study number, and their interview tapes and transcripts were anonymized, a master code key was kept that can link the study number back to the individual; however, this master code key is kept separate from all other source documents in a locked filing cabinet in a secure office.

[17] Although participants were given the opportunity to read the transcripts and highlight information that was particularly sensitive and/or potentially identifiable, this did not extend to findings; Participants were not given the opportunity to alter results or final data analysis.

comments were not identifiable. As an additional measure of precaution, any decision to use direct quotes and narratives from interview data was made in consultation with the CHSIHR study team to ensure that the identity of the informants was sufficiently masked and unidentifiable. Lastly, some informants occupy very visible or unique roles, and therefore were identifiable as a result of their distinct position and/or views despite every effort to ensure confidentiality was maintained, and individual identity masked. Accordingly, such revealing narratives were not utilized for this student research project.

This student thesis project explores the roles and relationships of various individuals involved in the research process, and also discussed topics relating to power differentials, research practices – both ethical and otherwise – and/or personal accounts and perceptions of participants involved in research processes. Therefore the potential risks relating to involvement in this study, such new and/or emotional issues raised during interviews, was mitigated by assuring participants that they needed only to answer questions or express their views when they wished to do so. Furthermore, as noted above, considerable effort was made to ensure the confidentiality of any sensitive information that could potentially identify a participant and/or a particular research project or team discussed in interviews.

As part of the wider CHSIHR project, this student initiative will comply with the security measures already approved and specified in the original CHSIHR study protocol. Thus, data from interviews will be collected, analyzed, and kept for a period of time that will not exceed 10 years after publication of the original analysis. All tapes, transcripts and consent forms are identified only by an assigned study number and are kept in a locked filing cabinet in a secure office area. De-identified transcripts, field notes and

other research documents related to the study are kept on a password-protected computer or in a locked filing cabinet in the secure project office. All these precautionary measures were described to potential participants in the consent form prior to study participation. The only persons who have access to the data are the immediate members of the CHSIHR research team.

3.6 *Significance of the Study*

The results of this research are relevant for several reasons. New understandings of the relationships and contexts that influence the process of informed consent will: (**1**) help reveal the underlying rationale and decision frameworks, and separate individual points of impact of those involved in the consent processes at all levels; (**2**) document the influence of context and the inter-play between the process, people and events as well as attempt to explain the relations between organizations, individuals and other extenuating factors. Such insights are key in identifying some of the organizational barriers and facilitators as perceived by varied actors involved at all levels of the consent process. Properly translated, this knowledge is useful in facilitating communication (or what needs to be communicated) and establishing methods to improve human subject protections and ensure appropriate policies for informed consent procedures are implemented.

Up to now, researchers have studied human subject protections with an emphasis on the consent form, but this body of research does not differentiate or include the views of key players who are directly involved in informed consent processes at all levels of

health research. There are unrealized possibilities for exchange between researchers, REB members, policy-makers and front-line research workers that could also be of benefit. These individuals have expertise in different areas, but an integrated approach, which incorporates the perspectives of these varied stakeholders, could lead to potential improvement and recommendations for informed consent procedures and ethical governance. This study explores the perceptions of those directly involved with research participants as they sign consent forms, and those who are responsible for creating templates or policies that guide informed consent procedures. These actors are ideally positioned to effect change, as these individuals will most likely be charged with the task of putting policies into practice. It is the intent of this research to foster communication and feedback amongst a variety of stakeholders, and facilitate productive dialogue between those who regulate the process of informed consent, and those responsible for obtaining and ensuring meaningful informed consent, and will therefore make an important contribution to the literature.

An integrated approach, which incorporates the perspectives of varied stakeholders, may help to improve acceptance of proposed recommendations for more meaningful informed consent guidelines and policies. The outcomes of this research initiative are useful to identify the issues, problems and priorities to reform the current process of informed consent, and particularly identify those that are not evident using a conventional top-down policy approach. This research initiative strives to work across disciplines, sectors, and institutions, in order to respond to issues that concern individuals from a wide range of perspectives; not just those traditionally included in health-care policy development and research ethics. Such implications could prove important for

ethical governance, potentially identifying relevant policy options that could work in 'real-world' settings, and enhance 'buy-in' from front-line workers and others outside the policy area (Pérez & Martinez, 2008). At the conclusion of this manuscript, recommendations and some concluding reflections are discussed and evaluated within existing frameworks.

Lastly, given that the proposed student project is associated with a much larger CIHR-funded study, there will be more opportunity to connect with persons and organizations outside the province of Manitoba. With this in mind, the opportunities for dissemination and communication of research results will likely include a much wider audience, such as policy-makers and others responsible for policy implementation and education at the provincial, national and international levels. An emphasis on the importance of research that affects populations at the local, national and international levels should prove positive; ensuring that the focus of this research study is sufficiently applicable across all levels of health services research and throughout Canada.

4.0 CHAPTER 4: Informed Consent

4.1 *Informed Consent*

Turning the focus of discussion to now explore the significant themes that emerged from the data, this chapter will center on informed consent for health research. The decision to participate in research is generally documented through the process of informed consent, wherein all relevant information about a specific research project, including the purpose of research, its risks and possible benefits, is disclosed to potential human subjects. Upon signing the consent form, the documentation implies that human subjects have full knowledge of the research and conditions of participation, and have willingly agreed to participate. The consent form document is only one aspect of informed consent, and in keeping with the Tri-Council Policy Statement [TCPS] guidelines for the ethical conduct of research involving human subjects (Interagency Advisory Panel on Research Ethics, 2008), informed consent should be viewed as a process, encompassing a much wider scope than simply focusing on how consent is documented. Thus, it is intended that the process of informed consent be interpreted broadly, referring to the dialogue, information sharing, and general process through which prospective participants choose to participate in research (Interagency Advisory Panel on Research Ethics, 2008). The research ethics literature however, has tended to be much narrower in scope, focusing on the signing of the consent form and consent form as a formal printed document. Similarly reflecting the focus of the majority of empirical research in this area, narrative data from key informants, including researchers, front-line

research workers, research ethics board [REB] members and other 'experts' including policy-makers and scholars, initially revealed this very preoccupation; that is, themes relating to signing the consent form and the structure of the printed document. When asked about some of the most pressing issues, problems and priority areas for improvement and/or change in contemporary health research, key informants frequently focused on the consent form and their criticisms of the document itself. Yet, in addition to some of the more familiar critiques, key informant narratives also provided further insight into how ethical and legal requirements challenge the real-life practicalities of recruitment and obtaining consent from human subjects for research participation. The narratives of individuals involved in consent processes provide concrete examples of the limitations of the consent form document and insight into features of the informed consent process as it happens in practice. Focusing on the varied perceptions of those who oversee, and are involved – both directly and in-directly – in the consent process, reveals uncertainties amongst key informants with respect to expectations, responsibilities and accountability, which with more clarity and communication, could help to improve informed consent processes and alleviate ethical dilemmas as they arise.

4.2 *Purpose of the Consent Form*

The meaning and practice of informed consent were common and re-occurring areas of discussion throughout interviews with key informants. Originally introduced with the intention of promoting respect for human dignity and choice, consent forms were

thought to provide security that full and frank disclosure of relevant information specific to the research had occurred. As such, informed consent has become an important feature of ethical research involving human subjects; but in recent years, there has been both steady and increasing uncertainty about the effectiveness of informed consent, and in particular, a primary focus on the printed consent form. Central to this focus is the criticism that consent forms have become overly technical, including statements and incorporating language from legislated or governing laws and prevailing organizational policies. The list of information that researchers are required to provide to prospective research participants has only increased despite the fact that the language and concepts are extremely difficult for human subjects to read through and fully comprehend. Thus, it has been argued that current consent forms undermine the very tenets it was intended to promote, and in fact, may serve the interests of organizations and researchers much more so than that of human subjects. With the addition of such requirements and consequently longer and more complex consent forms, perhaps the function of the consent form has changed. In what follows, discussion with researchers, research workers, and REB members contemplate this, and at what costs some of these changes have been incorporated into the consent form.

4.3 *Legal and Administrative Function of the Consent Form*

As consent forms become increasingly standardized, there are lingering questions as to the impact such changes have had on the consent process. Several Interviews with

key informants revealed that this was indeed a topic of interest, and researchers, research workers, REB members and scholars discussed these issues in some detail. Frequently, the topic of conversation turned to the intended purpose of consent forms, and whether this has become lost within the extensive list of information and other requirements that must be included in consent forms. Concerns that increasingly, fewer individuals actually read and understand information conveyed in the consent form has raised criticism about the inclusion of formal language and standardization. Looking beyond constituted provisions and statutes, at a more basic level the process of informed consent is intended to grant individuals the freedom of choice to decide what happens to them, including an awareness of the corresponding risks and benefits that could incur as a result and their acceptance or refusal of research participation. Indeed, the atrocities committed by Nazi researchers under the Hitler regime were so horrific given that human subjects were used as human guinea pigs against their will in experiments that were typically excruciatingly painful and generally led to death or permanent disfigurement (Levine, 1986). Thus, the original intent, which is to ensure voluntary and informed choice, still seems absolutely relevant. One individual who served as Chair of an REB asserts his/her criticisms of the current process of informed consent, which currently seems to be more focused on the legal aspect and function of the form, rather than the needs of human subjects in order to facilitate their decision to participate in research:

> I think that, uh, it has become bureaucratized to the extent that the choice is lost in having to read through a whole series of conditions and clauses that protect everybody under the sun, and well, what is your real choice here? (REB_302)

This individual further goes on to express his/her concerns with the current practice of informed consent, which places much effort and attention on the consent form

document, despite research guidelines that advise the opposite. That is, with respect to free and informed consent, guidelines for the ethical conduct of research involving human subjects state that the primary focus of ethical concern should rest on the quality of consent and not on how it is documented, or merely the signing of the consent form (Interagency Advisory Panel on Research Ethics, 2008). In the following excerpt, this former REB member laments the way in which the consent process is framed around documentation, rather than on the quality of the consent and the process itself:

> I think the whole informed consent form issue is a major problem, because I think the more we formalized the multiple issues that had to be addressed in the form, it became a consent *form*, rather than a consent *process*... I really thought that ...the consent process is lost in what we've done with the form. (REB_302)

In practice, an individual's decision to accept or decline research participation should be based on a reasonable appreciation of the research and what involvement – including potential harms and benefits – would entail. Expectations around informed consent and the procedures for documenting it were among the central objections raised by research workers. The majority of interviews highlighted the concerns of research workers about the proliferation of legal and policy information required in consent forms, and their perception of the impact incorporating such language has on human subjects. In what follows, one research worker identifies his/her main concern; namely, that bureaucratic requirements only reinforce the legal function of consent forms, and take attention away from other important aspects of consent:

> I really have issues with these consents. I have raised it in different forms and I always get back the legal stuff that has to be in there, and I argue, "But if you can't read it and can't understand it... I don't get it". (RW_308)

An obvious consequence of standardizing the information provided to human subjects is that the consent form becomes non-specific, and includes generic explanations or statements that don't always fit within protocol descriptions. In this sense, the introduction of consent form templates, as a means of trying to ensure that the information provided to human subjects is consistent, may contribute to the problem. Generic explanations referencing privacy legislations, confidentiality and other organizational and governance policies may be useful to researchers and the REB, but ultimately it adds to the volume of information human subjects are asked to read through and understand. In this sense, consent forms have become even more difficult for human subjects to navigate in order to determine exactly what is being asked, what information is most relevant and perhaps most importantly, what they are agreeing to. From the perspective of front-line workers, such disclosures do not add to the overall consent process, and there is uncertainty as to who benefits and who is ultimately protected by such requirements: the human subject, the researcher, the organization and/or funding body or sponsor? One research worker poses this very question, and goes so far as to suggest that current consent forms provide protections – whether rightly or wrongly – for researchers and organizations inasmuch, and maybe even more so, than they are meant to provide protections for human subjects:

> I really question whether sometimes it's truly informed consent when the language is convoluted, or it sounds more complicated than it needs to be and then are people really, truly informed? I don't think that people raise objections because they think that's the way it is and that's the way it has to be... Does it really protect the human subject or is it protecting the organization? Yeah, I mean obviously this whole business of the initials and, "I consent to this, this, and this", I mean somebody's covering their asses. (RW_409)

Amongst key informants this was a shared theme, and in fact both researchers and scholars also acknowledged what they believed to be a shift in the purpose of the consent form. While it may have been a subtle shift, the perception that the information provided on consent forms, which was once clearly intended to protect the welfare and rights of human subjects, has more recently taken on a much more defensive stance, seemingly aimed at protecting researchers, organizations and funding agencies. One researcher succinctly captures this trepidation, stating:

> When you read it carefully you think, this is to protect the university, honestly that's the basic impression I have when I read it [the consent form]... (R_404)

The notion of the purpose of the consent form, and whose interests it is intended to serve becomes more prominent and complex with respect to research that is privately funded by commercial sponsors and/or pharmaceutical companies. Due to the ethical sensitivities of such collaborations, research backed by commercial sponsors typically receives much more scrutiny by the REB to ensure limits are clearly outlined at the outset and regulations comply with current standards of acceptability. Given the development of many REBs towards standardized consent forms, the idea that consent forms are becoming much more focused on protecting the interests of organizations, funding bodies and sponsors, is particularly worrisome. While research and researchers that receive support must disclose such information to human subjects, the worry is that such disclosures do not indicate the impact of the sponsor's involvement in terms of study procedures, findings, results and dissemination, and therefore fails to convey the significance of such disclosures to human subjects. In order for such discloses to be truly informative, steps should be taken to help subjects understand information about conflicts

of interest and how to interpret this information. Thus, it would seem that information of this nature currently serves the obligation of researchers and sponsors to report such information much more so than it serves the interests of informing research subjects. Aware of this undercurrent, a very intuitive key informant with much scholarly expertise in policy development for research involving human subjects commented on this issue as well as the concern about what it means for human subject protections more generally:

> So it became clear, especially in the industry sponsored protocols that when you read the consent forms and really looked at the way the study was being conducted that the whole human subject's protection enterprise had been subverted and it had been completely transformed 180 degrees from the original goal of enhancing the power of the subject and that it was now completely oriented toward protecting the financial interests of the sponsors of research. So that's been my big concern... (S/P_314)

Within the scope of his/her work, this informant spoke about the noticeable shift in the focus of the consent form, from that of a safeguard for human subjects to one that protects the interests of organizations that support research. Herein lies an undercurrent in which protections have been directed away from the individual participating in research, which from the previous passage, is both unacceptable and should be of much concern to the research community at large. In light of such concerns, several key informants went on to suggest that perhaps it is time to reassess the meaning and structure of the consent form. Such an evaluation could be useful to ensure that it is indeed fulfilling its intended purpose and to affirm its relevancy to human subjects, so as not to become another unread form that only serves as a formality. While one scholar comments:

> One of the things that I always say is we really should be going back to basic principles. (S/P_407)

Another researcher, who does not go so far as to suggest we should return to basic principles, does however contemplate the negative impact of standardization and reflects on some of the changes that have occurred throughout his career in research, with particular attention to the consent form. Within this context, this individual summarizes some of the key issues, and indicates that while not all changes have been bad, the lack of consideration of the consequences or limited attempts to balance competing interests, has been a difficulty for many involved in research, and perhaps reevaluation is warranted:

> It was considered unethical for a consent form to be more than two pages because people would not read it all... I see today's consent form mainly as defensive medicine, as a protective mechanism to prevent you from being sued, and not to make sure that you really have done an ethical job of describing the study to the perspective volunteer. Not that some of the things that have been instituted are not correct or not appropriate, they shouldn't have been standardized. But it has gone away from the original intent and I would hope that some time in the future people will look at these consent forms that are ten and twenty pages and consider them unethical... (R_410)

Several key informants spoke of their concerns with requirements that necessitate legal and policy terminology be incorporated into the consent form. Although most individuals we interviewed did not disagree that such information is valuable, many questioned whether such information was actually of value to the human subject. The purpose of the consent form is to provide prospective human subjects with the facts they need to make an informed choice about study enrollment. As such, the consent form should, first and foremost, serve the needs of human subjects in order to facilitate this process. The extent to which actual or potential conflicts of interest are acknowledged to potential human subjects and the limits of disclosure is somewhat ambiguous. Still, failures to disclose such conflicts are thought to "impede the informed and autonomous choices of individuals to participate in research" (Interagency Advisory Panel on

Research Ethics, 2008, p.75). Institutions and researchers have an obligation to ensure that research is conducted in an ethical manner that respects the choices of human subjects, and therefore, it must ensure that research is not compromised by conflicts of interest, whether real, perceived or otherwise. Accordingly, key informants expressed their unease with the addition of consent form requirements that seemingly protect the interests of organizations rather than that of the human subject. The perception amongst key players involved in research is that there has been a noticeable shift towards a much broader view of protection. This broader view of protection now incorporates the interests of organizations, funding agencies and sponsors in addition to that of human subjects. Attempts to standardize consent forms through the provision of consent form templates may be a contributing factor to this noticeable shift. Further discussions with key informants went on to reveal their perceptions of templates, which outline information requirements, and its utility for those involved in research and consent processes.

4.4 *Consent Form Templates*

Consent form templates have been introduced by some Research Ethics Boards [REBs] in an attempt to both standardize information communicated to human subjects, and improve the quality of consent forms by ensuring that a minimum amount of information is provided to human subjects. Communication of research risks, benefits and other ethical and governance issues, including references to the rights of human

subjects, can be difficult to formulate and design. A standard format or template serves as a guide to outline the important elements that need to be incorporated in the consent form document; however, standardized descriptions have come at a cost of longer and more complex consent forms. Standardized templates are thought to be of benefit to researchers and the REB as they review research, but a review of the literature indicates that very few studies have addressed this issue in much detail. From interviews with researchers, research workers, REB members and scholars, this issue emerged as an important area of discussion. Key informants discussed both positive and negative features of templates and provided some insight into their perception of whether templates should be considered a help or hindrance to the overall process of informed consent.

In the past, communication of the risks, benefits and other ethical issues for consideration had been left to the discretion of each individual researcher to convey. Thus, the information disclosed to potential human subjects, primarily via the consent form, varied widely from study to study. Given the current ethical and policy climate, such variation is no longer acceptable; guidelines for research involving human subjects list several elements that must be incorporated into the consent process, in order to ensure that adequately informed consent has occurred (Interagency Advisory Panel on Research Ethics, 2008). Although such guidelines, including the Tri-Council Policy Statement [TCPS], do not provide researchers with a specific template to use, many REBs have created a consent form template, or "boilerplate" descriptions for researchers to use as a guide. While consent form templates may have been introduced to guide and expedite the creation and ethical review of consent forms, one research worker comments that

such developments actually discourage researchers from really attempting to understand the ethical issues applicable to a specific research project. By utilizing a template as is, a researcher can ensure that all possible ethical issues are addressed without having to comprehend the reasoning behind the provision of such information; however, this individual goes on to say that in some ways, this is also what the REB finds attractive. Standardizing the process of consent renders research review a little less demanding – consent forms are both tangible and immediately available to the REB – which is a positive thing considering how overworked REB members are and how under-resourced the organizational base of the REB is (McDonald, 2000). Encouraging the use of consent form templates ensures that researchers are upholding an acceptable standard and it is quick and easy for the REB to review:

> Well it's unfortunate that we've had to evolve to the template because it speaks to the fact that people just don't understand the ethical issues that are involved… I expect it also makes the review easier for the REB because you recognize the format and you know where you are in all of the consents… (RW_307)

So, while templates may allow for an easier, more targeted REB review, the dilemma that again presents is that by following templates that address all ethical issues – even those that are not necessarily applicable to every research project – the consent form again becomes very complex and almost excessive in the amount of information provided to human subjects. In particular, this approach has been criticized by social scientists because standardized templates tend to follow a distinctly biomedical paradigm. Many have argued that the risks associated with social sciences research can differ significantly from research in biomedicine, which can involve invasive and inherently risky procedures. To this end, social scientists have tried to emphasize the distinctiveness of

their own research and the unique ethical concerns generated as such. Thus, social scientists question the applicability of a biomedical model of informed consent for all types of research, and the appropriateness of templates that continue to emphasize this paradigm (Miller & Boulton, 2007; Dixon-Woods et al. 2007; Murphy & Dingwall, 2007; Boulton & Parker, 2007). A policy expert who has had much experience at the interface between research practice and policy formation commented on this and stated his/her concerns. In essence, templates or boilerplate language suggested in templates may be a convenient tool; however, such language is undifferentiated or so non-specific and generic that it does not convey useful information to human subjects. In this sense, perhaps the advent of templates and corresponding boilerplate descriptions have had the unfortunate effect of complicating the consent process, rather than as researcher might think, simplifying the communication of risk to potential human subjects:

> This is my other sort of pet peeve in the whole enterprise is the problem of boilerplate language. So the boilerplate language said, "We can't guarantee that basically your brain won't explode because of the fact that these probes might have metal in it and we have to look at it" and blah, blah, blah, and my response was, "Well this is just ridiculous... But then the boilerplate required [it]. So you'll have five different sets of boiler plates in your own consent form and they'll all be conflicting and so if anyone really tried to read it they would have no idea ... well, not even really the risks but what the procedures were. (S/P_314)

An equally important issue as indicated in the previous passage, is whether *all* possible risks should be disclosed to human subjects despite the projected likelihood of actual occurrence; this inevitably leads to a dilemma about what risks should be omitted and/or shared with human subjects as they consider research participation. Disclosure guidelines indicate that there are three aspects relevant to assessment and categorization of risks: the nature of the harm, magnitude or seriousness of harm and probability of

occurrence (Interagency Advisory Panel on Research Ethics, 2008, p.12). Potential harms are understood in relation to risks, and defined in terms of probability and magnitude. Although the TCPS does not qualify the risks that should be included in consent forms, the implication is that all harms specific to the research should be identified, but also recognizing that in some cases it may be difficult to predict the exact nature and magnitude of potential harms. In fact, the task of predicting and conveying risks and benefits is complex, particularly given that the public commonly ignores base rates and misunderstands chance phenomena when estimating probabilities (Applebaum, Roth & Lidz, 1987; Kimmelman, 2007). Another factor adding to this complexity is that culture, values and beliefs can also influence how risks are perceived. Thus, risk analysis is very personalized and should, to the extent possible, be framed within the context of the subject population and from the perspective of potential research participants (Interagency Advisory Panel on Research Ethics, 2008).

The provision of templates by the REB gives the impression that all information as outlined in the template is a necessary requirement of adequate informed consent. The notion that consent form templates prescribe stipulations that are not to be altered was a theme that emerged from the interview narratives of researchers and research workers. Rather than viewing such guides as useful examples, members of the research team perceived such templates to be prescriptive, wherein any deviation would require due justification. Furthermore, there was a sense that despite their misgivings, researchers and other members of the research team continue to utilize templates out of organizational expediency. In this way, researchers have accepted informed consent templates without much resistance given that the REB is less likely to take issue with

consent forms that comply with standard formats. One research worker confirms this general belief, and in doing so, also acknowledges her disapproval of current consent forms, and the way in which such information is conveyed to human subjects. Again, the issue of whether the information provided in the consent form is actually useful to human subjects as they make their decision about research participation is at the forefront. This research worker even goes so far as to suggest that in light of this apparent disjoint, consultation between the REB and those members of the research team who are directly involved in consent processes could help to refine consent form templates, or at least help members of the research team gain a better understanding of the reasons why some elements have been suggested for inclusion in the consent form, and their applicability to different types of research:

> ...what I'm told is that this is something that the ethics boards have prescribed and you can see it... It's a template and you've got to have it like that and all you do is sort of plug in your individual information. So if that's the template then somebody needs to get to the person who's writing the templates or the people who decide how these templates should look and say, "Well they've got to be different than this"... I haven't. I haven't had that opportunity. I've always just had to use the consent form [as is]. (RW_409)

While the majority of the dialogue with respect to consent form templates was critical, some of it was much less so. Particularly for new or inexperienced researchers, such templates provided some much appreciated guidance; although, again the concern is that as a result of the convenience and accessibility of consent form templates, researchers are less inclined to consult the REB directly when in doubt about an issue. Despite this obvious worry, one novice researcher acknowledged her limited knowledge of ethics and therefore, her appreciation of templates as a tool in developing a consent form that would address the issues that the REB would look for in their review:

> ...providing the [template consent] forms, you know how they [the REB] have forms and tell you what you should be considering to put in a form was very helpful... Yeah, I found that really good, because I would never would've considered what to put in, I wouldn't have had any idea how to structure one, and I thought that was really useful. (R_306)

From the perspective of the REB, the notion of templates just makes sense. There are obvious compromises made by providing such templates, but as one REB member points out, recognizing the limitations can mitigate such issues. That is, templates are purposefully broad, and not intended to be used as an all-encompassing document. Researchers and other members of the research team should use such templates to guide their thinking about ethical issues, and modify the template as necessary to include information relevant to the specific research project. As this key informant indicates, such recognition would eliminate superfluous descriptions that are of no use to the specific project protocol or human subject(s), and could have added benefit of improving the success rate at which consent forms are reviewed and approved by the REB:

> Personally, I think the idea of a template is an excellent one as long as it's construed as a guideline rather than a rigid document. I think in specific cases ...a template can certainly create problems for certain researchers and certain cases but at the same time I think it's valuable to have a template, and especially an all-inclusive one so that people aren't constantly having to go back to the drawing board after having feedback from the Ethics Board and re-design their consent and send it back in again... and yet sometimes you'll get researchers who seem to be treating it as a rigid document that needs to be followed, putting in some statements that would just be confusing... given the nature of the research that they're actually doing. (REB_310)

Although consent form templates have caused some confusion, some researchers are aware that templates should be considered as suggested examples rather than as prescriptive documents defining mandatory elements of consent. A very active researcher with much experience submitting to the REB suggests that perhaps the REB

could be more proactive in trying to eliminate this common misunderstanding. Although there may be some flexibility, given that templates are not intended to be all encompassing, the REB should clearly communicate the expectations as well as the circumstances under which such deviations would be acceptable if such templates are to be truly useful to researchers and others who contribute to research processes:

> Ethics committees have always put up the informed consent template as something that could be modified, but to researchers I think many see it as something that shouldn't be tampered with. As a result you end up with some study designs, very survey-based, with a consent that really doesn't fit well to the individuals. So it's possible that the REB's need to be a bit more open with researchers about where there can be flexibilities in the way the consents are put together. I think we've learned over time that yes, there is actually a lot more flexibility but when you're new to it you feel that you have to stick with the template, and this shouldn't be modified too severely... (R_403)

Another research worker involved in the design and implementation of the consent form also acknowledged her hesitation in deviating from the consent form template as provided by the REB. Unaware that the REB does allow a modified version of the template, the research team put forth a much more paired down version of the template only to find out that such changes were acceptable. For this front-line worker, this experience served as a valuable, if unexpected lesson:

> We are concerned that these consent form [templates] are very difficult to understand and people read them but do they really understand them? [Ours had] lots of white space, lots of short sentences, simpler words, and they accepted it no problem. Because I was concerned about the template as well that you had to stick to it. (RW_312)

Confirming that indeed, the REB is open to the idea that in some circumstances the nature of the research may permit a departure from standard consent templates and procedures, one REB member comments:

> We do move forward, we do recognize that you sometimes don't have to jump and then go through every single point on every consent form, depending on the potential target audience, and that's a good thing. (REB_302)

Consent form templates did garner attention throughout narratives from interviews with all key informant groups. Mostly, discussion centered on whether such templates were useful or otherwise, and opinions here varied. Although in some respects templates are useful tools, it became apparent that there is still much confusion as to whether such templates should be considered prescriptive, or whether there is some allowance for revision. While templates have generally been put fourth by the REB to guide thinking about ethical issues, and are not intended to be all encompassing, this point has not been communicated in the most effective way. In fact, the provision of templates may have had an opposite effect; wherein researchers are less inclined to deviate from the information outlined in standard consent form templates, despite the general openness of the REB to consider variations. In this way, consent form templates are useful inasmuch as the purpose and expectations of its use are understood amongst key players. Otherwise, without much context, templates may help perpetuate some of the major challenges associated with current consent form documents; namely, that consent forms are very complex and almost excessive in the amount of information provided to human subjects. Thus, in all practicality it would seem that the advent of consent form templates has not been any more effective in helping researchers communicate the risks associated with research participation to human subjects.

4.5 *The Printed Consent Form Document*

Overall, while researchers and REB members play an important role in the consent process, research workers or those directly charged with the task of obtaining consent and explaining aspects of the consent document to potential human subjects had the most to contribute on the topic of the printed consent form document. Typical criticisms addressed issues of content and readability – citing difficult or complex language – which, when compounded with the consent form length, highlighted the major limitations associated with traditional consent forms. For the most part, key informants recognized the value of informed consent and support the underlying ethical principles; yet, despite much attention and concerted efforts to improve the consent form document, significant problems still remain.

Key informants identified many of the same limitations associated with consent forms as described in the literature, addressing issues related to the reading level, format and language. One front-line research worker contemplating some of these limitations expresses her criticisms of consent forms, which was similarly echoed across other key informant narratives. That is, despite the recognized limitations, there is still uncertainty as to how to improve or respond to these identified shortcomings:

> The consent forms are too long and the language level is too high without a doubt, but I don't know how to fix that. (RW_307)

Similarly, criticisms of the consent form are reiterated in a narrative with another research worker who described her diverse experiences interacting with human subjects at the initial stages of the consent process. During the interview, this individual suggests that requirements for increased documentation and complete disclosure has had the

unfortunate consequence of limiting comprehension of key information, rather than appropriately informing and empowering human subjects. This research worker stated:

> I find consent forms to be wordy, long-winded. They're way too long. For people who are healthy and are able to read, okay, so you're prepared and you can sort of struggle through it, but for people who are really sick or for people with low literacy skills... I just think that they're overwhelming. They could be formatted differently and better delineated... they could have shorter sentences, shorter words. (RW_409)

The most commonly cited limitations of current consent forms are an issue to which there is no single remedy. The structure of consent forms is such that the list of requirements with respect to general information, descriptions, explanation and disclosures require researchers to develop longer and more complex forms. However, narratives reflect the widespread perception amongst research workers that changes designed to improve the consent form and enhance human subject understanding have been both limited and ineffective. One research worker reflects on the implication of such changes from the perspective of the person most affected, the human subject. In the following passage, this informant suggests that at least some measures aimed at improving consent forms may be inappropriate, and have been implemented with little attention to important aspects such as the accessibility of the information, or even consideration of the public's expectations[18]. Furthermore, the notion that ethicists and REB members are well positioned (or at least better positioned) to decide which

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[18] Some groups, for example HIV/AIDS advocacy groups, have been both very vocal and successful in challenging paternalistic aspects of research design including, the criteria used for human subject selection in health research, how subjects could get access to drugs after research participation, and how others could get access to drugs, despite not being a part of a research study. These advocates managed to elicit changes that better met the needs of AIDS patients and research subjects, while at the same time helped incite changes that required researchers and REBs to revise ideas about risks and benefits associated with research participation, as well as what constitutes ethically sound research methodology and experiment.

protections for human subjects involved in research are most appropriate, implies that human subjects are not capable of reflecting and deciding on such issues themselves:

> From a trust-based structure to now, where... everything is so protocolized and almost rigid. I'm not sure the public really wants that either. How do we know that's what the public wants? They obviously want the best ...and safeguards in place to make sure that happens - I think there has to be some more common ground. It's gone too far. (RW_308)

Although front line workers may have more direct contact with human subjects throughout the consent process, researchers reflecting on both their current role and in some cases, past experiences as a front-line research worker, had much to contribute to the discussion. Researchers expressed disapproval with certain aspects of the consent form, which paralleled many of the same criticisms brought forward by research workers. A common theme throughout researcher narratives was that of uncertainty as to whether consent forms convey information to human subjects in a way that is both effective and clear. In particular, researchers questioned whether current consent forms truly provide human subjects with useful information to adequately inform their decision to participate in research. In order for consent to be considered valid, it must be voluntary, informed, comprehending and competent (Levine, 1986). If one of the four elements is absent, then informed consent is inevitably compromised. A veteran researcher notes that, in his experience, one tradeoff of providing more information in the consent form has been that fewer research subjects read through and/or ask questions during the consent process, which ultimately discourages understanding. The inclusion of more information has had the consequence of placing more emphasis on documentation and much less on the quality of information exchange. The informant reflected on changes in the structure of consent forms and expectations of the REB:

> Well, over fifteen years of submitting to the REB of course I can identify order of magnitude changes in terms of the length of the consents... sometimes the important aspects get lost in all the detail. I think especially for projects with individuals whose educational level makes it difficult to work through these long, convoluted consents... We've had the experience that they may actually sign off on some of these long consents more quickly and with less discussion and questioning than perhaps they might have done with a shorter form. (R_403)

Amid such concerns, researchers for the most part acknowledge the importance of the printed consent form in providing potential research subjects with information. Perhaps even more importantly, the consent form also provides human subjects with some degree of confidence, whether warranted or not, that the research is ethically justified and methodologically sound. In light of this, an experienced researcher reflects on some of the changes that have now been implemented as standard requirements for consent forms. Here, he argues that such additions while appropriate are still somewhat contentious, particularly with respect to the limits placed on what constitutes appropriate disclosure:

> ...one of the parts of the consent form is the declaration that it is funded by the private sector or it is funded by the public sector or the investigator is being paid or not being paid for conducting this trial... Those things have to be declared in the consent form. That's probably one of the good things that's happened in the evolution of the consent form. But really you could write that in two or three sentences and not in a page or a page and a half that it takes to address that issue nowadays. (R_410)

Both researchers and research workers shared their concerns about the printed consent form document. Criticisms focused on commonly cited issues of content, readability and the length of consent forms; yet, in light of these criticisms key informants still acknowledged the importance of consent forms and the critical information they present to potential research participants. The notion of how to balance the provision of information to human subjects in a way that is both comprehensive and

relevant was a constant theme. The challenge of ensuring human subjects understand the information presented to them and the key aspects of research participation, such as the risks and benefits, procedures, and their rights as human subjects, is one in which researchers and front-line research workers went on to discuss in more detail. So, while narratives initially focused broadly on the printed consent form, key informants went on to further reveal their perspective about some of the real-life practicalities of human subject recruitment.

4.6 *Practicalities of Human Subject Recruitment and Consent*

Researchers and other members of the research team, most prominently front-line research workers, are responsible for obtaining and ensuring that the consent process is respected and carried out in an appropriate manner. Whereas in the past, there were fewer constraints with respect to how consent should be initiated, current standards defining what is acceptable are much more objective and require that specific processes are followed. That is to say, ethical guidelines including the TCPS outline exceptions for departures from general principles of consent, list expectations with respect to incentives for research participation and define the limits of consent, including the nature of appropriate/inappropriate researcher – human subject relationships and instances when authority should be delegated to others to obtain informed consent. This shift has created both barriers and facilitators impacting human subject recruitment and informed consent for research participation. By focusing only on the paper consent form, the unique

features of the consent process and social interactions that occur during the negotiation of consent as it happens in practice is lost. Thus, exploring some of the real-world experiences of those involved in such processes may help to clearly identify areas for improvement and change in order to ensure a much more meaningful process of informed consent for not only human subjects, but also others, including researchers, research workers and REB members, involved in health research at all levels.

Both researchers and research workers revealed some of the issues that they perceived had an impact on the quality of consent. For some, quality was compromised simply given that human subjects do not easily understand the information presented to them, or even why such information is relevant. Consent forms expressly delineate the rights of human subjects and ethical responsibilities of researchers and institutions. However, both researchers and research workers expressed concern that legal and policy jargon in consent forms is intimidating and difficult to grasp. So, while consent forms, and the corresponding information they provide, do help promote research as an ethical endeavor and provide some degree of legitimacy, the way in which this information is communicated may actually limit the overall goal of the consent process; that is, adequately informing human subjects. Indeed, even the TCPS acknowledges that there may be instances of tension between the requirements of law and ethical principles, and advises that in such situations, "researchers should do their best to uphold ethical principles while complying with the law" (Interagency Advisory Panel on Research Ethics, 2008, p.17). One researcher speaks to this very concern, and acknowledges the challenge in trying to find a balance between upholding ethical and legal obligations, and

the responsibility to ensure that human subjects are appropriately aware of the research and understand the pertinent information specific to their participation:

> The REB wants a lot of information given or issues discussed, I mean, perhaps appropriately ... but to put that in simple terms, uh, or simple, meaning appropriate to the population... is challenging, and then the longer the consent form becomes, the more of a turn-off it is to the person. So I find it difficult to balance the two needs. (R_305)

A research worker reiterates this sentiment in much the same way. The informant, who works directly with human subjects to facilitate the informed consent process, specifically acknowledges the importance of the consent document. At the same time, he/she emphasizes how easy it is to lose sight of the overall goal of informed consent, which is to provide comprehensible information in order to facilitate human subjects' informed choice to accept or decline research participation, and this should ultimately take precedence:

> I guess, just my opinion... consent, very important/ very important that it's something written, and I would say, if it's too long, you sometimes lose the intent of, you know, informing people. I think it's important to try to remember what the essential components are so that people understand them more clearly. (RW_405)

The same informant later went on to discuss some of the practical challenges for research workers, or those responsible for presenting the consent form to potential research subjects. Again, the structure and content of the consent form is clearly a barrier. The research worker's narrative alludes to the ways in which such limitations impact the quality of the consent process, the research workers' perception about the effectiveness of current consent forms, and it provides a sense of how potential human subjects respond to these forms:

> Well there's the double-edge sword again... with consent forms. I think there is really a fine line between, you want to give enough information,

> so that the person truly understands what they're getting into, but you don't wanna give so much that the person will not want to read the whole thing, because it's just too long and onerous, and... (sighs) it's a hard one... I mean I understand what the Research Board is trying to do. They want people to be completely informed, so that's good... I don't think it needs to be done with necessarily more words. I think it just needs to be spelled out very clearly.... as a front-line worker, you do go paragraph-by-paragraph, (sighs) y'know, the person is almost asleep by the time you get [to the end] (laughter) so that's not good, you know. That's not good. (RW_405)

The majority of research workers identified the complexity of the forms and excessive amounts of information found in consent forms as a concern. Within these narratives, such misgivings were typically framed in reference to how such issues had an impact as workers sought consent from potential research participants. One individual paraphrased her thoughts, which was similar across narratives with other research workers. Specifically, as a front-line research worker, this informant acknowledges that current consent forms pose barriers for research workers as they negotiate consent, as well for human subjects as they try to understand and interpret the information disclosed:

> [Consent forms] are really detailed and it's really a pain to go through eleven pages with a patient, because they are looking at you after a while like, "Good night. I'm signing my life away. This feels like a will". That's the attitude they're giving you. (RW_306)

While the above statement seemed to be the prevailing sentiment amongst research workers interviewed, another research worker acknowledges that human subjects do accept some of the formalities associated with the process of consent for research participation. In the following narrative, the key informant describes her experiences with human subjects, who are quite cognizant of the fact that the descriptions found in consent forms are all part of the research enterprise. Accordingly, from her perspective, formal consent form requirements are not a barrier to research participation:

> I don't know –it is a sort of a process. Most [human subjects] take it all in stride and understand that the statements about risks and benefits are part of the formal consent agreement. (RW_412)

Other front-line research workers also commented on some of the other difficulties they have experienced when going through study information with human subjects as it is presented in the consent form. One issue that reappeared throughout narratives with several key informants was the notion that, despite the emphasis placed on the consent form document, human subjects rarely rely on this written information alone. Rather, when forming the basis of a decision to decline or accept participation in research, human subjects rely much more on the interactions and discussions with research workers present during the informed consent process. In this sense, research workers, or those responsible for negotiating consent processes, act as agents or representatives of the project, and may have more influence on a potential participant's decision to partake in research than the form itself. In fact, research workers observe that few human subjects read the consent form in a detailed way, unless prompted or encouraged to do so, and even fewer subjects base their decision on the formal written presentation of risk-benefit information provided in the consent form. This point comes across in the following passage, wherein a researcher describes his/her past experiences as a front-line research worker. Within this narrative, the key informant recalls some of the practical issues faced with respect to difficult language and lengthy consent forms, but goes on to also acknowledge the complex interactions that occur with human subjects during the consent process, and their trust in him/her as a source of information about the study via informal discussions[19]:

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[19] The role of the research worker as a focus of trust in encounters with human subjects in health research is engaged in greater detail elsewhere and will not be discussed in more detail here. See: McDonald M,

> The consent thing is really an issue... even for me because I'm not a lawyer and I'm still not used to it. I know it gets technical lawyer type ...but I got scared reading it... what I understood were the key aspects of the consent, we basically emphasized that... but it became really / people would tune out – that was one. Some people would kind of look puzzled, and it came down to trust... and that I was saying, "Yeah, it's okay". That's basically what it came down to. (R_404)

Clearly, front-line research workers make practical decisions[20] that shape the recruitment encounter and process of informed consent. Research workers emphasize that they act in order to compensate for what they perceive to be the limitations of the consent form. In the previous excerpt, the research worker indicates that he/she emphasizes what he/she understood as the key aspects of information about the research study; however, one's perception of the key aspects may very well depend on many factors and vary widely amongst individuals. The ways in which front-line workers "compensate" can influence how potential participants arrive at a decision to participate in research. Admittedly, the ways in which research workers "compensate" can differ, and their actions may be positive in some instances, but have a negative impact in others. For example, in practice some research workers may choose to expand on only some of the descriptions pertaining to research participation, try to define or simplify terms and language, while others may remain silent or may be ignorant of key ethical points and therefore, fail to emphasize such features as important. In theory, the process of

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Townsend A, Cox SM, Damiano Paterson N, LaFreniere D (2008). Trust in Health Research Relationships: Accounts of Human Subjects. *Journal of Empirical Research on Human Research Ethics*, 1556(2646), 35-47.

[20]Research workers emphasize what they understand to be the key aspects of consent, or try to 'compensate' for what they perceive to be the limitations of the consent form, and this can vary amongst individuals. Thus, there is the potential for a range in variation that occurs during this interaction. The differences between what is done versus what the guidelines suggest is referred to as 'practical decisions'; however, this term is not intended to suggest that such decisions do not have ethical content or importance simply because they are 'practical' in nature. Rather from a relational ethics perspective, the most ordinary exchanges and decisions made within the context of the process of informed consent give expression to 'what is valued' or harms to be avoided, and is therefore ethical in nature even if the word 'ethics' is not used.

informed consent should include a discussion of the purpose of the research, the research procedures and methods, benefits and risks of the research, alternatives, measures taken to protect confidentiality, costs and payments (if any), compensation for injury (if relevant), potential termination of the subjects' participation in research, the number of subjects in the study, the right to withdraw from the study without penalty, notification of new findings that may affect the subject's decision to participate in the study, and whom to contact for more information or questions; all of these topics should be discussed prior to research participation (Interagency Advisory Panel on Research Ethics, 2008).

An awareness of the role of the research worker and the way in which their actions can influence the process of informed consent is important because human subjects look to research workers as a resource to provide further explanation and to guide them through the information presented in consent forms. From in-depth interviews, research workers view their presence and active participation during the consent process as important. Whereas the consent form primarily serves a legal function of written evidence and proof that consent was obtained, discussions that occur between research workers and potential human subjects can often go beyond such information and as such, promote the ethical validity of the process by ensuring human subjects have an adequate understanding of important aspects of the research. The distinction between relationship-based communication with research workers and the official reading of the consent form is significant, and suggests that the consent process is much more complex and interactive than a simple signed consent form would imply. One research worker alludes to this, stating that often the research worker must provide information beyond that which is presented in the consent form in order to be sure that human subjects truly

comprehend the implications of their decision. In this way, discussions between research workers and potential human subjects might go beyond that which is expressly outlined in the consent form. In addition, this narrative also exemplifies the research worker's ethical commitment to ensure that information is accessible and that interactions with human subjects throughout the informed consent process are dynamic:

> Yes you have a responsibility… for them [human subjects] to be informed. In some situations you have to be very proactive if you don't think that they understand the research or their options. If you think of situations where you throw medical terminology at them- they may need a great deal of clarification and sometimes this is outside the written protocol. (RW_412)

Research workers spoke about their genuine concerns with consent forms, and how some of these issues render the task of obtaining informed consent much more difficult. From research workers narratives, there was an overall sense that research workers take on a lot of responsibility in their role throughout the consent process, particularly given that human subjects look to them more so than the information presented in the consent form, to make a decision about research participation. In fact, in this role, workers may be faced conflicting ethical obligations. Research workers feel a deep sense of duty towards human subjects and therefore endeavor to serve the interests of each individual by ensuring that human subjects are adequately informed about the research, but at the same time, they may be faced with other obligations, for example ensuring adequate numbers for enrollment in a given study, which may at times conflict. Subsequently, the research workers' loyalty may be split between the human subjects, the researcher or Principal Investigator and the organization that may provide sponsorship or contribute to overall project funds (Hill & MacArthur, 2006).

Certainly, there are additional benefits for organizations and its staff that run research studies. In terms of research workers, their career progression and sometimes even their jobs are supported by the completion of a successful research study. As such, this can result in a conflict of interest in that research workers who are responsible for informing human subjects about a research project have a vested interest in the study recruitment and its successful completion. Therefore, in some cases they may not be impartial or necessarily the best advocates for potential human subjects during the informed consent process (Jayson & Harris 2006). In situations where duties conflict, the obligation to the human subject should take priority; however, conflicts of interest are complicated and multilayered, which makes them difficult to resolve in ways that are transparent and easily understood by potential human subjects (Levine, 1986).

Given that the quality of consent seems less dependent on the information provided via the consent form than on the relationship-based communication that occurs between research workers and human subjects during the consent process, it would seem that a better understanding of the dynamics of these relationships is warranted. It is important to recognize that outside interests, beyond those directly relevant to human subjects' interests, impact the consent process as it happens in practice. Research workers' actions, including communication and dialogue with potential human subjects during the consent process are important; yet, these interactions remain largely unknown to other key players in research including researchers and REB members. Currently, the role of research workers during the process of informed consent is one that is over-looked or under-estimated. Researchers and REB members need to be aware that front-line research workers assigned to the task of obtaining informed consent must make practical

or 'real-time' decisions that can impact this process. Perhaps a better understanding of the perceptions of those who oversee, and are involved – both directly and indirectly – in the consent process can help facilitate constructive relationships through knowledge exchange, and bring some of the issues identified by research workers to the forefront. Additionally, opportunities for more open discussion and communication amongst key players involved in research can play a part overcoming some of the lingering moral concerns with respect to the process of informed consent and call attention to needed areas (Bird, 1996). An integrated approach, which incorporates the perspectives of varied stakeholders and emphasizes informed consent as a process that focuses on communication, understanding and relationships, may help to relinquish some of the attention from the consent form as a formal document. Drawing attention to the consent process as it happens in practice could help to improve informed consent processes and alleviate ethical dilemmas as they arise.

5.0 CHAPTER 5: Roles and Relationships

5.1 *Roles and Relationships*

The focus of the previous chapter centered on informed consent, while this chapter will explore roles and relationships, which emerged as another central theme. Not only did roles and relationships emerge as an important aspect with respect to the social interactions that take place with human subjects during the consent process, but it also emerged as a key feature in understanding the differing roles and varying visibility of those players involved in research in order to gain a more complete picture of some of the outside influences that also impact their actions, circumstances and environments.

While much empirical research has focused on the consent form as a document, very little research has looked beyond this narrow, albeit important piece, to explore some of the outside influences that may also impact communication, or what is communicated to potential human subjects. This notion of looking beyond that which is presented in the context of the consent form to examine the exchange of information that happens at the individual level grew partly out of a continued interest within the research ethics literature to improve communication with research participants, and partly as it emerged as a central theme from a content analysis of interview data. So, although narratives with key informants including researchers, research workers, REB members and other scholars frequently engaged informed consent within a broader contextual and relationship-oriented approach, this approach is rarely discussed in the literature.

Research is a collaborative undertaking and within such collaborations there are complex and interdependent dynamics of context, practice, agency and power that shape interactions amongst players in ways that may not always be apparent. From interviews with key stakeholders who all play a role – albeit varied and distinct – throughout the process of health research, what emerged from these narratives was a sense that the roles and relationships individuals occupy within the context of research ultimately impact how the research unfolds. Researchers, research workers, REB members, scholars and policy-makers all have differing roles and varying visibility within the research enterprise; however, all of these roles coalesce around the process of informed consent. The relationships amongst these varied players have an impact on the process of informed consent as it happens in practice (Hill & MacArthur, 2006). So for example, the way in which research workers view their role in research processes and relationship with the researcher can shape whether they feel comfortable reporting concerns and issues that may arise when they communicate information in the consent form to human subjects. Thus, in acknowledging the influence of these contexts and relationships, it is possible to explore how these varied players actually think and act, and its impact on the process of informed consent.

Typically, a research team consists of a Principal Investigator who oversees all aspects of the research project and is considered accountable from the beginning of a study right through to completion, including the interpretation of study results. The rest of the health research team can vary in composition and depending on the size of the project and/or funding available, may include other researchers or Co-Investigators, research workers including, research coordinators, nurses and other healthcare

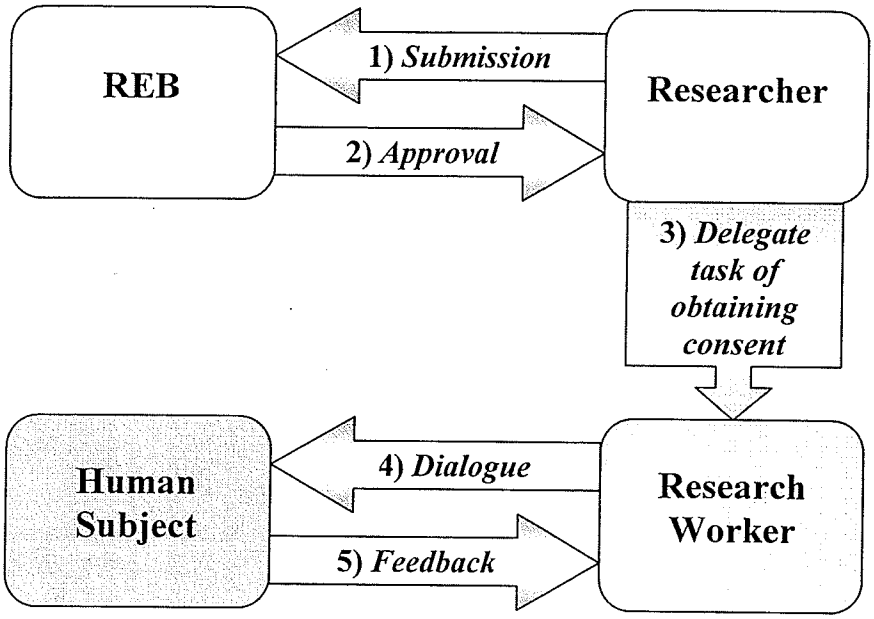
professionals, interviewers, translators, interpreters, research assistants, graduate and post-graduate students. Although not intended to be either comprehensive or exhaustive, this list of individuals typically represents the varied individuals who carry out research procedures. These individuals may have differing roles and their relationships to each other may be characterized by their distinct roles, but all of them share a common link in their connection to the research project.

The Principal Investigator [PI] assumes responsibility for most activities related to the project; however, the task of obtaining consent from eligible human subjects to participate in research is typically delegated to a qualified representative on the research team. In some cases, wherein research poses more than minimal risk, it may even be advisable to have a person who is independent of the research team altogether in this role (Interagency Advisory Panel on Research Ethics, 2008, p.22). The intent of this constraint is to create a separation between the researcher and potential human subjects in order to eliminate potential or actual conflicts of interest and/or undue pressure on research subjects to join (or remain in) a research study, which would significantly limit what is considered free and informed consent. So, recognizing the importance to preserve and not abuse the trust on which many professional relations reside, ethical guidelines that govern research practice advise researchers to disassociate themselves from human subjects during the recruitment process, and particularly with respect to the informed consent process (Interagency Advisory Panel on Research Ethics, 2008, p.22).

The process of informed consent is much more complex than a signed consent form. Figure 3 (See Figure 3: *Research Context: Varied Players and their Role in Informed Consent*) depicts some of this complexity and illustrates the different players

involved in the process and the flow of information amongst them. So for example, a researcher submits a proposal to the Research Ethics Board [REB] for review (1) and once the REB approves the research (2) the research can then begin. At this time, the researcher can delegate various tasks to the rest of the research team, including the task of obtaining informed consent (3), which is typically assigned to a research worker on the project. Most accounts overlook that in many (but not all) cases, the process of consent necessitates a personal encounter between human subjects and research workers. Thus, research workers take on the role as liaison between human subjects and researcher and in doing so, take on the communication, dialogue and information sharing that occurs during this process. Accordingly, research workers engage in dialogue with potential human subjects (4) about the possibility of research participation, go over the information conveyed in the consent form (or at least ensure that human subjects are given this information), and they also typically 'witness' as human subjects sign the consent form, which authorizes participation in the research study. As a result of the dialogue that occurs between human subjects and research workers, human subjects may provide feedback (5) in terms of their perception of the process, and insight into aspects into certain aspects of the research or consent form that they find confusing or difficult. In this sense, there are many layers and stages of the consent process that occur before a human subject even signs the consent form. Yet at the same time, the circle of communication does not complete and there are few, if any, opportunities for communication or direct relationships between human subjects and others involved in research processes (See Figure 3: *Research Context: Varied Players and their Role in Informed Consent*).

Figure 3: Research Context: Varied Players and their Role in Informed Consent



5.2 *Relationships and Human Subject Recruitment*

The notion of roles and relationships seems relevant with respect to informed consent and the social interactions that occur, particularly between research workers and human research subjects at the time of consent. In fact, research workers acknowledge that their presence during the consent process and negotiation of the consent agreement has an impact on potential human subjects that goes beyond the information conveyed in the consent form. One research worker's narrative conveyed this point while discussing her experiences and her involvement in the consent process. Here, the informant recognizes that there are certain subtleties and cues that can only be observed through

direct contact with human subjects, and in turn, human subjects communicate in ways that are not always strictly verbal:

> I think it's really important because they cannot get the sense from a piece of paper with words on it – the same sense that you get when you're sitting across from a person… When you're across from the person this whole interaction goes on, this physical thing with the eye contact and all that. (RW_409)

The active engagement that occurs between human subjects and members of the research team during the consent process is unique to research involving human subjects, and consequently adds an element of complexity. One researcher, with experience working both in animal research as well as research involving human subjects, emphasizes this point stating:

> …it does certainly have dynamics that working with mice does not have (laughter). (R_401)

The previous excerpt also calls attention to another important issue, which is that individual and professional experiences, as well as one's research background can influence theoretical constructions of informed consent. The way in which individuals perceive and interpret the notion of informed consent may differ depending on their biases. Perhaps one of the best examples is that of the ongoing debate between biomedical paradigms and social science frameworks. While current models of informed consent follow a biomedical model, many social scientists claim that the current formal consent procedures and review of consent forms by the REB are excessive given that most social science research, it is argued, tends to be minimal risk, or at least no more risky than that which is encountered in everyday life (Boulton & Parker, 2007). Thus, notions of what constitutes adequate informed consent may not be shared amongst all individuals or even across all disciplines. The process of consent is meant to provide

human subjects with relevant information about a specific research project, including the purpose of research, its risks and potential benefits. This process should be, informed, genuine, specific and/or explicit, and encompass the dialogue, information sharing, and general process through which prospective participants choose to participate in research (Interagency Advisory Panel on Research Ethics, 2008).

In most cases research workers, not the principal researcher(s), are charged with the task of obtaining consent from human subjects for research participation. A prevalent theme common throughout narratives of research workers was the relationship-based communication that occurs during this interaction. One researcher worker commented on relationships that develop, and observes that even under circumstances with limited correspondence, the interactions that occur at this early stage may significantly impact a potential human subject's willingness to participate in research[21]:

> You develop, in those three or four hours you meet people and you're privileged to listen to their experiences... I think you've connected with them. I think that if you don't connect with them, I don't think they would have agreed [to the research] in the first place. There has to be something there to make them say yes. (RW_308)

Although the overall circumstances are decidedly different, the above narrative evokes some vague similarities to Tuskegee Syphilis study, in that again, the research worker plays a pivotal role in the initial consent procedures and securing continued participation throughout research (Smith, 1996). In this way, research workers shape ethical conduct through these dynamic interactions and encounters with human subjects.

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[21] Research workers' perspectives on trust, and the depth of trust that develops between research workers and human subjects as a study progresses is discussed elsewhere, and will not be engaged further in this student thesis. Please see: McDonald M, Cox S, Kaufert P, Preto N (2009 August). Published in the Society of Clinical Research Associates [SoCRA] publication '*Source*'. The original work was prepared as part of a workshop for the June 2008 meeting of the Canadian Bioethics Society, and based on a keynote presentation at SoCRA's annual general meeting in October 2008.

Given that the process of informed consent, which begins prior to research participation, is often the research subjects' first introduction to the research, study procedures as well as the first point of contact with research workers, human subjects' initial impressions at this time factor into their decision to accept or decline research participation. And, while relationships at the beginning stages are clearly important, another research worker recognizes the importance of such connections on the future success of the project as well. That is, positive connections formed at the outset of a study between research workers and human subjects help to secure continued involvement in research and promote ongoing participation. An experienced research worker states:

> You really do need to have very intricate strategies that are ethical but nevertheless allow you to bring those people back in time and time and time again. (RW_406)

The majority of research workers acknowledged the importance of their role in maintaining relationships with human subjects, and its contribution to the ongoing success of a project as it progresses. The relationships that develop throughout the research process and the conversations that occur outside the parameters of the specific research questions or goals, impact human subjects and research workers. Within the context of these interactions it can be the subtle communications such as a wink, a look of confusion, or an exchange of information that is not necessarily captured by the formal research procedures that can be the most candid, and even influence the direction the research ultimately takes. Even feedback and/or questions that research workers receive from human subjects with respect to information conveyed in the consent form can reveal important insights into how research subjects understand certain aspects of participation, or which areas remain unclear. Thus, research workers as a result of their front-line role,

communicate with human subjects, and in doing so, may provide information beyond that which is conveyed in the consent form to provide more clarity or further explanation if human subjects require that. In this way, discussions between research workers and human subjects might go beyond that which is expressly outlined in the consent form. The resultant feedback they receive from human subjects as a result of these interactions, as one research worker points out, is important:

> Well what I found the most interesting part of research is the stuff that was never written, actually, because ...y'know, there's conversations that happen ...when people are finished filling out the questionnaire, and then it's like, we need to talk about it... but mostly for them, because that wasn't the goal of the research ... I think, [the PI] went on to say, "Okay, we need to explore more on this", just based on what the [research workers] were saying, you know, our team was saying that this is an area that we need to explore... (RW_405)

The emergence of roles and relationships as a central theme was common throughout interviews with diverse stakeholders, and not only with respect to the circumstances surrounding the informed consent process or those in the role as a research worker. The varied roles and relationships that play out amongst individuals working together as part of a larger research team also influence how individuals interact and relate to each other as the research progresses. Researchers, REB members and research workers articulated the complexity and diversity of their experiences and the ways in which varied roles and relationships had an impact on team processes, the work environment, and context in which the research and the informed consent process ultimately play out. The reality of some of these wider relationships tends to be over-looked or under-estimated, particularly with respect to research workers assigned to the task of obtaining informed consent. As evidenced in the previous chapter, the role of the research worker can be unclear both to the REB, since research workers are virtually

'invisible' as key players in the consent process, and to human subjects who may have trouble distinguishing the difference between research procedures and standard clinical care (Davis et al., 2002; Huntington & Robinson, 2007; Kaufert, forthcoming). It is important to recognize that outside interests, beyond those directly relevant to human subjects' interests, impact the consent process as it happens in practice, and this includes the dynamics of the relationships amongst those who oversee, and are involved – both directly and indirectly – in the consent process and health research more generally.

5.3 *Roles & Relationships with Human Subjects*

Research design and ethical protocol are set up to create a distance or separation between the researcher and the human subject, as a means of controlling for conflicts of interest and defining boundaries between research and care. This is particularly important in cases where clinicians also conduct research, since human subjects often conflate research and therapy, or what is otherwise known as the therapeutic misconception (Kimmelman, 2007). Many human subjects fail to understand that "research imposes practices on investigators that conflict with conventional ways of practicing medicine", and therefore fail to appreciate how research procedures actually interfere and/or differ from medical care (Kimmelman, 2007, p.37). So, whereas clinical care mandates " 'optimal medical care for individual patients', the obligations of researchers to their subjects consist only of protecting research participants from exploitation" (Kimmelman, 2007, p.38). Also adding to the confusion is the fact that

consent forms contain language that promotes or does little to dispel therapeutic misconception, and as a result human subjects are misinformed and tend to overestimate the medical benefits associated with research participation. Thus, the concern about therapeutic misconception is that it leads to exploitation and compromises informed consent (Kimmelman & Levendstadt, 2005). One mechanism, which has been established to avoid such misconceptions, has been for researchers to assign the task of obtaining consent to a qualified representative on the research team; typically, a research worker. Research workers recognize their role in liaison between the researcher(s) and the human subject as a means of emphasizing the distinction between research and care. A research worker comments on the dual and potentially conflicting role of clinicians who also conduct research, but frequently blur their role as a researcher with that of the caregiver:

> He was the researcher and he's also their clinician. Their roles are mixed – they do not see them having two hats. They do not see themselves as having two hats and neither do the patients because if they don't they can't show the patient two hats. They don't even understand that they're wearing two hats. They don't understand that… (RW_306)

Measures aimed at controlling for conflicts of interest and defining boundaries between research and care were intended to strengthen the responsibility of investigators to human subjects to avoid therapeutic misconceptions. However as Kimmelman (2007) notes, such measures may actually "flirt with excusing physician [researchers] from ethical commitments" (Kimmelman, 2007, p.39). Research workers who are delegated to the task of obtaining informed consent from human subjects take on this role and therefore have the added responsibility of dispelling misconceptions that are not clearly dismissed in the consent form; so, providing accurate explanations of the risks and

benefits, the completely voluntary nature of research participation, and that refusal to participate in research would not impact health care and/or access to services. Thus, the importance of the research worker's role lies in its seeming independence from clinical care and emphasis on distinguishing necessary medical intervention from voluntary health research; however, it is still not clear that human subjects always make this distinction at the time of consent. Nonetheless, one research worker succinctly captures the importance of this role in the overall scheme of research:

> I think that they have a research nurse so that they're trying to put a space between the critical care and the research... people are free to say no to me because they know that they'll never see me again as part of clinical care. I'm only the research nurse... my role is intended to put a nice old tight package around the research and separate it from the clinical care. (RW_307)

Within this intermediate position research workers take on much of the social interactions that occur, both informally as they try to establish a rapport with human subjects to engage them in a discussion about the possibility of research participation, and formally as they engage in consent procedures, such as witnessing the signing of the consent form. Given that such interactions are the first point of contact with research workers, this interface is pivotal. As a result of these interactions, research workers develop a unique yet complex connection with human subjects and come to be seen as a representative of the study. As agents who take on the formalities of consent processes, human subjects tend to view research workers as directly accountable for the research that they represent. As a result, research workers frequently spoke about their role as it is perceived by the human subject, and particularly how their visibility within the project as a front-line worker creates a sense of duty or accountability that may not be as immediate for others on the researcher team (for example, wherein the human subject is simply a

study number and/or completely anonymous). Throughout interviews, research workers acknowledge that human subjects come to see them as the 'face of the study'; they connect with human subjects, particularly at the time of consent, and inevitably, develop a rapport with them.

Even before a project commences or the research workers have been appointed to various tasks such as human subject recruitment and obtaining consent, there is a sense that a belief in the importance of the research is essential; this seemed particularly true for front-line research workers. Research workers alluded to the significance of the overall research goals in their decision to initially become involved as a member of the research team. From these narratives, research workers discussed how human subjects see them as the primary representative of a given research project and an object of trust[22], due in part to their role as the 'visible face' of research and engagement with human subjects during the process of informed consent. As such, research workers expressed their discomfort with being seen as a representative of a study that they do not entirely support, or one in which the goals of research were such that they did not feel comfortable endorsing. As Bird (1996) notes, individuals feel discomfort and distress when their moral convictions are compromised; yet, it is common for individuals to accept such distressing situations because they presume that such issues cannot be easily and/or effectively changed. Research workers may have moral concerns with specific research projects; however, the extent to which workers feel both willing and able to

[22] Research workers' perspectives on trust, and the depth of trust that develops between research workers and human subjects as a study progresses is discussed elsewhere, and will not be engaged further in this student thesis. Please see: McDonald M, Cox S, Kaufert P, Preto N (2009 August). Published in the Society of Clinical Research Associates [SoCRA] publication '*Source*'. The original work was prepared as part of a workshop for the June 2008 meeting of the Canadian Bioethics Society, and based on a keynote presentation at SoCRA's annual general meeting in October 2008.

voice such concerns is directly related to the emphasis on honest and reciprocating conversation within the larger research team. Communication amongst the research team can help to reduce stress over moral concerns (Bird, 1996). In this sense, research workers acknowledged the role in which they are placed as a person developing and maintaining relationships with human subjects, but at the same time recognized the implications of this role, both personally and within the larger scheme of the informed consent:

> There's a few studies that I wasn't able to do, or uhm, would start doing it and say, "Whoa, whoa, whoa, you know, I'm not sold on this, I will not be able to recruit one person" because y'know, I'm not comfortable with some aspect, either the research question, or you know, maybe what [human subjects] need to do. That was pretty rare. Uh, that happened maybe once. Uh, so I guess the first thing I'd always have to do is ensure that I was comfortable with the question, felt it was a noble goal... (RW_405)

As evidenced in the previous chapter, during the informed consent process, human subjects view research workers as an object of trust, and rely on them as a source of information about the research study. In fact, a common perception amongst research workers was the notion that human subjects rely much less on the information provided to them via the consent form, than on information provided to them via discussions with research workers. In this way, although research workers may not have a great deal of formal power to affect change with respect to the overall research project and its progress, they communicatively exercised informal power strategies in the performance of their role during interactions with human subjects. Thus, the preceding narrative reveals at least some of the ways that research workers are able to draw on informal power to manage both organizational and also hierarchical constraints in order to advocate for what they believe to be appropriate ethical oversight.

Many research workers identified the importance of their belief in the underlying objective(s) of research in which they were involved, and this theme resonated across narratives. Specifically, one research worker reported much greater personal and professional satisfaction when she believed in the goals of research and that the project could hold real benefits, whether immediate, direct or otherwise, for human subjects. Interestingly, this belief, which focuses on the value of research in terms of risks and benefits specific to human subjects is distinct from ethical guidelines and consent form requirements that articulate the importance of informing human subjects about the foreseeable risks and benefits of research participation; however caution that in most cases, the primary benefits produced are for society at large and the advancement of knowledge, and very rarely does research directly benefit the participants themselves. The research worker stated:

> I found that it's not been difficult to approach people. I think when I'm clear in my own mind why I'm there and I think also having come from a background of not really believing that research was a benefit to now seeing that who knows in the big picture what the study will prove, but I know in my heart that for some people research is really beneficial just to talk. (RW_312)

Again, the resounding theme within research worker narratives was that of the importance of a belief in the overall research project. Another research worker commented on this, but added that this belief also served another function in contributing to the overall functioning of the research team, which ultimately plays a part in success and accomplishing the overall goals of research:

> The research team… even the front-line worker's, to be a good front-line worker… you have to, I think anyway, you have to believe in the… overall mission. (RW_405)

Regardless of their own beliefs in the overall benefits of research participation, research workers were cognizant to not let their feelings of enthusiasm influence human subjects and their willingness to participate in research. For the most part, research workers recognize that the decision to participate in research should be based on the human subjects own appreciation of the risks and benefits of research, and their choice to accept or decline participation based on such assessments. In fact, research workers remained remarkably sensitive to the ways in which research participation can impinge on human subjects, their daily lives and their even families and friends in varied ways. Research workers spoke of the deep sense of responsibility they feel towards human subjects as it relates to their unique position as delegates assigned to the task of obtaining informed consent. Accordingly, research workers described their efforts to remain accountable and ensure human subjects have a thorough understanding of all the relevant risks and harms that could directly result from study participation. One research worker, acknowledging both the impact of research but also her own important role in the formal consent process as he/she negotiated these consent relationships, stated:

> We [research workers] were the security blanket to make sure. We were the only ones looking out for the patient's rights, and you felt that all the time. (RW_306)

As key players who are often viewed as representatives of the study by human subjects, research workers interact with human subjects at points throughout research participation as well. Through these interactions, research workers gain a sense of the extent to which the research has progressed as human subjects understood from the consent agreement. Thus, research workers occupy an ideal position to view first-hand the impact of research and garner feedback from human subjects with respect to their

research participation experiences. This interface between human subjects and research workers creates a feeling of continual accountability for research processes and procedures as conveyed in the initial consent process. In the following passage, an informant elaborates on the role in which research workers are placed as someone responsible for developing and maintaining relationships with human subjects not only at the beginning stages when negotiating consent, but also over time and the sense of responsibility that this continual engagement elicits:

> So there's an accountability for what's been done since you saw them last, and there's a hope and an expectation [on the part of human subject] that things could be improved and all of that... and a bit of a cheerleader sometimes just to help them on the road of longevity or recovery depending on the study. (RW_307)

Similarly, another research worker acknowledges the practicalities of her role and conveys the sense of duty that she feels towards human subjects, not only at the outset during the consent process, but also as the research is carried through to completion. Such notions are particularly important with respect to cultural contexts, for example research involving First Nations or Aboriginal peoples, wherein the way in which results are interpreted can contribute to negative stereotypes or inaccurate perceptions, and therefore can have a deep impact on communities and individuals long after the research has ended. For this reason, even before securing voluntary informed consent from individual community members, community engagement is required in order to ensure cultural sensitivity and culturally informed advice on ethical protections (Interagency Advisory Panel on Research Ethics, 2008). Speaking from experiences as a front-line research worker, this informant indicates that although study participation ends, the

experience of research participation continues to have a powerful effect on human subjects:

> I guess I also am aware that people continue to think about those [research] questions when I leave and that just because I leave doesn't mean that they don't think about it anymore. So I feel some responsibility for how I leave. (RW_312)

In discussions about the nature of their work, what emerged was a unique view of the complex interactions that occur between research workers and human subjects participating in research[23]. Although, the research workers interviewed were involved in a wide range of research projects and performed different tasks, it became apparent from their narratives that despite these differences, there was a similar bond or connection that develops between human subjects and research workers both during research participation, and even after research participation was complete. And while it may seem as though the relationships and encounters that carry on past the initial informed consent process are no longer relevant to the connections that were established at this early stage of research, in fact, the social interaction that research workers take on as they obtain consent from human subjects is a significant first point at which this relationship was established. As substantiated earlier in the chapter, research workers establish a rapport with human subjects in order to engage them in a discussion about the possibility of research participation, and also more formally within the context of the process of informed consent. Even under such circumstances wherein the consent may only constitute limited correspondence, the interactions that occur at this early stage may significantly impact a potential human subject's willingness to participate in research.

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[23] Further discussion of the roles of research workers and its impact on their professional role and duty to human subjects in health research can be found in Kaufert P, Kaufert JM, LaBine LJ (fourthcoming). *The Invisibility of the Health Research Worker.*

Essentially, there is connection that is made between the research worker and a human subject during the consent process that then carries on throughout research participation, and encourages their continued involvement in research. Hill & MacArthur (2006) even describe research workers as the "vital link" between human subjects, researchers, study sponsors and other research team members, and particularly with respect to how the research unfolds in practice. A research worker commented on this connection, and the circumstances in which it is established:

> ...you are asking questions that emote answers of various kinds. Some people just fill it in and that's it and other people like to tell you why they gave you that answer... and we're given so much information. I don't know if [human subjects] remember us [research workers] or not but I think for that time sometimes I feel a greater relationship than I did caring for somebody on a ward physically doing things for them. There's something much more there but I think it's probably very temporary." (RW_312)

From the preceding narrative, the informant recognizes that due to the personal nature and/or the sheer amount of information collected about human subjects for the purpose of research, there is a very deep and personal bond is created in that moment. Whether this bond is temporary or long-term, or even mutually shared amongst human subjects as it is with research workers, can vary from project to project and across humans subjects themselves. Another informant, speaking about his/her experiences on a project in palliative care, indicates that the highly sensitive subject matter and vulnerability of the subjects and the situation overall can also influence the immediacy of this rapport[24]. This research worker states:

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[24] This issue is discussed in more detail in McDonald M, Cox S, Kaufert P, Preto N (2009 August). Published in the Society of Clinical Research Associates [SoCRA] publication '*Source*'. The original work was prepared as part of a workshop for the June 2008 meeting of the Canadian Bioethics Society, and based on a keynote presentation at SoCRA's annual general meeting in October 2008.

> But when you go and all these patients are dying within days weeks or months of when you get to know them and their kids come up and hug you and the wives are crying, the husbands are upset. I mean, whatever is going on... I didn't really know what the connections were that you have to jump into, but they tell you their life story. It's a privilege but it's also very exhausting... (RW_307)

While research workers similarly expressed a distinct connection to human subjects, many were also conflicted when it came to what their perceived role in relation to human subjects should necessitate. For research involving First Nation and Aboriginal Peoples, informal encounters to establish relations and engage communities in research are encouraged (Interagency Advisory Panel on Research Ethics, 2008). A scholar with much research experience working within multi-cultural contexts and communities, indicates that relating to human subjects informally and on a personal level was appropriate, if not an expected part of a community-centered approach to research:

> For example, going and sitting in someone's house, and having a cup of tea to interview them, to me, that would be normal. And I don't think for non-native scholars that would be "not-normal" either... (S/P_301)

As indicated in the previous narrative, for those working in other areas aside from research involving First Nations or Aboriginal Peoples, this notion of relating to human subjects outside the specific parameters of the research protocol seemed appropriate to some, while others had a much different view[25]. Recounting his/her experiences as a research worker, an informant spoke about the duality of the research worker's role as both an information collector and object of social exchange. Within this context, the

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[25] The notion of role conflict was prevalent within the research worker category, and this may be due to the fact that research workers have a wide, yet perhaps poorly understood and ill-defined role (Hill & MacArthur, 2006). An additional factor that may contribute to these discrepancies is that research workers vary widely in their background and professional experience. While some may have a background in nursing and therefore are guide by those professional codes of ethics, others do not ascribe to such professional dictums.

research worker describes his/her duty to complete the objectives of research, but not at the expense of ignoring issues as they arise and above all, participants at risk:

> I turned off the tape recorder and... you have to be very comfortable in your mind, "Well that may be it for the research part of this but that's okay because this is more important right now", and we dealt with it. (RW_308)

While some research workers felt that their primary responsibility was to protect the individual interests of human subjects, others felt their obligation was to "support the accrual of knowledge" which focused more generally on the responsibility to generate knowledge that could benefit society as a whole (Hill & MacArthur, 2006). There was some discrepancy with respect to how research workers perceive their role and subsequent duty to human subjects, particularly as it pertains to incidental findings that may have important psychological, social, health-related or other implications for human subjects, and arise from carrying out study procedures, but are not the focus of research itself. As evidenced by the previous narrative, while some research workers are inclined to take control of such situations and handle incidental findings directly, others felt it was beyond the realm of their research responsibility. The issues regarding what needs to be done and the obligations of researchers and research workers with respect to incidental findings are generally divided into two streams. One stream concerns what should be done about the vast range of findings that may arise incidentally to research conduct. The other asks whether researchers owe human subjects ancillary care; that is, medical care that study participants need but that goes beyond what is required to conduct research and complete the study objectives (Richardson, 2008). Once again, this issue raises some concerns about the blurring of medical care versus research, and the question of what to do about incidental findings still remains a much debated challenge in research ethics

(Richardson, 2008). One research worker expressed his/her view about the extent to which research workers should involve themselves in issues outside the specific project parameters, even if such issues arise during the course of research participation. In the following excerpt this informant acknowledges his/her obligation to advise human subjects of the appropriate resources if help is required, but refrains from taking on this responsibility directly. The informant stated:

> So when I do the interviews I don't have to try and find a way to resolve issues. I'm there as a sounding board and if you want resolution I'll help you find that in someone else." (RW_312)

In practice, how a research worker responds to incidental findings in the context of research participation is a function of his/her understanding of the purpose of their work and role in facilitating research. The position of the research worker is often complex due to a combination of contractual or professional obligations as well as their perceived duty to remain accountable to human subjects. The conflicted role of the research worker frequently emerged as a topic of discussion, and as Hill & MacArthur note (2006), this may be a consequence of the wide, yet perhaps poorly understood and ill-defined role of the research worker (Hill & MacArthur, 2006). An additional factor that may also contribute to role confusion is that research workers vary widely in their background and professional experiences. So for example, while some may have a background in nursing and therefore are guided by professional nursing codes of ethics, others do not ascribe to such professional dictums and the corresponding ethical and professional responsibilities. In the following passage, a research worker comments on the importance of maintaining objectivity throughout data collection despite the apparent relationship that develops amongst human subjects and research workers. During the

course of research participation, this informant argues that research workers must uphold some level of neutrality in order to remain focused on the task at hand, which is to conduct good research that will benefit society at large and perhaps even more importantly, not to interfere or influence research results as they emerge:

> I mean as data collectors it's really not our role to sort of start getting into stuff with people. I mean you kind of walk this line between sort of being warm and friendly and allowing someone to express stuff but at the same time knowing that you've got these questions that you need to get through and that you don't want to influence too much… (RW_409)

Regardless of their perceived role in relation to human subjects, it is clear that research workers feel a sense of duty to the human subject, if not merely to assist them in navigating through their research experience, then to ensure that the research is carried out in a respectful manner. The relationships that form begin when research workers first engage human subjects within the context of the informed consent process. The theme of roles and relationships between human subjects and research workers figured prominently throughout interviews with research workers; however, this theme also emerged in a much different sense. Roles and relationships between research workers and researcher(s) or the principal investigator as members of the research team were also significant. Throughout interviews with workers and researchers, narratives revealed the ways in which roles and relationships strongly affect each project, related tasks, as well as the overall management, coordination of the research study and teamwork in general. In this sense, the roles and relationships amongst team members were important as it relates to the research team and successful collaboration.

5.4 *Roles & Relationships with the Research Team*

Within the context of research, there are many individuals that fulfill varied roles and activities in order to meet research objectives. Individuals must work together towards a common goal and team coordination strongly affects research activities, productivity and collaboration, even at the initial stages of a project. From the narratives of key players involved in the research process, both research workers and researchers revealed their experiences working as part of a large research team. Emerging from these narratives was the notion that human resource dimensions such the personal characteristics of collaborators and the effectiveness of the group in communicating with each other, factor prominently in the overall productivity of the team and ultimately, the end result of research.

As part of the larger research team, research workers are hired by researcher(s) or the PI, and are typically paid out of project funds. Under these circumstances, the PI manages the terms of the research worker's employment agreement and other structural factors, such as authority structures, training and participation in decision-making. Therefore, these structural dynamics can influence the overall organizational disposition, and implications for research workers to contribute and participate as a fully engaged member of the research team. As is apparent with any collaboration in which there is some disparity within the group, inevitably dynamics of agency and power shape interactions amongst research team members. In particular, despite the fact that research workers play such a central role in the front-line negotiations of consent agreements, this role is rarely acknowledged and research workers are seldom given the opportunity to

contribute to the development of consent forms or offer practical advice from their experiences with human subjects. Although not all experiences discussed were negative, research workers tended to characterize their role in relations to the researcher and research team as subordinate, despite their involvement as central members. One research worker iterates this point, indicating satisfaction with his/her role as a research worker, yet acknowledging the marginalization of this role and the clear division that exists. This informant states:

> I love this work. I really do. In some ways I feel like maybe I sort of missed the boat years ago. Maybe I ought to have done a career in research… so I'm just kind of like the – I'm just one of the peons you know. (RW_409)

Amongst key informants this was a shared theme and narratives with research workers revealed their perception of power imbalances amongst team members. Another research worker perceived that such imbalances often leave little room for influence or authority in relation to the PI, particularly in instances of disagreement:

> …it's not an equal relationship, it's a power relationship… and your job is on the line the minute you start questioning… (RW_306)

As indicated in the narrative above, research workers often feel as though they occupy a position of marginal importance, power or influence within the larger research team. Dynamics and relationships amongst research team members become particularly important in instances where research workers raise concerns about disclosures and information conveyed in consent forms, standards of practice or even preliminary research results. Structural factors can influence the circumstances under which research workers act, for example, by reporting or stopping a situation that they deem inappropriate, or not part of the risks and/or benefits initially negotiated in the consent

agreement. Research workers' fears of repercussions, labeling and blame, along with doubts about whether anything would be done, factor into their decision to raise such concerns to the Principal researcher and/or research subjects. One research worker commented on the lack of confidence many research workers have in current reporting systems and some of the reasoning behind this doubt:

> There are… prominent stories of research coordinators who suffered when they tried to whistle-blow… and ultimately when somebody did listen the [workers] lost their jobs… (RW_307)

In recognition of the complex relationships that exist between researchers and hired team members, research workers openly discussed their experiences – both positive and negative – and noted the circumstances in which they found the most satisfaction in their professional role. More often than not, research workers spoke of the importance of the opportunity to voice their opinion in a way that allowed such views to be fully acknowledged as a valued member of the research team. Such considerations emerged as important for research workers as they weighed potential opportunities for employment. The following response reflects this and emphasizes one research worker's decision to actively seek out work opportunities that support these ideals:

> So there are people I wouldn't work for and job opportunities I've passed up. I want to stay where I can practice with integrity but my voice can still be heard… which I've tried to seek out those opportunities, by not working for somebody that would be too intimidating, you don't need the little battles every day… (RW_307)

Clearly there are motivational forces, both conscious and unconscious that determine behavior, attitudes and choices. Participation as a valued member of the research team was an important theme that appeared throughout narratives with research workers. One veteran research worker acknowledged that her many years of experience

has provided the confidence to offer an opinion, and provide objective feedback to researchers without issue. For some novice research workers, this can be a real issue in that they may be less empowered to contribute or even less valued within the hierarchy of the research team. In such cases, the practical knowledge that research workers gain from their interactions with human subjects, during the consent process for example is ignored. This informant spoke from experience and commented on the way in which structural determinants may have an impact on some less experienced workers:

> I'm at a place in my life and my career that if I thought I had a contribution to make in [some] regard I'd just say it. They [the researchers] could do with it what they wanted but I would just say, "This is what I think". I know that would be more difficult for people in different circumstances. I can imagine circumstances where some researchers just think that they have all the ideas and they don't need to hear about it from anybody else. I wouldn't really want to work with someone like that. (RW_409)

Yet another research worker further commented on the dynamic interplay between research team members, and the importance of engaging all members of the team equally. More specifically, this informant discusses the informal patterns of communication and the importance of the opportunity to provide feedback to colleagues in a manner that is well received. This informant states:

> I try to talk about [issues that come up] with the team I'm working with. I can be quite forceful in my opinions but my opinions matter. I'm lucky. My opinions matter so I'm taken seriously. I'm lucky. I'm never ignored. (RW_308)

While research workers commented on the dynamics of working relationships, researchers focused much less on personal relationships, and reflected more on some of the general aspects of successful research teams. Despite the fact that the researchers interviewed were representative of several different methodological backgrounds, their

narratives similarly acknowledged the importance of training and preparation as a means to ensure the team was on the same page and working towards the same goals. One researcher captures this sentiment, clarifying the selection process and training that that should occur prior to initiating study procedures:

> ...we do really thorough training before we send people into the field and we do competition... you have to have a CV. So we do it that way rather than just hiring just almost anybody. (R_406)

While training emerged as a central concept amongst researchers' narratives, another underlying theme that became apparent was that of communication. In order for teams to function effectively all players, including research workers, must be aware of what is expected of them in their role. Communication at several points throughout the research process was an essential strategy to facilitate collaborative links between research workers and researchers. From the perspective of researchers, frequent contact with workers provided an opportunity for exchange, particularly if assistance or expertise was required. Equally, this interface provided researchers with a sense of what workers were encountering on the front lines. The overall sense that emerged from researcher narratives was that communication creates a better working environment, which leads to a much more effective and creative means of answering complex research questions; although, the extent to which communication occurs in an open and effective manner in practice is still somewhat debatable. Nonetheless, in the following passage, a researcher tries to clarify the important nature of this relationship or rather, how both monitoring and communicating with research workers throughout the study helps to maintain the integrity of the research project:

> So what we have opted to do this time is to limit the number of interviewers ...we hopefully have a smaller number of better trained

> interviewers, and we've tightened up on the monitoring process on the questionnaires so that they will be reviewed at a very early stage for completeness and accuracy... So we're hoping that by doing that we can provide rapid feedback to the interviewers and help them to improve the quality of their data collection at source rather than trying to clean it after the fact, which is near impossible. (R_403)

The above excerpt points to another important feature, which is that given their position as a vital link to human subjects, researchers, study sponsors and other research team members, research workers could effectively contribute to learning or feedback loops. So for example, research workers could play a key role in communicating the extent to which consent processes are both effective and efficient, and wherein improvements might be made. Along the same lines as the previous narrative, a researcher worker with much experience working closely with researchers to train new workers hired to the research team, also spoke about the importance of a continuous dialogue between all members of the research team. This informant goes on to acknowledge that eliciting feedback as part of a constant exchange of ideas has been the most effective way of engaging issues and effectively addressing problems as they occur in research practice. He/she states:

> What we've done... we thought it's best to do a fair amount of training at the beginning... and then two weeks down the road you engage them [research workers] again, and actually, you keep engaging the team, and I think that's the best way to do it, so that if something is not working well ...you hear about it much more quickly. And then... kind'a hear what's going on, it's absolutely important. (RW_405)

The importance of communication was not only an important theme emerging from researcher narratives; it frequently came up in dialogue with research workers as well. As research workers acknowledged the expertise of researchers and their efforts to provide workers with support and training, workers also emphasized the importance of

communication throughout the research process. Inevitably, the practicalities of social relationships, such as those that develop between human subjects and research workers at the time of consent, are such that issues can arise that would not always apparent if research workers were not present during this process. One research worker spoke to this, but also about his/her thoughts about the researchers' responsibility to promote openness and sharing amongst the research team in order set a good example and encourage a productive work environment:

> I think researchers – if I could say – need to know the entire scientific or research process. Not just the generation of ideas, not just measurement issues, they need to know what they're frontline workers are doing and how they're doing it, because as one [researcher] once said to me, "garbage in, garbage out". If the researcher doesn't know and isn't committed to making sure they're training the frontline workers really well …I really admired [named researcher] for being right down at the intersection between the data collector and the human subject because that assured, I think, some quality assurance in the data collection, so that he/she had confidence in the process. I think that's really, really important. (RW_409)

Another research worker also recognizes communication as an important element, and clearly emphasizes its benefits not only for the research team, but also in the overall scheme of research productivity and achievement. This informant summarizes his/her thoughts as follows:

> …if you're communicating well, and you're working as a team, and you've really thought through the [research] process. Uh, that's a good thing for your question, and it's also a good thing for everyone involved, including the participants. (RW_405)

Interview narratives from key players directly involved in research reveal that there are several factors that play out and affect the functioning of the overall research team. One of the most central ideas reiterated across researcher and research worker interviews was that of communication. Communication developed as a key concern for

researchers in the overall management and coordination of the research project and research workers echoed the importance of communication between team members as a means of expressing and resolving issues that arise in a concerted way. Given that the relationships between researchers and research workers are influenced by dynamics of agency and power, communication emerged as a key feature in establishing collaborative links amongst team members and in contributing to a productive research endeavor. Honest and reciprocating conversations can help reduce stress over moral concerns and call attention to pressing issues (Bird, 1996). Again, the wider context of roles and relationships is important because it has an impact how individuals work together to complete the goals of research, and this includes how ethical principles for research involving human subjects are incorporated, emphasized and operationalized. In order to explore some of the outside influences that impact circumstances and environments, it is important to gain a complete picture. That is, for example, there are many individuals who all play varied roles in the informed consent process – REB members, researchers and research workers. These individuals are collectively responsible for regulating, obtaining and assuring informed consent, and they are all subject to various moderating influences that place constraints on fulfilling these roles. Exploring some of the dimensions of these relationships can perhaps provide more insight into some of the practical and ethical concerns involved in the day-to-day work of these individuals and their role in consent processes. The roles and relationships that develop amongst research team members is important in understanding how research plays out; however, the Research Ethics Board [REB] and Organizations (e.g., university, private agency, etc.) also play a role in research processes. Researchers, research workers and REB members

also discussed some of the ways in which institutional guidelines, regulations and/or policies can impact research and commented on the flow of information between these key players. In what follows, discussion of some of the outside relationships and roles of others involved in research in various ways is explored.

5.5 *Roles and Relationships with Institutions and the Research Ethics Board*

In addition to the core research team, there are other players who influence research processes in terms of how research should play out according to policies and best practice guidelines for ethical research. In this regard, the Research Ethics Board [REB] plays a central role, given that institutions such as universities, hospitals and even government agencies, require review and approval by the REB prior to a study's initiation. In this assigned role, the REB fulfills its duty to represent the interests of the human research subjects on behalf of the institution and inevitably engages researchers, particularly at the initial stages of a project with respect to protocol development, research ethics and adherence to specific legislative requirements. Essentially, the REB acts as a gatekeeper, responsible for taking the ethical principles reflected in research guidelines such as the Tri-Council Policy Statement [TCPS], and turning them into workable canons to which all research involving human subjects must adhere (Corrigan, 2003; Knoppers, 2009; Whittaker, 2005). For the most part, REB review has been both 'front-end and paper based', which means that REB review has tended to focus it efforts on review of the consent form, and there is little follow up and/or ethical oversight once a

project has been approved (McDonald, 2000; 2001; Knoppers, 2009). As indicated in the first chapter, there are challenges to ethics review for health research, and particularly one that focuses almost exclusively on the formal printed document. Exploring the exchange of information that occurs between the REB, researchers and the study team and the way in which these key players relate to each other is important in understanding the overall landscape of the research environment. Quality research depends on clear communication and collaborative working relationships between these key players, and an understanding of some of the challenges that arise. Looking more closely at the roles and relationships between these individuals may give an indication as to whether there are gaps in the flow of communication, and point to possible areas for improvement that could influence both the process and outcomes of research and improve accountability and governance of research overall.

Created in response to a history of unethical research, the REB was formed in an attempt to streamline a variety of processes to ensure the protection of human subjects. At some institutions the REB has an additional role; that is, to take a further look at proposed scientific methods to ensure the highest quality research (Enfield & Truwit, 2008). Although the REB has become an established step in the research process, there are still concerns, predominantly amongst researchers, that the REB is akin to an oppressive oversight body bound by overly bureaucratic regulations that are designed to inhibit research and protect institutions rather than human subjects involved in research. In actuality, the REB should offer the added benefit of perspective, which is afforded by the REB members' distance from both the research/researcher(s) and research subjects (Burke, 2005). At the same time, this distance can create tension between the REB,

researchers and research workers, wherein the REB is characterized more as an obstacle, which in turn, obscures the original intent of REB review and discourages didactic benefit (Knoppers, 2009). A former REB member, who is now actively involved in research involving human subjects, comments on this relationship. This informant offers a straightforward view of what he believes to be a common perception amongst researchers about REB review, and he/she stated:

> The work of the REBs not respected by researchers in general. It's not something that they think, "Gee, good, I'm gonna get some good feedback from the REB, thanks so much."... a necessary evil, yeah, it's very much something they don't want. (REB_302)

Another individual with expertise in ethics and policy reiterated this very same perception, noting that the REB is often unfairly characterized as a barrier to research and progress overall:

> Usually the ethics board is, for whatever reason – the idea is that members of the REB just for the sheer thrill of it want to hold up research so that the researchers can't get on with the business of saving lives (laugh). (S/P_415)

To be clear, narratives from interviews with key informants also revealed some very positive discussion with respect to the overall REB process. For the most part, informants revealed that the REBs comments were useful and ultimately added to the overall strength of the project. However within the context of REB review, repeatedly researchers, research workers and scholars called attention to one major concern; that is, informants criticized the elusiveness of the REB, particularly in the earlier stages before a project is submitted for ethics review. The lack of availability of the REB for consultation or advice about ethical issues was viewed as problematic, and contributed to the frustrations of researchers and research workers as they tried to anticipate potential

ethical concerns in advance of ethical review. Further adding to these frustrations is, as Knoppers (2009) notes, the limited availability of the most recent REB decisions and approved supporting research documents, such as consent forms, to guide applicants or even demonstrate transparency. One researcher reflected on these issues when asked to discuss some of her experiences with REB review:

> Submitting proposals... well in general it's been ...I would say on the positive side, when they [the REB] have a question, it's usually relevant... it's not flippant. I think it probably does make the study stronger. So I find their remarks thoughtful... on a challenge, or negative side, I don't think perhaps they are as available to go to, at the beginning, before submission, to assist us the researchers in meeting their requirements... it hasn't been that easy to set up a meeting, and to get the kind of feedback from them, the assistance. I think they really should set up an entire office where they welcome you, you know, they like to see you, they make time for you, and they answer questions so that when you've finally submitted, it's all in order ...so that's a problem. (R_305)

Still, other informants went on to comment on the availability of the REB as a resource, not only prior to research, but even as the research progresses as well. One theme that clearly resonated across all informant groups was the notion that there are few outlets to really engage the REB other than through the process of blind review itself. Currently, attention to the consent form, both the wording and structure, constitutes much of the focus of REB review. The review and approval of consent forms occurs prior to research recruitment, and therefore there is little engagement with the REB beyond this point; that is, when human subjects are actually given the approved consent forms. If issues happen to arise during the process of informed consent, such as concerns about clarity of the descriptions conveyed in the consent form, there are few opportunities to engage the REB and inform them of such concerns aside from re-submitting the consent form and proposed amendments for further REB review and approval. In this way, the

REB currently functions as a "gate-keeper", monitoring the approval of research, rather than playing a more interactive or educational role in ethical development that might incorporate consultative services.

In fact, researchers, study staff and scholars went on to say that more could be done by way of communication, for example, to let them know how the REB operates and what is expected, in order to make the process of review clear for applicants. As one research worker points out, some of the frustration associated with REB review may be attributed to the difficulty the research team feels in trying to navigate their way through such processes, anticipate the requirements of the REB, and what policies and regulations are applicable to their own research, and therefore must be incorporated or described in the consent form. This informant states:

> I think the REB have a critical role in helping me and my colleagues really navigate the sea of quality …research and where goes where and what do we do for this, and how does that impact on the privacy legislation? It's very convoluted. Trying to help us sort that out and – I've never had an issue. We've always done a good job but you really do need to know who to go to… (RW_308)

Another research worker, who further specified wherein some of the confusion lies, iterated similar sentiments and questioned what it is that the REB is really looking for when they review consent forms:

> I guess probably it would be really helpful for me to have an understanding of how ethics committees really work… I've never found the ethics committee to be difficult. I think I did when I didn't understand what I had to do and I was frustrated with myself but I think it would help me to understand what they're really looking for. Are they just looking to make sure that you have your I's dotted and your T's crossed? How do they really gauge what is ethically sound? I guess it would be in my advantage to know more about them and to be able to know that would be more helpful. (RW_312)

For the most part, communication between researchers and the REB centered on commentary directly relevant to the consent form, and researchers indicated that very little communication occurred outside this specific scope. For their part, narratives from interviews with REB members did not acknowledge this gap in communication or consultation with researchers and/or other members of the research team; however, there was a sense that communication between parties was important. In fact, as one REB member points out, the dialogue between the REB and the research team should be continuous and even encouraged as a means to ensure a more thorough understanding of the issues and the research methods specific to a project. Recalling his/her experiences as an REB member, one informant stressed the importance of creating a dialogue between researchers and REB members as an effective means to mutually understand the ethical concerns and to work through what are thought to be the problematic aspects of a research proposal:

> I think once in my years [on the REB] we actually eventually rejected one study, and said, "No you cannot do this." Uh, but it was always a case of, "Help us understand, we think this is a problem. Help us understand," to the researchers, "why this isn't a problem, and what're understanding of this issue is." And to do that, you really have to discuss amongst yourselves what your (chuckling) understanding is. So it's not a matter of just, "yes" or "no". (REB_302)

Most individuals we interviewed felt strongly that more engagement with the REB would not only improve collaborative relationships, but also could lead to improved research practices overall. Narratives revealed that the scope of ethics review and the function of the REB are not well understood, and this can lead to uncertainty amongst researchers and research workers with respect to the expectations of the REB. Furthermore, both researchers and other members of the research team commented on the

fact that the REB is not readily available to offer advice or guidance, and without such resources in place, the research team ultimately does not feel supported in its endeavors. This sentiment came across as one researcher described her criticism of the REB:

> ...what they [the REB] should be emanating is a feeling of, "We strongly support and believe in research, and we believe in ethical research, and we will HELP you. We have expertise, and please come and we'll assist you." And that's of course what [they] should do... if I had to guess why they don't do this, I think maybe they're under-funded, and maybe uh... that it costs money. (R_305)

While recognizing some of the monetary barriers that prevent the REB from playing a much larger and more interactive role, there are other limitations that would seem much easier to change. In order to improve dynamics amongst researchers, research workers and the REB, both an attitudinal shift and perhaps a change in the function of the REB, needs to occur. In her book, *Moral Contexts*, Margaret Urban Walker (2003) addresses a similar issue, noting that it is important for organizations to maintain reflective spaces, figuratively and literally, that both enables and encourages ethical consultation. Currently the REB functions as a gate-keeper with the authority to deliver verdicts about what is considered ethically appropriate research, and there is little opportunity for interactive consultation or shared deliberation about ethical issues. All of this has "generated a trend in which researchers increasingly think of the [REB] as the ethics police" (Knoppers, 2009, p.48). A scholar with much expertise analyzing the interface between ethical governance for research and its impact on research practice comments on this trend:

> What really has to change is the way that research ethics is perceived... You know this whole idea that it's the ethics police... There's a perception that's been out there for probably forever and it's certainly still there that research ethics committees are the bad guys. If somehow we can make a shift away from research ethics guys as being the bad guys or the ethics

> police into the idea that the ethics board is there as a resource and as educators or something like that where people know they can submit a draft of what they're doing and just get some help and feedback but they can do it properly, you know. (S/P_415)

Views of the structure and function of the REB emerged as an important area within key informant narratives. Another and perhaps related issue frequently discussed was the notion that the REB is either unable or reluctant to implement a monitoring process as a means of tracking ongoing research. For the most part, there is little if any follow-up on research that receives REB approval. While those we interviewed did acknowledged the constraints that currently impinge on the REB and therefore limiting such endeavors, there is still a sense of unease with the lack of follow-up, not only as a means of monitoring and providing guidance, but also as a way for the REB to evaluate their own performance and outcomes. Clearly a gap exists between REB involvement prior to a research study and later as the research progresses. As noted previously, for those research workers involved in day-to-day research procedures, issues that were not identified at the outset of a study can surface, particularly with respect to recruitment and consent. Since REB involvement is mostly front-end, there are countless practical decisions that research workers must make that shape these processes; however they tend to be made in isolation or at least without guidance from the REB. One research worker succinctly identifies the main barrier to systematic monitoring of research by the REB, stating:

> The ethics board has NOTHING to do with it except for their stupid / regular annual reviews, which doesn't actually deal with the process of research. There's nothing in place for the research. There's no way, at this point, with the way it's structured for the REB to be able to deal with the process of research as it's going on. There isn't. The infrastructure doesn't exist right now. (RW_306)

This comment was reiterated in another narrative with an individual who is knowledgeable in governance issues as it relates to research ethics, when asked to comment on the notion of ongoing REB review:

> Yeah, it's one of these things where there's an ideal world and then there's money or time – I guess I should say money and time. What's missing of course at the levels of the REB is just having enough infrastructure and support in place that you can have a large enough pool of administrators that you can actually do some sort of follow-up. If you're asking me how practically on the ground that's going to happen I don't have a clue. (S/P_415)

Speaking from the experience of going through independent auditing processes outside the research ethics domain, one researcher advocates for the concept and the potential benefits that could result if the REB were to incorporate this as an ongoing aspect of REB review:

> [Currently] there is not really anybody that follows up and walks into the researcher's office, or lab, or whatever, and says, "You know, I'm here to make sure… from an auditing point of view. I've been involved in audits at other institutions, a very useful experience retrospectively… I guess the thing that is really important, I think, to put in there is that you're not in with a checklist necessarily, lookin' over the researcher's shoulder, it's there as an educational piece to help the researcher, uh, maintain files, to, you know, to keep him or her out of trouble down the road, versus "I've caught you doing something…" I mean, you know, that latter scenario, I think, can get dangerous in there… I think it's key to have it be an ongoing support that ethics is providing [to] the researcher …that will benefit the researcher in the long run. (R_303)

Presently, the oversight system in place operates largely on the basis of trust; that is, the REB trusts that what is written in the research proposal will be carried out by the research team as it is initially outlined and approved[26]. While there is nothing inherently wrong with this system, the potential for error and the occurrence of unethical events and

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[26] For a lengthier discussion of the role of trust and the way it plays out in the research setting, please see: McDonald M, Townsend A, Cox, S, Damiano Paterson N, Lafreniere D (2008). Trust in Health Research Relationships: Accounts of Human Subjects. *Journal of Empirical Research on Human Research Ethics*, 1556(2646): 35-47.

behavior, whether intended or not, is significant. An experienced researcher and a former REB member candidly spoke about this issue; specifically, without some kind of system in place to detect indiscretions, there is little motivation to change and equally few opportunities to learn from experience:

> The fact of the matter is, there is, and because of the stress on the system the odds of getting caught are relatively low. It's like being a bank robber. The punishment doesn't fit the crime ... we are asking for too many things to be done for free. (R_410)

Researchers, research workers and REB members frequently discussed the impact the lack of oversight has on research practices in general. A former REB member discussed this issue and articulated his/her main concern about the lack of continuity and exchange amongst key players involved in important yet varied aspects of the research process. This informant stated:

> The REB has *no* contact with the people who're *doing* the research... that relationship doesn't exist directly... because you can set up a series of processes that, "This is the way things should work, and this is the ethical way we expect it to happen," and the researcher submits a protocol that is consistent with that, and signs off that that's gonna happen, but beyond that, the actual people who're doing that, in some cases, I suspect, have never even read the protocol, and certainly are unaware of the ethical issues and to *why* it's being suggested that way.... So the protocol was written that we can recruit in the following way, but the [research worker] was doing the recruitment [and] went about it the good 'ol way she'd done it before... So, there was an example of that disconnect between the whole research ethics process and the research process, and I think that's why audit is an essential part of... closing the loop, of finding what's really happening... It's all very well for the PI to know what [the REB is] looking for, and putting in the forms, but the people doing it need to understand that. (REB_302)

A research worker with much experience working on research projects in Canada and internationally also recognizes this as an issue. This informant acknowledged that discrepancies can occur between what is proposed and what is practiced, and this holds

particularly true for multi-jurisdictional research. In some cases, the host country or local research workers may adhere to alternative models, policies, and/or laws governing the conduct of research involving human subjects, and the boundaries between what are ethical and appropriate may not be as well-defined. This holds particularly true for informed consent, wherein an emphasis on written consent by means of a signed consent form, may not be universally applicable across all jurisdictions. Differences in worldviews, interpretations of concepts and understandings of health and illness can all play an important role in how individuals interpret consent and view participation in health research (Jegede, 2008; McDonald, 2001). Under such circumstances, practices considered appropriate for research in Canada may not apply elsewhere. Within this context, this research worker comments on the issue of discrepancies between the research protocol versus actual conduct, and the complexity of the situation:

> I mean the REB is useful because they get you to really focus on those [ethical] issues. It gets you to direct your attention there but it really comes down to you being an ethical person practicing – you need to think about these in advance but you also can go through wonderful protocol and if you're not someone who is sensitive to the people you're working with you can still be very unethical and have a perfect research protocol. (RW_414)

Narratives from both the research team and REB members continually highlight the importance of the integrity of those who contribute to research processes, particularly in absence of a systematic process of research oversight. One long-time REB member's comments capture many of the same sentiments that were articulated by other key informants. That is, given that there are few if any mechanisms to monitor research and ensure ethical compliance, a huge assumption of trust placed on researchers and the team as a whole. This informant notes:

> I honestly don't think there is any oversight once it's [research project] approved. I don't think there is any follow-up. So there is no oversight. It operates on the basis of trust. It has to. I think it comes down to trust ...Because how do you monitor? This is where I think the principal investigator or the Ph.D. advisor has to take on the responsibility and ...I don't think anybody takes it lightly. Because as an ethical person you cannot ignore the fact that you may be putting your subject at some kind of risk. (REB_309)

A researcher who has also served a term on the REB made another inference to the integrity of those involved in research. While this informant clearly recognizes that most researchers try to uphold the scientific integrity of the profession, research misconduct still occurs. Thus, all individuals involved in research, regardless of their role, should be mindful and informed of ethical conduct for research involving human subjects:

> Science is such an ethical profession. It's the same like any other profession. There are all kinds of players in there and hopefully you get to play with the most interesting and most ethical. (R_410)

Lastly, within the context of roles and relationships in relation to the REB, one other theme emerged, wherein the focus here related primarily to the consent form. The roles and relationships between key players involved in research have implications for the process of informed consent. As front-line personnel, research workers work closely with human subjects, particularly as they administer the consent form. During this process, research workers gain a greater sense and to some extent, a unique awareness, of some of the areas of the consent form that human subjects find difficult or troublesome. Despite this insider knowledge, research workers feel as thought there is little opportunity, and few outlets to voice these important observations. In particular, several researcher workers we interviewed acknowledged that they have little contact at all with the REB, which effectively limits any opportunity on the part of research workers to

identify possible areas for improvement and change. One research worker commented on some of the more concerning implications that this apparent disconnect has between those who regulate the process of informed consent and those responsible for obtaining and ensuring informed consent. He/she states:

> There's nowhere for you to go... Even when there was a small question, before it becomes a huge problem, there should have been a route or an ombudsman. Like, the REB should have an ombudsman who's confidential for research [workers] to discuss their issues... so that you can mull through how you're going to approach it with someone ...who actually is trained in ethics and understands what you're going through... [Currently research workers] have no power to actually make any change. (RW_306)

Similarly, another research worker commented on the fact that despite their contribution to the research process and experience working directly with human subjects, research workers have few opportunities to share the insights they have gained as a result of their role. In the following narrative, one informant succinctly captures this perception and more importantly points to the central position of the Principal Investigator in this relationship. It is within this context that this research worker perceives the researcher to be the main link, and therefore the only viable outlet by which research workers can express their concern, knowledge and contributions about the research and related ethical processes:

> I have thought about how does one influence those [REB] committees / how does one influence that process? I really don't think that people like myself can influence them directly. I think the influence has to come up through principle investigators and then they have to use their channels. (RW_409)

The lack of direct communication between key players, and specifically in this case the REB and research worker, creates an incomplete and often disconnected view of the processes of information flow during informed consent. Without outlets to convey

their concerns to the REB, research workers are left to describe the constraints of negotiating meaningful consent with the researcher. However as one researcher worker describes, this tactic does not always succeed in getting the message out to those who have the motivation to affect change. From her experience, although researchers may be interested hearing feedback from front-line research workers, they are also reluctant to implement changes or incorporate the suggestions of research workers into the research design, and particularly the structure and descriptions as outlined in the consent form. As acknowledged by a research worker in the following excerpt, likely this is due to the fact that researchers are not interested in making significant changes that would require additional approvals from the REB prior to implementation:

> I think we talk about [the consent form and template] but I think the feeling of investigators is that this is what's prescribed by the ethics board, so unless they're prepared to make a fuss about it, and they're busy with all kinds of other stuff . . . the instruments have been decided beforehand and what they're measuring and so on, so once you get into the study it's hard then to, "Well ...we're finding it difficult for people to do this", or whatever. Well at that point it's a little bit late to think about wording changes and stuff. . . (RW_409)

Adding to this notion, a research worker describing similar experiences notes the following:

> And sometimes ...you thought something would work as far as a recruitment, or y'know, going through [a consent form] a protocol needs to be adjusted... but in my experience, we've usually kind've stuck the course... 'coz, y'know... it's the approved version, and from a research point-of-view, changing an instrument halfway is kind've...you have to go, "Y'know, next time... next study." (RW_405)

From interviews across all categories of key informants, there was an overall sense that information flow between key players – the REB, researchers and research workers – is somewhat disjointed. Nearly all the individuals we interviewed

acknowledged their different roles in the research process, and the unique perspective they gain as a result of their role; yet, there is relatively little opportunity for these key players to share this knowledge with each other for any didactic benefit. Without strong and productive relationships, tensions amongst key players begin to emerge. During interviews, researchers and research workers spoke just as frequently about the benefits of REB review as their frustrations with the current process, and in this respect, much of their dissatisfaction stems from not clearly understanding the expectations of the REB, and the general lack of accessibility of the REB to answer questions and offer guidance to the research team. Equally, REB members expressed concern over select or limited communication within research teams, particularly if it results in discrepancies between theory, or what is described in the research protocol and practice, and what is actually carried out by research team members. In other words, the primary concern focuses on the coordination of the research team and whether all individuals fully understand and implement all aspects of the research design as described in the protocol and approved by the REB. Overall, without concerted efforts to encourage communication amongst all key players, gaps in understanding the important role that all stakeholders play in the research process will persist. If we are to develop adequate means to share information and expertise across disciplines and amongst researchers, research workers, and REB members, then we need to begin paying attention to what is really happening in practice; otherwise valuable knowledge will be lost.

6.0 CHAPTER 6: Discussion and Conclusions

Consent is a process, rather than an event, and therefore, the process of informed consent is intended to encompass a much wider scope than simply a focus on formal documentation, or the signing of the consent form. In fact, the Tri-Council Policy Statement [TCPS] incorporates notions of relationship-based interactions and communication, which recognizes the unique social features of consent as it happens in practice. Thus, in addition to formal documentation, the process of informed consent also refers to dialogue, information sharing, and general process through which prospective participants choose to participate in research (Interagency Advisory Panel on Research Ethics, 2008). The qualitative data generated from this study only reinforced the notion that the discussions that take place with human subjects, in addition to the written information at the time of consent, is important in order to understand the complete picture. In this manuscript, a picture of the relationship-based interactions that occur during the process of consent emerged from accounts with key informants including researchers, front-line research workers, research ethics board [REB] members, scholars and policy-makers who all play central, yet varying roles in the process of informed consent.

In common with the literature, key informants in this study initially focused on the consent form and issues relating to content and readability – citing difficult or complex language – which, when compounded with the consent form length, highlights the traditional limitations associated consent forms (Eyler & Jeste, 2006; Flory & Emmanuel, 2004). For the most part, key informants from all stakeholder categories

agreed with the inherent value of informed consent and supported its underlying ethical principles; yet, despite much attention and concerted efforts to improve the consent form document, they acknowledge that significant problems still remain. Guidelines for informed consent were established as a means to both protect human subjects and promote the ethical conduct of research. To give informed consent, human subjects should understand the purpose, process, risks, benefits, and alternatives to research (or standard care procedures) and make a free, voluntary decision about whether to accept or decline research participation. Therefore, informed consent has two main aims: first, to respect and promote participants' autonomy; and second, to protect them from potential harm. The provision of information via the consent form lends support to both these aims, and in the most simplistic of terms, consent is seen as an action, concluded by signing a form (Levine, 1986). However, disclosure and a signature are not sufficient for informed consent, and an understanding of the research project as well as the voluntary nature of the decision to participate is a necessary element as well. Alongside the written information come discussions and relationship-based interactions with human subjects, research workers and other members of the research team. Focusing on the consent form alone takes away from other important ethical aspects, such as the quality of the consent process and the communication that happens during this interaction to facilitate human subjects understanding of research participation. So, although a signature on the consent form might represent confirmation of an agreement to participate in research, it does not imply understanding; it might be evidence of consent, but not proof (Pullman, 2001).

Narrative data from key informants provided insight into how ethical and legal requirements challenge the real-life practicalities of recruitment and obtaining consent

from human subjects for research participation. Focusing only on the paper consent form underestimates the unique features of the consent process and social interactions that occur during the negotiation of consent, and as it happens in practice. As agents who take on the formalities of consent processes, research workers are the vital link between human subjects, researchers, study sponsors and other research team members. Human subjects view research workers as directly accountable for the research that they represent, and research workers frequently spoke about how their visibility within the project as a front-line worker creates an immediate sense of duty or accountability to human subjects. Thus, narratives highlighted that research workers occupy an ideal position to view first-hand the impact of research and garner feedback from human subjects with respect to their research participation experiences (Hill & MacArthur, 2006). In turn, this interface between human subjects and research workers creates a feeling of continual accountability for research processes and procedures as conveyed in the initial consent process.

The findings from this study show that research workers, as a result of their front-line role, communicate with human subjects during the process of informed consent. The feedback and/or questions that research workers receive from human subjects with respect to information conveyed in the consent form reveal important insights into how research subjects understand certain aspects of participation, or which areas remain unclear. How human subjects respond to consent forms, then, raises questions about what information is most relevant to them in such processes. Key informant accounts reflect Peter's (2006) conceptual work, which suggests that while ethical guidelines for research practice are representative of the theoretical, the actual consideration and

application of these principles in practice is representative of moral life. In this study, research workers spoke about how current consent forms pose barriers for them as they negotiate consent, as well for human subjects as they try to understand and interpret the information disclosed. Perhaps as a result of the difficulty human subjects have comprehending the information conveyed in consent forms, research workers acknowledge that human subjects rarely rely on this written information alone. Rather, when deciding whether to consent or refuse participation in research, human subjects rely much more on the interactions and discussions with research workers present during the informed consent process.

In this sense, it seems that human subjects do not necessarily define the meaning of being informed by the formal information offered via the consent form, and instead draw on different resources and wider social aspects as they make their decision. This concept illuminates Corrigan (2003) and Felt's (2009) conceptualization of decision-making that emphasizes the importance of interpersonal relationships and its influence on choice, and calls for more socially nuanced concepts of autonomy and consent. The distinction between relationship-based communication with research workers and the official reading of the consent form is significant, and suggests that the consent process is much more complex and interactive than a simple signed consent form would imply. Whereas the consent form primarily serves a legal function of written evidence and proof that consent was obtained, the quality of consent seems less dependent on the information provided via the consent form than on the relationship-based communication that occurs between research workers and human subjects during the consent process.

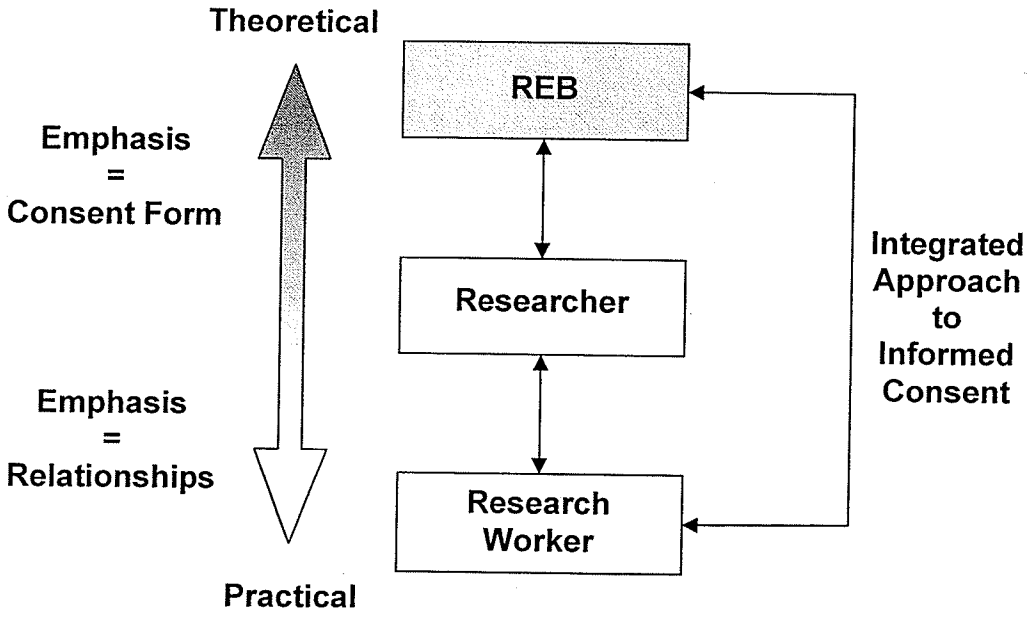
If there is a gap between the ideal and practice of informed consent, perhaps a

more desirable ethical goal would be to emphasize informed consent as a process, which focuses on communication, understanding and relationships. Drawing on the work of Albrecht et al. (2005), very little is known about the actual ways in which research workers explain and relay information provided in consent forms to human subjects during the consent process. The extent to which problems with informed consent are identified and consequently, how research workers act to rectify such issues is also largely unknown (Murff et al., 2006). Similarly, participants in this study revealed that the role of the research worker is one that is over-looked or under-estimated. As front-line personnel, research workers work closely with human subjects, particularly as they administer the consent form. During this process, research workers gain a greater sense and to some extent, a unique awareness, of some of the areas of the consent form that human subjects find difficult or troublesome. Despite this knowledge, research workers expressed their frustration over the lack of opportunity and/or outlets to voice these important observations. Without outlets to convey their concerns to the REB, research workers are left to describe the constraints of negotiating meaningful consent with researchers. However, research worker narratives revealed that this does not always succeed in getting the message out to those who have the motivation to affect change. Although researchers may be interested in feedback from front-line research workers, they are also reluctant to implement changes to the structure and descriptions as outlined in the consent form, which would require additional approvals from the REB prior to implementation.

Overall, it was clear that research workers have very little contact with the REB, which effectively limits the opportunity to fully define and understand the challenges

they face with respect to the process of informed consent, and identify areas for improvement and change. In order to gain a more complete picture, we must look beyond the consent form to consider some of the wider contextual issues that influence the consent encounter and how ethical principles play out; this includes considering the perspectives of different stakeholders who all play varied roles in the process of informed consent. So, as illustrated in Figure 4 (See: Figure 4: *An Integrated Approach to the Process of Informed Consent*), currently there may be communication between the REB and researchers, or researchers and research workers, but what we do not see is an integrated approach, which closes the loop along with some of the communication gaps between key players, and connects the theoretical with the practical.

Figure 4: An Integrated Approach to the Process of Informed Consent



Turning attention from research workers to focus more broadly on the varied perceptions of those who oversee, and are involved – both directly and in-directly – in the consent process, another common criticism that emerged from researchers, research workers, REB member and scholar narratives was that consent forms have become overly technical, incorporating language and/or concepts that are extremely difficult for human subjects to read through and fully comprehend. In particular, research workers, or those delegated to the task of obtaining consent from human subjects, cited concerns about the proliferation of legal and policy information, which reinforces the legal function of consent forms, and takes attention away from other important aspects of consent.

Current consent forms provide protections – whether rightly or wrongly – for researchers and organizations inasmuch, and maybe even more so, than they are meant to provide protections for human subjects. A common perception amongst all key informants interviewed, including researchers, research workers, REB members and scholars was that the information provided in consent forms, which was once clearly intended to protect the welfare and rights of human subjects, has more recently taken on a much more defensive stance, seemingly aimed at protecting researchers, organizations and funding agencies. As a result, the process of informed consent has been subverted into one of the many routinized procedures associated with research that first and foremost, serves the needs of researchers and the institution, thereby undermining the very tenets it was intended to promote. Herein lies an undercurrent in which protections have been directed away from the human subjects participating in research, which ends up placing more emphasis on documentation and much less on the quality of information exchange.

Key informants called attention to the advent of standardized consent forms, which provide templates or "boilerplate" descriptions for researchers to use as a guide, for the increasing routinization and formalization of the consent process. Generally, while template are intended to expedite both the creation and review of consent forms, key informants expressed concern that such developments represent a one-size-fits-all solution without taking into consideration that the selected information might be devoid of meaning to human subjects. Additionally, researchers use consent form templates to ensure that research projects are formulated in a way that passes ethical review. As a result, templates discourage attempts to really understand the relevant ethical issues, and thereby limit the potential for reflective and didactic learning.

The findings of this study show that researchers, research workers, REB members, scholars and policy-makers all have differing roles and varying visibility within the research enterprise; however, all of these roles coalesce around the process of informed consent. Research is a collaborative undertaking and within such collaborations there are complex and interdependent dynamics of context, practice, agency and power that shape interactions amongst players in ways that may not always be apparent. From interviews with key stakeholders what emerged from these narratives was the importance of a continuous dialogue between individuals who all play a role – albeit varied and distinct –in health research. Eliciting feedback as part of a constant exchange of ideas may be a way of engaging issues and effectively addressing problems as they occur in research practice. This concept was reflected by McDonald (2000) wherein the concept of "virtuous learning loops" is suggested as a means to learn from successes and failures in order to improve ethical performance. Here, an integrated approach that promotes

constructive, communicative relationships and information exchange between key stakeholders, and in this case, REB members, researchers and research workers, as a means to identify issues or concerns seem appropriate. The information acquired at this initial stage of exchange would then form the basis of possible modifications or reformed actions, which would then be applied in a practical setting in order to gauge the degree to which the new ideas work in practice. Again, the same players would come together to then assess and audit the new practice, which then starts a new wave of information sharing, and so on. In this way, information exchange plays a key role in establishing whether we are meeting the ethical objectives that we want to achieve, and whether theoretical principles play out in a way that is proclaimed in both research ethics guidelines for informed consent, and the study protocols approved by the REB. Opportunities for more open discussion and 'virtuous learning loops' could play a part calling attention to needed areas and overcoming moral concerns with respect to the process of informed consent.

Nearly all the individuals we interviewed acknowledged their different roles in the research process, and the unique perspective they gain as a result of their role; yet, there is relatively little opportunity for these key players to share this knowledge with each other for any didactic benefit. It is important for organizations to maintain reflective spaces, figuratively and literally, which both enables and encourages ethical consultation. This is somewhat lacking, as the REB currently functions as a gate-keeper with the authority to deliver verdicts about what is considered ethically appropriate research; as such, there is little opportunity for interactive consultation or shared deliberation about ethical issues. For research workers who are involved in day-to-day

research procedures, unanticipated issues with respect to informed consent can arise. Since the REB does not engage in an interactive or educational role, there are countless decisions that research workers must make that shape these processes; however they tend to be made in isolation or at least without guidance from the REB. Furthermore, research workers do not have much formal power in relation to researchers to affect change with respect to the overall project and consent procedures, although they may communicatively exercise informal power strategies in their interactions with human subjects during the consent process. The findings suggest that perhaps consultation between the REB and those members of the research team who are directly involved in consent processes could help to refine consent form templates, and at the same time help members of the research team gain a better understanding of the reasons why some elements have been suggested for inclusion in the consent form, and their applicability to different types of research. Without concerted efforts to encourage communication amongst all key players, gaps in understanding the important role that all stakeholders play in the research process will persist. If we are to develop adequate means to share information and expertise across disciplines and amongst researchers, research workers, and REB members, then we need to begin paying attention to what is really happening in practice; otherwise valuable knowledge will be lost.

The findings of this study contribute to the body of knowledge on informed consent for research involving human subjects. Unlike the most empirical work in this area that has focused primarily on the consent form, addressing issues of content, readability, or assessing the competency of specific populations to provide consent, this study looked at some of the wider contextual issues, practicalities and relationships that

impact negotiating meaningful consent. The results, while limited in scope, do reveal the importance of exploring the nuanced relationships of relevant stakeholders at all levels and their role in the process of informed consent. As such, further research that explores the active negotiation that takes place during the consent process seems warranted. In particular, a case study which focuses on the consent negotiations within a single study, and looks at the perspectives of the researchers, research workers working on the study and even REB members who approved the study, would be useful to further explore the barriers and facilitators to informed consent at all levels, because this research project explored experiences elicited from individuals involved in diverse projects.

The primary focus of ethical concern should ultimately rest on the quality of consent and not merely on how it is documented, or the signing of the consent form. Therefore, it is important to acknowledge the unique social features of the process of informed consent as it happens in practice. If this context continues to be ignored, moral thinking, and thinking about morality for ethics in health research, can be misleading or irrelevant. When contexts are acknowledged and studied, only then can we learn things about how we actually think and live, and whether we need to change (Urban Walker 2003).

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APPENDIX A: Project Summary: '*Centring the Human Subject in Health Research*'

'Centring the Human Subject in Health Research: Understanding the Meaning and Experience of Research Participation'

The University of British Columbia

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The University of Manitoba

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Advocates for the development of an evidence-based research ethics call for empirical studies on the governance of research and research ethics. As such, there are now projects underway looking at the work of research ethics boards (REBs) as well as the appropriateness of various methods of oversight. The proposed research project addresses a neglected area such that we focus on the meaning and experience of being a human subject in health research. The overarching goals of the proposed study are to:

1. Explore the meanings and experiences of being a research subject from the standpoint of subjects.
2. Compare and contrast the perspectives of research subjects with the perspectives and practices of researchers and members of REBs.
3. Assess the ethical and other implications of recent and emerging changes in the context and design of health research.
4. Pilot methods for implementing new understandings of the experience of being a research subject in research design, the process of ethical review and the governance of research ethics.

Support for an 'evidenced-based' research ethics coincides with changes in the research environment affecting researchers, research subjects and REBs. The traditional model of direct relationship between researcher and research subject, overseen and regulated by an REB, still predominates but alongside an increase in large scale multidisciplinary, multi-investigator projects, spanning several institutions, and international in focus. These structural and organizational characteristics have complicated the ethical review process and fragmented the relationship of researchers and research subjects. The development of data banks, some string biological data (e.g., BioBank in the UK or HapMap project), coupled with the technical ability to link information on the same individual across several data banks has major implications for issues of privacy and confidentiality. The introduction of participatory research designs has, in some cases, also transformed the human subject from a passive to an active participant in the research process. REBs now may require evidence of community as well as individual consent and in come First Nations and other communities have set up their own independent review boards.

The proposed project will explore the ramifications of these and other changes from the perspectives of different members of the research community (i.e., REB members, health researchers, sponsors and policy makers) but always with an primary focus on what they mean for, and to, the subjects of research. We will consider such questions as "why do human subjects decide to participate in health research and why not? How do human subjects interpret information on the risks and benefits of research participation? How do they balance the short and/or long term implications for themselves, their family and community? Is trustworthiness of the researcher or institution of major importance?

The project will adopt a qualitative research design. In each of the three phases, we will be guided by an international advisory board of experts in research involving humans. Phase I includes an intensive literature review ranging across the social science, epidemiological, legal and ethical literatures. This will assist in categorization of different types of health research design and the issue that each raises for research ethics and governance. We will also conduct in-depth interviews with research participants, members of REBs, clinical and social science health researchers, funding agencies and policy makers. Phase II involves the selection of four health research projects with a design reflecting significant issues identified during the literature review and analysis of in-depth interviews. Each case study will involve use of documentary materials (i.e., proposal, consent forms, revisions requested by the REB) with in-depth interviews and focus groups with researchers, research subjects and others. In Phase III, the finding will be presented to experts in ethics and human subjects research. Feedback will inform a series of focus groups, consultation workshops and public forums to which we will invite REB members, researchers and other participants in human subject research. A final report will describe our findings and offer recommendations on the process of ethical review and governance of research ethics.

Susan Cox (Principal Investigator), Michael McDonald (Co-Principal Investigator), Patricia Kaufert (Co-Investigator), Joseph Kaufert (Co-Investigator), Anne Townsend (Co-Investigator)

APPENDIX B: Copy of Research Ethics Board Approval (H2006:083; H2008:121)

COPY

UNIVERSITY OF MANITOBA

BANNATYNE CAMPUS
Research Ethics Boards

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Tel: (204) 789-3255
Fax: (204) 789-3414

APPROVAL FORM

Principal Investigator: Dr. P. Kaufert

Ethics Reference Number: H2006:083
Date of Approval: April 7, 2009
Date of Expiry: April 28, 2010

Protocol Title: "Centring the Human Subject in Health Research"

The following is/are approved for use:

- **Annual Approval**
- **Research Participant Information and Consent Form, version dated April 20, 2007**

The above was approved by Dr. John Arnett, Ph.D., C. Psych., Chair, Health Research Ethics Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your submission dated April 6, 2009. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations of Canada*.

This approval is valid until the expiry date only. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval must be sought from the relevant institution, if required.

Sincerely yours,

John Arnett, PhD., C. Psych.
Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above Ethics Reference Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255 / Fax: (204) 789-3414

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APPROVAL FORM

Principal Investigator: Ms. L. Labine

Ethics Reference Number: H2008:121
Date of Approval: May 1, 2009
Date of Expiry: May 21, 2010

Protocol Title: "A Qualitative Study of Informed Consent: Moving the Discussion beyond the Consent Form" linked to H2006:083

The following is/are approved for use:

- **Annual Approval**

The above was approved by Dr. John Arnett, Ph.D., C. Psych., Chair, Health Research Ethics Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your submission dated March 23, 2009. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations of Canada.*

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This approval is for the ethics of human use only. For the logistics of performing the study, approval must be sought from the relevant institution, if required.

Sincerely yours,

John Arnett, PhD., C. Psych.
Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above Ethics Reference Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255 / Fax: (204) 789-3414

APPENDIX C: Copy of Research Participant Information and Consent Form
'*Centring the Human Subject in Health Research*' [Version: April 20, 2007]

The University of British Columbia

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Research Participant Information and Consent Form

Centring the Human Subject in Health Research: Understanding the Meaning and Experience of Research Participation

Study Funded by: Canadian Institutes of Health Research

Research Team
Patricia Kaufert (Co-Investigator) and Joseph Kaufert (Co-Investigator)
Department of Community Health Sciences, University of Manitoba
204-789-3681 or 204-789-3798
Susan M. Cox (Principal Investigator) and Michael McDonald (Co-Principal Investigator)
The W. Maurice Young Centre for Applied Ethics, University of British Columbia
604-822-0536 or 604-822-8626

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family, or (if applicable) you doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study

The purpose of this study is to explore the meanings and experiences of being a human subject in health research. We will do so within the context of understanding the relationship between human subjects, health researchers and research ethics boards (REBs) but always with an emphasis on the perspectives of human subjects. This is why we have titled our project "Centring the human subject in health research."

Our study will determine what issues are relevant to human subjects, researchers and members of REBs and how these differ. The study will also explore how the topic, design, structure and organization of different types of health research gives rise to new or overlooked ethical issues. This will inform the development of new understandings of the experience of being a research subject and new methods of implementing these understandings in research design, the process of ethical review and the governance of research involving humans. A total of 133 participants will participate in this study.

Study Procedures

The first phase of our study involves individual interviews with human subjects, health researchers, research workers, members of research ethics boards (REBs), scholars and other key informants in research ethics. As a [Insert correct category of interviewee from preceding list] you are being asked to participate in one individual interview about your experiences of conducting health research.

The interview will be conducted in person or on the telephone by one of the researchers listed above or one of the research assistants working with the researchers listed above. It will be conducted at a time and location convenient to you and last approximately 45 to 90 minutes. With your permission, it will be tape–recorded and transcribed. If necessary, the interviewer may also need to conduct a 10 to 30 minute follow-up telephone call with you (up to one month after the interview) to clarify any issues arising from transcription and analysis of your interview.

During the interview, you may wish to describe particular experiences related to your involvement with health research. This is encouraged and supported because of our interest in learning about what is occurring.

In the event that you believe it is important to follow up on concerns you may have about a particular health research study, we will provide the names and contact information for appropriate institutional personnel who are responsible for these matters. We are, however, not undertaking to engage, in any way, in the monitoring or oversight of research ethics.

At the close of the interview, you will also be asked if you are willing to be re-contacted about continuing your involvement in this study as it progresses over the next few years. Your future involvement could, for example, include participation in a focus group with other participants in this study to comment on our findings. Agreement to be re-contacted about this or other aspects of the study will, however, not mean that you have agreed to participate again. Re-contact would simply be to ask if you are interested in considering another form of participation in this study.

Your participation

Your participation in this study is entirely voluntary. You may refuse to participate or decide to withdraw at any time without affecting your health care and/or access to services or the health care and/or services provided to other members of your family.

Confidentiality

All information provided by you and other study participants will be treated with the utmost respect. Specific measures will be taken to protect your privacy and ensure that identifying information is kept confidential. Pseudonyms (false names) will be substituted for your real name and the names of anyone else mentioned in the interviews. All tapes, transcripts and consent forms will be identified by code and kept on a password-protected computer or in a locked filing cabinet in the project offices at the University of British Columbia or the University of Manitoba. The only persons who will have access to the data are the immediate members of the research team (listed

above) and the research assistants working directly with members of the research team. All personnel will be trained in how to protect the privacy and confidentiality of our participants throughout the project.

The information gained from this research will be written up in publications and/or reports and these will be shared with all study participants as well as other interested agencies. All efforts will be made to ensure that your individual comments will not be identifiable. You may request copies of these publications or reports about the findings of the study.

When this study is complete, the researchers will likely conduct additional studies on the meaning and experience of being a human subject. As such, we are requesting your permission to keep the anonymized transcripts, field notes and other research documents related to the present study for an indefinite period of time. If you agree, they will be kept by the Principal Investigators (Drs Susan M. Cox and Michael McDonald) or Co-investigators (Drs Patricia Kaufert and Joseph Kaufert) on a password-protected computer or in a locked filing cabinet in the project offices at the University of British Columbia or the University of Manitoba. Should you only wish to participate in the present study with the stipulation that all research documents related to your participation be destroyed 5 years after publication of the original analysis, there is an option allowing for this on the signature page.

Risks and Potential Benefits

There are some potential risks related to involvement in this research. It is possible that some topics discussed in the interview may raise new and/or emotional issues but you need only answer questions or express your views when you wish to do so. The interviewee will be respectful of your preferences. She/he is not equipped to provide counselling or medical advice but, if you wish, she/he will assist you in contacting an appropriate health care or other professional.

You may or may not find any personal benefit from your participation in the study. Discussion with others about your experiences or perspectives may assist you in sorting through issues that are not always easily discussed elsewhere although there can be no guarantee of this.

Remuneration/Compensation

There is no payment related to participation in this research but we will compensate you for any out of pocket expenses directly related to your participation (i.e., parking, transportation, child or elder care).

Contact

It is very important that your participation is entirely voluntary and based on a clear understanding. You may contact Dr. Patricia Kaufert (Co-Investigator) at (204) 789-3681 or Dr. Susan M. Cox (Principal Investigator) at (604) 822–0536 to ask questions or request additional information. Further, if you have concerns about your rights or treatment as a research subject, you may contact The University of Manitoba Bannatyne campus Research Ethics Board Office at (204) 789-3389, or the University of British Columbia's Director of Research Services at (604) 822–8598. Do not sign this

consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

Consent

My signature below indicates that:

1) The study has been explained to me and any questions have been answered to my satisfaction,
2) I understand that my participation is entirely voluntary and that I may refuse to participate in this research or decide to withdraw at any time without affecting my health care and/or access to services or the health care and/or services provided to other members of my family,
3) I have a signed copy of the consent form to keep for my records.

Further, in checking the appropriate box below,

☐ I understand this consent form and I agree to participate in an interview dealing with the issues and experiences described above.

☐ I agree that the anonymized data and research documents resulting from my participation in this project may be kept by the Principal Investigator in a secure location for an indefinite period of time for the purpose of ongoing research on the meaning and experience of being a human subject.

☐ I do **not** agree that the anonymized data and research documents resulting from my participation in this project may be kept by the Principal Investigator in a secure location for an indefinite period of time for the purpose of conducting comparative analysis with other similar studies and I therefore request that all such documents be destroyed 5 years after publication of the original analysis.

☐ I agree to be contacted in the future for studies related to this project.

☐ I do **not** agree to be contacted in the future for studies related to this project.

Name (Please Print) _____

Signature_____ Date Signed_____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent:

Name (Please Print) _____ Date Signed _____

Signature _____ Role in the Study _____