Université de Montréal

Conflicts, Ethical Dilemmas and the Role of the Clinical Trial Nurse in the Informed Consent Process

par
Franca Cantini

Faculté des sciences infirmières

Mémoire présenté à la Faculté des études supérieures
en vue de l'obtention du grade de Maître (es) sciences (M.Sc.)

Avril 2002

Université de Montréal
Faculté des études supérieures

Ce mémoire intitulé:

Conflicts, Ethical Dilemmas and the Role of the Clinical Trial Nurse in the Informed Consent Process

Présentée par:

Franca Cantini

a été évalué par un jury composé des personnes suivantes :

Sylvie Lauzon
President-rapporteur

Jocelyne St-Arnaud
Directeur de recherche

Andre Duquette
Membre du jury

Mémoire accepté le : le 22mai, 2002

Sommaire

Cette étude descriptive, impliquant des infirmières travaillant en recherche clinique pour des médecins chercheurs, a été menée dans quatre hôpitaux affiliés à l'Université McGill. Le but de cette étude était de décrire le rôle des infirmières de recherche clinique (Clinical Trial Nurse) dans le processus de consentement libre et éclairé et d'explorer les enjeux éthiques liés à cette tâche.

Ce travail a apporté des données empiriques importantes, absentes de la littérature existante, sur le rôle des infirmières de recherche dans le processus de consentement libre et éclairé, sur l'ampleur de leurs implications et sur les enjeux éthiques reliés à ce rôle. Un questionnaire de 50 items a été créé et évalué pour la cohérence de son contenu par trois experts en soins infirmiers et en recherche. Quatre-vingt-cinq questionnaires ont été distribués parmi lesquels 65 ont été complétés, aprs deux relances, pour un taux de participation de 68,4%.

Les résultats de cette étude ont démontré que toutes les infirmières qui ont répondu au questionnaire ont participé au processus de consentement libre et éclairé et que la majorité d'entre elles (75%) étaient impliquées avant, pendant et après que le consentement ait été obtenu. La divulgation de l'information aux participants était effectuée conjointement par le médecin chercheur et l'infirmière de recherche clinique dans 75,5% des cas. Pour la plupart des participantes, l'information donnée concernant le but, les risques, les bénéfices et les autres traitements possibles constituait une responsabilité partagée entre le chercheur principal et l'infirmière de recherche clinique dans une proportion de 74,5%, 67,3%, 69,1%, et 65,5% respectivement. Par ailleurs, l'évaluation de la compréhension du participant en ce qui concerne l'information donnée, ainsi que l'assurance d'une participation volontaire étaient des responsabilités le plus souvent déléguées à l'infirmière de recherche clinique, dans une proportion de 40% et 92,3% respectivement.

Les infirmières de recherche clinique remplissent leur rôle malgré le fait qu'il n'existe pas de lignes directrices écrites définissant ce rôle et malgré le fait qu'elles ont eu peu ou pas de formation en éthique de la recherche. Ce vide renforcerait le fait que les infirmières aient davantage expérimenté des conflits et dilemmes éthiques. Les conflits seraient le plus souvent occasionnés par la structure organisationnelle impliquant le médecin chercheur, en tant qu'employeur de l'infirmière de recherche clinique (58,5%), alors que les dilemmes étaient reliés au manque de politique et de lignes directrices portant sur le rôle de l'infirmière de recherche clinique (23,8%), ainsi qu'un manque de clarté au niveau de la description des tâches (22,3%).

MOTS CLES : consentement libre et éclairé; respect de l'autonomie de la personne; infirmières de recherche clinique; éthique de la recherche

Summary

This descriptive study, involving clinical trial nurses working for physician investigators, was conducted within four McGill University affiliated teaching hospitals. The purpose of the study was to describe the role of the clinical trial nurse in the informed consent process, as well as to explore the ethical issues that arise from this role.

This work provided important empirical data, lacking in the literature, as to what extent nurses take part in the informed consent process, when they become involved, and the ethical implications arising from this involvement. A 50 item-questionnaire that was created and then tested by three experts within the research and nursing field for the reliability and face validity was distributed to ninety-five nurses. Sixty-five of them returned the completed questionnaire after a second mailing, for a 68.4% response rate.

The findings of this study demonstrated that all nurses in this study population participated in the informed consent process and most (75%) of them were involved before, during, and after the consent was obtained. In most cases disclosure of information to subjects regarding the purpose (74.5%), risks (67.3%), benefits (69.1%) and alternative treatments (65.5%) were a shared responsibility of the principal investigator and the clinical trial nurse. On the other hand, the assessment of the participant's understanding of the information (40%), and the assessment of the participants' voluntariness (92.3%) were responsibilities most commonly delegated to the clinical trial nurse.

The clinical trial nurses attempted to fulfill their role in spite of the fact that they did not have written guidelines defining their role and had received little if any education in research ethics. This void is what enforced situations where nurses were experiencing ethical conflicts and dilemmas. As explained and described by the respondents the conflicts were most commonly associated to the structural organization that involved the principal investigator as the employer of the clinical trial nurse (58.5%) while the dilemmas were most commonly due to the lack of guidelines (23.8%) and the lack of a clear job description (22.3%).

Key Words: Free and informed consent; respect for autonomy; clinical trial nurse; research ethics

Table of Content

List of Tables

List of Figures

Introduction

The literature suggests that clinical trial nurses are participating in the informed consent process within the research context. However, the extent of nurses' involvement in this process remains unclear, thus the purpose of this study is to describe the role of the nurse in the informed consent process, specifically the extent of their involvement in this process, as well as to explore the ethical implications that accompany this role. The ethical framework used to facilitate and guide this study is the principle approach to ethics by Beauchamp and Childress (2001). Through the use of the principle of "respect for autonomy" and the use of both the nursing ethical guidelines and guidelines and regulations set forth by the federal and provincial governments regarding the ethical conduct of research, key concepts were identified and defined. These very concepts were operationalized through the elaboration of a 50 items questionnaire. The questionnaire was distributed to nurses, data was collected and analyzed, and the results are presented in this thesis.

Within this document you will find the following chapters: research problem, review of the literature, method, presentation of results, and interpretation and discussion of results. These chapters provide details about the research problem, what the literature suggests, how this project was implemented, how the data were collected and analyzed. Finally the results are presented, interpreted and discussed.

Chapter One

Research Problem

In Quebec, as documented by Deschamps, Vinay and Cruess (1995), nurses are the professionals most commonly called upon to collaborate with a principal investigator (usually a physician) in clinical trial research. A *clinical trial* can be defined as "*a study conducted on humans and designed to answer specific questions using scientifically controlled methods*" (Cassidy & Macfarlane, 1991, p.124). The literature makes reference to several different titles to refer to this nurse working in collaboration with a principal investigator within this clinical trial setting; "Study Coordinator", "Study Nurse", "Research Assistant", "Nurse Coordinator", "Research Nurse", and "Clinical Trial Nurse" to mention a few. A standard title to refer to this nurse is lacking and has contributed to the confusion and uncertainty that exist regarding this role (Deschamps et al., 1995; Johnson, 1986). For example, "Research Nurse" is often used in this context despite the fact that the Canadian Nurses Association (1983) clearly defines a "Research Nurse" as a nurse involved in a systematic controlled investigation involving human subjects directed to the advancement of *nursing* knowledge. This title does not reflect the nurse working in collaboration with a principal investigator in the clinical trial setting. However, "Clinical Trial Nurse (CTN)" as defined by Berry, Dodd, Hinds and Ferrell (1996) refers to a nurse working with clinical trials, for which he/she is *not* the principal investigator of the study. Given this, "Clinical Trial Nurse (CTN)" is the title retained for the purpose of this study, since it appears to be the most transparent.

In addition to the need for an official standard title to refer to this role, clear practical guidelines defining the actual role and boundaries of the clinical trial nurse are lacking (Davis, 1989; Deschamps et al., 1995; Johnson, 1986). This situation, undefined role with unclear boundaries, creates the potential for and eventually results in ethical dilemmas and conflicts. In fact the literature (Davis, 1989; Johnson, 1986) supports this statement and demonstrates that the lack of guidelines and policies outlining the responsibilities of the CTN has resulted in nurses experiencing conflict of responsibility and dilemmas.

Although recommendations regarding the elaboration of practical guidelines for nurses working within the clinical trial setting were made to the OIIQ in the "Deschamps Report" (1995), an official title and standard guidelines are still lacking. Regardless, the literature reveals that nurses are indeed actively participating as members of research teams within the clinical trial setting. Johnson (1986) was one of the first to document and report an increase in the number of nurses participating in research studies of new treatments and underlined the fact that nurses are frequently being employed in special units for the exclusive conduct of clinical research projects. Initially the role of the clinical trial nurse was identified as, and limited to one of data collector (McEvoy, Cannon, & MacDermott, 1991) but subsequent to the development of the techno-science era and the explosion of pharmaceutically sponsored clinical trial research this role further developed. As a result, the role of the nurse grew from a limited data collector to a collaborator within a research team. Certain authors (Arrigo,

Gall, Delogne, & Molin, 1994; Cassidy & Macfarlane, 1991; McEvoy et al., 1991; White-Hershey & Nevidjon, 1990) describe the clinical trial nurse as an integral part of the research team and also mention that others, in the research team, perceived nurses as essential components of the research process. McEvoy and his colleagues (1991), as well as Arrigo and colleagues (1994), specified that the clinical trial nurse is a key player: in providing the patient and family with information and education, in the administration of the experimental treatment, in the monitoring of toxicities, and in the organization of follow-up. Similarly, White-Hershey and Nevidjon (1990) defined the role of the CTN as data collector, liaison person, teacher, and evaluator. The above-mentioned authors have all documented the expanded role of the clinical trial nurse however they did not provide specific information pertaining to the nurse's role in the informed consent process. Nevertheless, the activities described by these authors (provider of information, teacher, evaluator) undertaken by the CTN certainly imply that the nurse participates in the informed consent process, if not directly, at least indirectly.

An extensive literature review provided little documentation pertaining to the role played by the clinical trial nurse in the informed consent process. Certain authors documented that clinical trial nurses are ensuring informed consent (Arrigo et al., 1994; Barnes Davis, Moran, Portillo, & Koenig, 1998; Berry et al., 1996; Lynch, 1988; McEvoy et al., 1991; McLean, 1996; Papakonstantinou, Panarello, Sulpizio, Senosier, Cantini, & DiMatteo, 1997; Sadler, Lantz,

Fullerton, & Dault, 1999; Wager, Tooley, Emanuel, & Wood, 1995). However empirical data pertaining to the number of nurses participating and the actual level of participation of the nurse in the informed consent process is sparse.

Quinn (1990) stated that the level of participation of the nurse in clinical trials is poorly documented and often not recognized. The European Organization of Research and Treatment of Cancer (EORTC) realized this fact, and as a result, launched an Oncology Nurses Study Group (ONSG) to identify nurses involved in clinical trials, describe the extent of their participation, and document their specific needs. Interestingly, participation in patient information and obtaining informed consent were reported to be one of the most common tasks and activities of the CTN (Arrigo et al., 1994). In an earlier study by Davis (1988) the role of the clinical trial nurse, where others such as the physicians or researchers, obtained informed consent was described. Davis (1988) portrayed the CTN's involvement in the informed consent process as the watchdog, advocate, resource person, coordinator and facilitator. Both these studies provide valuable information (Arrigo et al., 1994; Davis, 1988) however they do not provide specific data regarding the role of the clinical trial nurse in obtaining informed consent. Nonetheless, these studies point out that CTNs are indeed participating in the informed consent process and therefore are participating in the important role of respect for the participant's autonomy.

The principle of "respect for autonomy" involves allowing the participant the possibility to choose a course of action based on pertinent information required in order to make an informed choice (Beauchamp & Childress, 2001). In participating in the informed consent process, the CTN is participating in the application of the principle of "respect for autonomy" for informed consent is one way of applying this principle (McLean, 1996).

Indeed Arrigo and his colleagues (1994) provided empirical data demonstrating that nurses are participating in the informed consent process, however they did not provide any description of how or when the nurse becomes involved in this process. Davis (1988) points out the need for more systematic data on what actually happens in situations of informed consent and the nurse's role in obtaining it, since her study was limited to nurses for whom obtaining consent was not their responsibility. It is the aim of this project to explore and describe the extent of the role played by the clinical trial nurse in the informed consent process: Are CTNs actually obtaining informed consent and when do they become involved in this process? To what extent is the CTN's involvement in this process? Also an objective of this study is to explore the ethical challenges that may arise from the clinical trial nurse's participation in the informed consent process. At the foundation of this research question are findings from previous studies that suggest participation in the informed consent process results in clinical trial nurses finding themselves questioning their duty and moral obligations, as well as what their responsibilities entail (Davis, 1989; Johnson,

1986). Furthermore, these authors suggest that the undefined role together with the lack of educational preparation has contributed and resulted in the experience of moral and ethical problems by the CTN. This is evidenced in Johnson's (1986) study that underlines accompanying this expanded role are moral and ethical issues that required high levels of clinical judgment for which few received educational preparation. In fact, Papakonstantinou and colleagues (1997) disclosed that the role of the clinical trial nurse is rarely part of the university-level curriculum resulting in "on the job training" being the norm. Similarly, the "Deschamps Report" (1995) revealed that clinical trial nurses had received very little, if any, educational preparation, while others (Arrigo et al., 1994; Luker, 1999) added that the level of educational preparation, experience, and in the actual responsibilities of the CTN vary greatly.

With regard to the ethical implications surrounding the role of the clinical trial nurse in the informed consent process, Davis (1989) specifies that as a result of unclear boundaries and the lack of a defined role, questions of loyalty arise between the nurses' obligation to the researcher and their duty as caregivers to the participant, resulting in the nurses' experiencing a state of conflict of responsibility. Similarly Johnson (1986) reported that CTNs are unsure of their boundaries and as a result are experiencing conflicts of responsibility. This project will examine and explore these conflicts. Are clinical trial nurses in Quebec encountering ethical dilemmas and conflicts in performing their duties as clinical trial nurses? What role do they play in the informed consent process and

what ethical issues arise from this role? There are no clear answers to these questions. The need for clear boundaries, practical and ethical guidelines are eminent; however, in order for any guidelines to be developed, a descriptive study must first be executed, documenting the reality in which clinical trial nurses' are practicing, what their responsibilities are, and the ethical issues or concerns that arise from such a practice.

Although some agencies (Canadian Nurses Association, 1997; International Council of Nurses, 1996; Gouvernement du Québec, 1993) have developed and published codes of ethics and ethical guidelines to direct and facilitate the understanding of behaviors of nurses' in all roles, these codes and guidelines do not address the specific areas of ethical concern for the CTN participating in the informed consent process. This fact further substantiates the need for exploration and documentation of this role as well as underlines the importance of this research study. The results of this study may provide the profession with the information required for the development of specific practical and ethical guidelines in this area of nursing practice. As well may underline the need for standard educational programs for nurses working in this setting.

Research Purpose

The purpose of this study is to describe the role of the clinical trial nurse in the informed consent process here in Quebec, where the principle investigator

is a physician and to explore the conflicts and ethical dilemmas that are encountered from such a role.

Research Questions:

What is the role of the clinical trial nurse with regard to disclosure of information?

What is the role of the clinical trial nurse with regard to assessing the comprehension of the informed consent process?

What is the role of the clinical trial nurse with regard to assuring the voluntariness of patient participation in clinical trials?

What is the frequency at which conflicts and ethical dilemmas are encountered by clinical trial nurses participating in the informed consent process?

What are the types of conflicts and ethical dilemmas encountered by clinical trial nurses participating in the informed consent process?

In order to meet these objectives, the ethical framework that will be used to facilitate and guide this study is the principle approach to ethics by Beauchamp and Childress (2001).

Contribution to the Advancement of Knowledge

This study will allow the documentation of the clinical trial nurse's role and involvement in the informed consent process. It will contribute and add to the sparse body of knowledge regarding the role played by the nurse, the extent of

his/her involvement, and when and how he/she becomes involved in the informed consent process. Furthermore, it will provide a better understanding of the potential and actual ethical issues that may arise from such a role and provide insight with regard to the potential ethical implications that can result when a role is poorly defined. In addition, it will provide us with a better understanding of the educational needs of this group with regard to the informed consent process.

Finally, the results of this study may contribute and provide information required for the elaboration of norms and standards needed in order for the role of the nurse in the informed consent process to be defined. As well, the information gained from this study may afford to the elaboration of nursing educational programs that include the role of the clinical trial nurse and the ethical implications involved when nurses participate in the informed consent process within the clinical trial setting.

Chapter II

Review of the Literature

The primary aim of this study is to identify the role of the clinical trial nurse in the informed consent process and the ethical issues they encounter within this role. This literature review chapter will illustrate what is known and documented thus far with regard to the CTNs role in the informed consent process as well as the ethical implications that arise from such participation. Obviously, this chapter serves to refine and clarify the problem and is essential since it allows for the retrieving of important information from existing studies and theories. Also, this chapter will not only illustrate what is known, but in addition demonstrate how this study will contribute and add to the existing body of knowledge.

Within this chapter you will find three themes: (a) the principle of respect for autonomy (framework), (b) ethics and informed consent, and (c) the role of the clinical trial nurse in the informed consent process and its ethical implications. The key concepts studied in this project that will be defined and measured are: disclosure of information, comprehension, voluntariness, conflict of interest and ethical dilemma. These are the very concepts that served to elaboration and are at the foundation of the research tool, the questionnaire. Through the use of diverse sources, the framework, themes and key concepts will be explained and elaborated within this chapter.

Principle of Respect for Autonomy

The principle approach to Biomedical Ethics as described by Beauchamp and Childress (2001) will be used as the framework guiding this study. These authors define "*principles*" as general guides that provide direction in the development of detailed rules and policies, although they are general in nature, principles allow room for judgment in specific cases. In their book entitled *Principles in Biomedical Ethics*, Beauchamp and Childress (2001) describe four basic principles of biomedical ethics. They are: *respect for autonomy* (a moral obligation that requires respecting the decision-making capacity of an autonomous individual), *non-maleficence* (a moral obligation of doing no harm), *beneficence* (a group of moral obligations for providing benefits that involves the balance of benefits and risks), and *justice* (a group of moral obligations for distribution of benefits, risks and costs fairly).

Given the fact that the main objective of this study is to explore the role of the CTN in the informed consent process, *the principle of respect for autonomy* has been chosen as the principle that will be described in detail. This choice is based on the assertion that informed consent is one way of applying the principle of respect for autonomy (McLean, 1996). In fact, several authors (Beauchamp & Childress, 2001; Davis, 1989; Haddad, 1996; Keatings & Smith, 1995; Yeo & Moorhouse, 1996; Yeo, 1991) claim that informed consent is based on the principle of respect for autonomy and an individual's rights to the information required to make decisions about his/her own health care. Given this, one can

appreciate the appropriateness in elaborating on the principle of *respect for autonomy* in this particular study in which informed consent is a main theme.

Autonomy or self-determination is the right of each individual to make independent decisions concerning one's own life and well being (Davis, 1989; Yeo, 1991) while *respect for autonomy* is based on the moral obligation requiring respecting the decision-making capacity of autonomous persons and based on the concept of autonomy (Beauchamp & Childress, 2001). For the purpose of this study, the concept of autonomy is used to examine decision-making in the clinical trial setting regarding one's health care. The word autonomous finds its origin in the Greek language, *"AUTOS"* meaning self and *"NOMOS"* meaning rule and was first used to refer to the self-rule or self-governance of independent cities in Greece. This concept was then extended to include individuals (Beauchamp & Childress, 2001).

"*Personal autonomy is, at a minimum, self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice*" (Beauchamp & Childress, 2001, p. 58). This definition makes evident the similarities that exist among personal autonomy and informed consent, both involving the freedom to make a choice without interference or limitation: such as coercion, manipulation, lack of information or lack of understanding. Given these similarities, once again it is

apparent that the principle of autonomy is indeed what is at the foundation of the informed consent process.

One of the objectives of this study is to determine how the clinical trial nurse is implicated in the decision-making process of an *autonomous person*. In other words, the role of the nurse in the *autonomous choice* process will be explored. Firstly, what is the definition of an "*autonomous person*"? It refers to the capacity of the individual to understand, to reason, to deliberate and to make an independent choice whereas "*autonomous choice*" refers to the actual act as oppose to the capacity to act (Beauchamp & Childress, 2001). Hence, *autonomous choice* differs from *autonomous person* insomuch as the interest lies with the actual choice of the individual rather than the capability of that individual to make a choice (Beauchamp & Childress, 2001). For instance, one may have the capacity to understand, reason, deliberate or make an independent choice, however, may not exercise their capacity and hence fail to govern-self. A classic example of this is when participants (autonomous person) sign the consent form without having read or understood it; he/she possesses the capacity to act autonomously, but has failed to do so in providing consent without reading or understanding the form. Hence, the individual's action plays a pivotal role in determining whether the person acted autonomously or not. Beauchamp and Childress (2001) define "*autonomous action*" as acts that are: (a) intentional; (b) with understanding; and (c) without controlling influences that determine their action. Again, the parallel between the elements of autonomous action

(intentional, with understanding, and without controlling influences) and the elements of the informed consent process (disclosure of information, comprehension, and voluntariness) are obvious. From the above one can conclude that the principle of *respect for autonomy* is the fundamental moral principle upon which the informed consent was developed.

Ethics tell us that competent adults have the right to make an informed decision based on enough information that is understandable, without interference or undue influence; this is the right to act as an autonomous person (Davis, 1989). With regard to the principle of "respect for autonomy", being autonomous, which refers to action, is not the same as being respected as an autonomous person, which refers to the possibility of exercising autonomy. To respect an autonomous person means to allow that person the right to hold views, to make choices, and to take actions based on their personal values and beliefs (Beauchamp & Childress, 2001). Autonomous actions should not be controlled by pressure from others. On the contrary, it underlines the obligation of respectful practice in disclosing information and in respecting the individual's choice. Accordingly, respect for autonomy in the clinical trial setting involves comprehensive information sharing, the involvement of decision-making that is free from undue pressures, and respect of the choice made by the individual (Yeo & Moorhouse, 1996).

The aim of this study is to determine the role of the clinical trial nurse in ensuring respect for autonomy of those participating in clinical trials. How can

nurses in the clinical trial setting ensure respect for autonomy? "*Respect for autonomy*" obliges professionals to communicate information, to assess and ensure the understanding and willingness of the participation, and in addition, oblige professionals to encourage adequate time for decision-making (Beauchamp & Childress, 2001). Essentially, respect for autonomy means allowing participants to be in command and control of themselves. The basic illustration of autonomy in health care is "informed consent", which has played a critical and pivotal role in the health care setting since a valid consent legitimates authority and actions that would otherwise not be allowed. Moreover, it provides access that would otherwise be unattainable. This study will therefore explore the extent of the CTN's participation in respecting the autonomy of clinical research participants, by measuring the extent of the nurse's involvement in the informed consent process.

According to Beauchamp and Childress (2001) the limit of this principle, that is, respect for autonomy, is that it does not include non-autonomous persons and therefore should not be used for persons who cannot act in an autonomous manner because of immaturity, incapacitation, ignorance, coercion or exploitation. A debate exists regarding this limit, for as described by Kant, every being ought to be respected on the basis that he/she is a human being, indicating that they are ends in themselves and therefore should not be treated merely as a means (Beck, 1987). Immanuel Kant's (1724-1804) theory explained that moral duties derive from a fundamental imperative binding rational individuals, called

"categorical imperative"(Kant, 1964). This imperative describes humans as rational beings, able to decide what their own moral duties are (Yeo & Moorhouse, 1996). This holds true for the incapacitated as well as for those who can exercise their own autonomy as rational agents. Nevertheless this study will be limited to research involving competent adult participants. This decision is based on the fact that Beauchamp and Childress (2001) raise this limit within their framework as well as the fact that guidelines and rules for obtaining consent from minors and inapt adults differ (Civil Code of Quebec, 1994) from those followed for competent adults. Although nurses are involved in clinical trials involving minors and inapt adults, in my experience as the coordinator of the research ethics committee of a University affiliated Hospital, the amount of research involving these groups is small and involves particular ethical questions that are different and perhaps more complex. This is an area that needs specific exploration and research, but for the purpose of this study will be excluded. Hence, this project is limited to nurses working in the clinical trial research involving competent adults.

One of Kant's most influential obligations is "*one must act to treat every person as an end and never as a means only*" (Beauchamp & Childress, 2001, p. 350). This obligation supports the principle of respect for autonomy and has influenced health care in general, in addition influenced and resulted in the elaboration of professional codes. Kant argued that respect for autonomy is reflective of the fact that all persons have unconditional worth, each having the capacity to determine his/her own morality (Beauchamp & Childress, 2001). To

violate a person's autonomy for the sake of his own interests is to treat that person merely as a means (Beck, 1987). In accordance to this paradigm, would recruiting human participants for the purpose of medical experimentation, to test a hypothesis, be an example of treating persons merely as means to others' ends? This would hold true if the individual was not properly informed, lacking understanding or not voluntarily participating. However, as prescribed by governmental ethical standards (Declaration of Helsinki, 2000; Nuremberg Code, 1947; Tri-Council Policy Statement, 1998), research participants must be given the choice to participate after information about the purpose, risks and benefits of the study have been disclosed and understood. Therefore, the participant retains control over his/her life and has the right to make choices based on his/her own values and beliefs. Kant's theory does not prohibit use of consenting persons; he insists only that they be treated with respect and moral dignity to which they are entitled.

Ethical theories provide a framework of principles and rules to help identify ethical issues and ethical dilemmas and deal with them (Keatings & Smith, 1995). In general, ethical theories describe how we ought to behave, in addition, provide reasons as to why we should act a certain way rather than another (Yeo & Moorhouse, 1996). Ethical principles such a "respect for autonomy" derive from moral theory and serve as rules to guide moral conduct. As a result, ethical principles are at the foundation of many professional codes. A professional code represents an articulated statement of the role morality of the

members of the profession (Beauchamp & Childress, 2001). Since it is the objective of this study to determine the ethical implications surrounding the role of the clinical trial nurse in the informed consent process, in addition to the principle of "respect for autonomy" as described by Beauchamp and Childress (2001), the Professional and Ethical Nursing Codes, will also be used as frameworks guiding this study since they expresses the profession's ethical ideals that are to guide the moral behavior of nurses (Yeo & Moorhouse, 1996).

The four ethical principles described by Beauchamp and Childress (2001) are embedded in the *Code of Ethics for Registered Nurses* (Canadian Nurses Association, 1997) which seeks to clarify the obligations of nurses to use their knowledge and skills for the benefits of others, to minimize harm, to *respect client autonomy* and to provide fair and just care for their clients (Keatings & Smith, 1995). Although this code was developed to provide guidance concerning ethical matters in nursing practice, it fails to provide specific guidance to nurses working in the clinical trial setting. Although the ethical concerns in the clinical and research setting are similar, the research setting involves additional concerns that this code of ethics does not address. Similarly, the guidelines set forth by the Canadian Nurses Association in 1983 entitled, *Ethical Guidelines for Nursing Research Involving Human Subjects*, as well as *Ethical Guidelines for Nursing Research* (International Council of Nurses, 1996), do not provide guidelines specific for the clinical trial nurse working in collaboration with a principal investigator in biomedical research, but rather provide guidelines for the

"Research Nurse", a nurse who is the principal investigator of a nursing study. However, the value statements described in the Code of Ethics for Registered Nurses (Canadian Nurses Association, 1997) can be applied in this clinical trial setting. Of interest are two particular values described in this code, they are "*respect for needs and values of clients*" (Value I) and "*respect for client choice*" (Value II). These values are both derived from the principle of respect for autonomy. The first value, respect for needs and values of clients, obliges the nurse to treat the client with respect and in accordance with their individual needs and values. It is the individual that decides what is in his/her best interest. The second value, respect for client choice, emphasizes the need to respect the client and his right to choose and control his/her own care as fundamental, and stresses the significance of informed choice. As prescribed by these values, the obligation of the nurse professional is truthful disclosure of information, assessment of the understanding of clients about their care, providing information as required, and finally, ensuring that force, coercion and manipulative tactics were not used in the obtaining of consent (Canadian Nurses Association, 1997). Moreover, the *Quebec Nurses Act* (1994) and the *Quebec Code of Ethics of Nurses* (1993) underline the fact that all nurses have the ethical responsibility to ensure protection of patients, be they research participants or not.

As described in the professional codes and as part of their professional role, nurses are held accountable to participants, their families, the health care team, their profession and society as a whole for acts and decisions they make

(Keatings & Smith, 1995). These codes provide the framework guiding the ethical behavior of nurses. Are clinical trial nurses participating in the informed consent process, and if so are they aware of the ethical issues surrounding this process? Are CTNs experiencing any ethical dilemma or conflicts from participating in the informed consent process? Through the use of the above-mentioned framework, this project seeks to answer these very questions.

Ethics and Informed Consent

Informed consent is a process of decision-making between the patient and the provider of care (Silva & Sorrell, 1988). This process involves the patient as an active partner in his/her own health care (Veatch & Fry, 1987). To actively participate in this process, the participant must have the capacity to make choices and must comprehend the nature, significance and outcome of the choices (Silva & Sorrell, 1988). This statement holds true since this study is limited to include clinical trial nurses participating in research involving competent adults, and as such will not include clinical trial research involving minors or incapable adults.

In law, the requirement of informed consent is grounded in the principle of *autonomy* - often referred to as the principle of *self-determination* by the courts (Veatch & Fry, 1987). It was in 1914 that Judge Cardozo articulated, during the landmark case of Schloendorff vs Society of New York Hospital, what became the fundamental principle of the consent document:

> *"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an*

operation without his patients' consent commits an assault for which he is liable for damages"

The courts, for the first time, recognized the right of the patient to be informed and give consent to medical therapy. As for medical experimentation, the issue of consent for research was not addressed until 1947 after the Nazi physicians, scientists and officers were prosecuted for war crimes and crimes against humanity (World War II) in Nuremberg, Germany. The Nuremberg Code, containing ten principles, was written and resulted in worldwide attention on the issue of informed consent in research (Mariner, 1997; Shuster, 1997; Watts, 1997).

The recognition, by the judges at Nuremberg, of the significant difference between medical therapy and medical experimentation together with the devastating crimes that took place against the Jews, during the second World War, served as the triggers for the development of the Nuremberg Code (Annas & Grodin, 1992; Mariner, 1997; Shuster, 1997; Watts, 1997). These judges realized that the aim of medical therapy is the treatment of the patient, whereas the goal of medical experimentation is to test a scientific hypothesis by following a protocol (Shuster, 1997). Given this fundamental difference, it was clear that more was needed to protect human research subjects, leaving it to the discretion of the researcher had obviously proven to be unsafe. Their solution was the elaboration of the Nuremberg Code (1947), emphasizing the right of individuals to determine their participation in medical research (Annas & Grodin, 1992; Mariner, 1997;

Shuster, 1997; Watts, 1997). The Nuremberg Code was the first code to describe ten basic principles of ethical behavior in the conduct of human experimentation (Rusnak, 1996). For the first time, informed consent became an absolute requirement (principle 1); furthermore, participants were given the right to withdraw from participating in an experiment, also a first (principle 9). These two principles of the Nuremberg Code (1947) proclaimed the research participant as a partner capable of actively protecting himself/herself. The remaining principles, (2 through 8 and 10), not only underline the importance of protecting the best interests of the participants but in addition require that the researcher does so. For the first time in history, the code provided clear ethical standards of behavior applicable to all nations (Rusnak, 1996). Undoubtedly, the Nuremberg Code (1947) has marked and forever changed the conduct of medical research on human participants, as did the Declaration of Helsinki (1964) set forth by the World Medical Association as a statement of ethical principles guiding physicians in medical research involving human subjects (Shuster, 1997; Watts, 1997).

The Declaration of Helsinki (1964) had a larger practical impact than the Nuremberg Code (1947). This was probably due to the relationship between the elaboration of the Nuremberg Code and the World War II crimes against humanity. The guilty parties were seen as Hitler's henchman as opposed to doctors, and as such, the code was perceived as a code that had very little to do with science and a lot to do with Nazis (Rusnak, 1996). The Declaration of Helsinki (1964) specifies that participants of research must be volunteers and

must have received *adequate information* concerning the aims of the project, methods used, expected benefits and potential hazards and discomforts. Secondly, it underlines that the participants must be informed of their rights to refuse to participate, to choose to participate now, and free to withdraw from the study at anytime without any repercussions. Finally, it states that only after the physician ensures that the participant has understood the information, should freely given informed consent be obtained.

Beecher (1970, p.272) characterized the Declaration of Helsinki as an "*ethical as opposed to a legalistic doctrine, and is thus a more broadly useful instrument than the one formulated at Nuremberg*" (p. 272). The Declaration of Helsinki (1964), formulated by physicians, focused on the investigator's integrity and experience as well as peer review of research protocols rather than emphasizing the informed consent process. Conversely, the Nuremberg Code placed the emphasis on the informed consent process, as the first of ten principles, which is not surprising since this Code was written by judges, legal professionals, whose preoccupation was the rights of the participants in research studies. Except for these above-mentioned differences, the Declaration of Helsinki mirrors the Nuremberg Code (Saunders, 1995), and as such stating that one is more useful than the other is rather difficult, since they are very similar. Regardless of variant opinions and interpretations, consensus exists with regard to the contribution and impact of these two documents. They have undoubtedly marked the historical evolution of research ethics and have impacted and influenced contemporary

ethics (Mariner, 1997; Shuster, 1997; Watts, 1997). In fact they are at the foundation of subsequent codes and regulations governing bioethical research on human subjects (Rusnak, 1996).

Prior to considering the codes and regulations that govern the present practice of research involving human subjects here in Quebec, let us define the term ethics. The word *ethics* finds it origin in the Greek language, *ethos*, meaning "character", and is defined by the Britanica Encyclopedia (1964) as: "*the systematic study of the nature of value concepts, "good", "bad", "ought", "right", "wrong", etc., and of the general principles which justify us in applying them in anything; also called "moral philosophy*" (p. 752). As per this definition, ethics provides justification of human behavior and attitude and as such is at the foundation of the regulations that govern our society.

For the purpose of this study ethics refers to a publicly stated and formal set of rules, principles, values or ideals of a particular group (Beauchamp & Steinbock, 1999; O'Connor, 1996). Therefore, clinical research ethics is the formal stated set of rules or values governing research involving human subjects.

Informed consent is not only a shared decision-making process but in addition is "*an autonomous authorization of a medical intervention or participation in research*" (Beauchamp & Childress, 2001, p.78). This definition emphasizes the fact that individuals must do more than express agreement, which

is what shared decision-making requires, "*they must authorize through an act of informed and voluntary consent*" (Beauchamp & Childress, 2001, p.78). For autonomous individuals are those who are able to freely choose a course of action without assistance or interference (Beauchamp & Childress, 2001; Davis, 1989; Deluca, Korcuska, Oberstar, Rosenthal, Welsh, & Topol, 1995). This definition reflects a "libertarian" attitude where the individual's freedom is the fundamental value (Baudouin & Parizeau, 1987). These authors (Baudouin & Parizeau, 1987) explain that within the libertarian paradigm, individuals are presumed autonomous; the participant chooses a strategy that he/she judges is the best. This choice is based on information received. Once the information is given, the decision is made freely, without undue constraints. The physician is informed of the decision, which is made outside of the patient-physician relationship. The rule that guides this paradigm is "respect of the individual's liberty to choose".

Several authors (Beauchamp & Childress, 2001; Davis, 1989; Deluca et al., 1995) specify that informed consent is a process, given over time and which can be withdrawn at any time. This definition underlines the temporal nature of informed consent, emphasizing that a moment in time when a participant signs a form is not the essence of informed consent but rather a component of an ongoing process. A review of the literature reveals that a general consensus exists regarding what the fundamental elements of the informed consent process are. According to several authors (Appelbaum, Lidz, & Meisel, 1987; Beauchamp & Childress, 2001; Belmont Report, 1982; Berry, Dodd, Hinds, & Ferrell, 1996;

Cisar & Bell, 1995; Deluca et al., 1995; Grady, 1991; Levine, 1986; Lynch, 1988; Speck, 1996; Tranter, 1997; Watts, 1997), the essential and fundamental elements of the informed consent process are disclosure of information, comprehension and voluntariness.

Disclosure of information refers to the amount of knowledge needed in order for an individual to make a rational decision (Beauchamp & Childress, 2001; Belmont Report, 1982; Cisar & Bell, 1995; Watts, 1997). As described in the most recently revised Declaration of Helsinki (2000) "*each potential participant must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail*". The question that arises is what amount of information is adequate? This has long been the subject of considerable debate (Beauchamp & Childress, 2001; Brewin, 1982; Deluca et al., 1995; Giertz, 1980; Lynch, 1988; Shafer, 1982). In fact, the courts have struggled with which norms should govern the disclosure of information: "The Professional Practice Standard" or "The Reasonable Person Standard".

The professional practice standard assumes that it is the professional's role to act in the participant's best medical interest. As such, adequate disclosure is determined by the professional community's customary practices (Beauchamp & Childress, 2001). In other words a practitioner has to disclose whatever his/her colleagues would have disclosed in a similar situation (Veatch & Fry, 1987).

Should the decision to participate in an experimental procedure be based on information provided to you that the researcher felt you should know? Or should it be based on what a participant like you would want to know? This is where the debate lies, for according to *the reasonable person standard*, the information that is given to participants is determined by what a reasonable person in that situation would want to know (Beauchamp & Childress, 2001). As interpreted by Veatch and Fry (1987) under this standard, the professional must disclose whatever a reasonable person, in the participant's position, would need to know in order to exercise an autonomous choice about the intervention. This norm shifts the authoritative determination of relevant information that needs to be provided to the potential participant from the researcher to the actual participant. This standard allows for autonomous choice, in fact the obligation to respect autonomy outweighs the obligation of beneficence, which is the obligation governing the professional practice standard. The Belmont Report (1982) suggests that the *reasonable person standard* should be the standard used to determine the amount and type of information provided to potential participants. Although the reasonable person standard better serves the autonomy of participants, it nevertheless leaves a lot to be desired in terms of clarity. How is a researcher to determine what a reasonable participant would want to know? One could therefore appreciate the need for clear guidelines regarding the information that is required for free and informed consent to occur.

Several articles address this issue of how much and what type of information should be provided to a potential participant in order for him/her to make an informed decision. Most agree that the purpose or goal of the study, the procedures involved, the possible risks, as well as the potential benefits constitutes essential information that must be provided and explained to potential participants of a research study (Belmont Report, 1982; Grady, 1991; Haddad, 1996; Speck, 1996; Tranter, 1997). Others (Harth & Thong, 1995; Watts, 1997) added that the possible alternatives as well as the duration of the participation should also be included as essential components in the disclosure of information.

In Quebec, the formal set of rules and guidelines that govern research involving human subjects include the Civil Code of Quebec (1991), le "Plan d'action ministériel en éthique de la recherche et en intégrité scientifique" (1998) and at a Federal level, the "Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans" (1998). At their foundation all these documents share the international historical principles of the Nuremberg Code and Declaration of Helsinki, explaining the circularity that exists amongst the national and international codes of research ethics. However, of the three documents named above, the Tri-Council Policy Statement (1998) is the only one that provides specific Canadian guidelines regarding the essential information that must be provided for true informed consent to take place. This document was set forth by the combined effort of three separate councils: The Medical Research Council of Canada (MRC), The Natural Science and Engineering Research

Council of Canada (NSERC), and The Social Science and Humanities Research Council of Canada (SSHRC). Their mandate was to promote research conducted with the highest ethical standard (Tri-Council Policy Statement, 1998). Section two of this document pertains to the issue of free and informed consent, and as such, will be explored in detail.

In the Tri-Council Policy Statement (1998), "Requirement for Free and Informed Consent- Article 2.1" is the first of four themes described in the "Free and informed Consent" section of this document. It is very clearly stated in this article that research can only take place if participants have been given the opportunity to give free and informed consent. In addition, it specifies that not only must free and informed consent be given, but it must be maintained throughout participation in the research. This article is congruent with the Civil Code of Quebec (1991) chapter 1, article 10, which describes that each person has the right to determine what will be done to his/her person. Governed by this civil right, others cannot perform any intervention, whether this action is performed during medical care or experimentation, without the consent of the person. Obviously there are exceptions to this, for instance in an emergency situation and when minors or incapable adults are involved, and these exceptions are described in detail in the Civil Code. However, these exceptions are not relevant to this study and they will not be elaborated any further. What still remains unanswered however, is what constitutes free and informed consent and what amount and type of information is considered adequate? Article 2.4 of the Tri-Council Policy Statement (1998) brings some clarity to this question. It explains that those

obtaining consent must provide full and frank disclosure of all relevant information in order for free and informed consent to be valid. More specifically it lists the following requirements for full and frank disclosure, they are: (a) the researcher must provide information pertaining to the fact that the individual is being invited to participate in a research project; (b) the purpose of the study, the identity of the researcher, the expected duration and nature of participation as well as a description of the procedures must be explained in a comprehensive manner; (c) an explanation and description of harms and benefits that may result from participation as well as likely consequences of not participating; and (d) the potential participants must be informed of their right to refuse to participate, that they are free to withdraw at any time without prejudice and will be given continuing opportunities for deciding whether or not to continue participating. This element emphasizes the fact that informed consent is not a single point in time. In fact, informed consent is an ongoing process that does not stop when the participant says "yes" and signs the form. Consent is a process that allows the participant the right to accept, refuse and/or withdraw at anytime (Barnes, Davis, Moran, Portillo, & Koenig, 1998; Berry et al., 1996; Haddad, 1996; Lynch, 1988; Sadler, Lantz, Fullerton, & Dault, 1999). Finally, the researcher must inform the participant of the presence of any conflict of interest as well as the possibility of commercialization of research findings. Article 20 of the Civil Code of Quebec (1991) adds that in order for a capable adult to participate in medical experimentation, not only must consent be given, but in addition the anticipated benefits of the experiment must outweigh the anticipated risks. This article is

congruent with the Nuremberg Code (1947) insofar as informed consent is a requirement, as is protecting the best interests of the participants. These two requirements are grounded in the principle of respect for autonomy and beneficence respectfully. Simply stated, if and only if both criteria are present, may capable adults subject themselves to medical experimentation.

The second element of the informed consent process is *comprehension.* Comprehension is the ability of the individual to understand what is being explained to him/her in order to make a decision (Beauchamp & Childress, 2001; Cisar & Bell, 1995; Deluca et al., 1995; Harth & Thong, 1995; Veatch & Fry, 1987). As discussed earlier, standards define the information required for disclosure of information to be judged adequate however; within these standards little attention is given to the participant's *comprehension* of the information provided (Lynch, 1988). From an ethical point of view, for the informed consent process to be valid, it must contain two key elements: freedom and comprehension (Deluca et al., 1995). Comprehension is indeed critical to decision-making for it is paramount for participants to understand the information provided for only then is consent truly "informed" (Silva, 1995; Watts, 1997). Evidently, in order for an individual to make an autonomous choice, information provided must be understood (Beauchamp & Childress, 2001; Veatch & Fry, 1987). As described by Cassileth, Zupkis, Sutton-Smith, and March (1980), comprehension is affected by the amount of information, the clarity of information, and the complexity of the information provided. Therefore,

information must be provided in an organized manner; in addition, the transmission of information must be adapted to the educational level, intelligence, maturity, language and cultural needs of the potential participant (Grady, 1991; Spivey, 1989; Watts, 1997). For as described by Haddad (1996), comprehension of the information provided is as important, if not more important, since information that is not understood is useless.

As described by the Declaration of Helsinki (2000) fully capable adults can consent to medical experimentation provided the participant understands the information and is fully capable of making a decision. This statement underlines the obligation of those obtaining consent to ascertain and ensure that the participant has comprehended the information provided prior to obtaining their consent (Grady, 1991; Harth & Thong, 1995). In addition, it brings the issue of competence (capable of making a decision) to the forefront. In general, a person is labeled competent if: (a) he/she has an understanding of the situation and the consequences of the decision, and (b) the decision is based upon rational reasons (Chell, 1998). Saint-Arnaud (1999) adds that the individual is considered capable if he/she can justify the choice based on their values and goals and secondly that they are able to communicate their decision.

In addition to the three elements of the informed consent process listed above (disclosure of information, comprehension, and voluntariness), certain authors include competence as an essential element to the informed consent

process (Beauchamp & Childress, 2001; Cisar & Bell, 1995; Harth & Thong, 1995; Lynch, 1988; Speck, 1996). They argue that in order for consent to be valid, the person giving consent must be competent. However, most authors incorporate competence within the element of *voluntariness* that will be addressed in the next paragraph. First, however, we must differentiate between comprehension and competency. Comprehension differs from competency insofar as it contains the element of understanding or ability to grasp the information whereas competency focuses on whether the person is psychologically and legally capable of adequate decision-making (Beauchamp & Childress, 2001). Therefore, an individual who is psychologically and legally competent has the capacity to understand but may not grasp the information that is being relayed to him or her.

The third and final element of the informed consent process that will be described is *voluntariness.* Voluntariness refers to having and exercising a free choice (Beauchamp & Childress, 2001; Belmont Report; 1982; Veatch & Fry, 1987). As prescribed by the ethical (Declaration of Helsinki, 2000; Nuremberg Code, 1947; Tri-Council Policy Statement, 1998) and the legal (Civil Code of Quebec, 1991) standards, consent to participate in research is *valid* only if *voluntary*. The central concept of clinical research ethics is informed consent, which is meant to ensure the voluntary nature of participation in research studies (Davis, 1989; Faden & Beauchamp, 1986). Voluntary consent means free from coercion, manipulation or other forms of controlling influences by others

(Beauchamp & Childress, 2001; Belmont Report, 1982; Deluca and al., 1995; Haddad, 1996; Harth & Thong, 1995; Lynch, 1988; Tranter, 1997; Veatch & Fry, 1987; Watts, 1997). These authors specify that not only must consent be obtained freely, and without coercion, but in addition, the potential participant must be free to refuse and/or free to withdraw at anytime without prejudice. Furthermore, voluntariness assumes competence and sufficiency of information (Lynch, 1988). Indeed, in order for a person to act freely, they must firstly be competent to do so, and secondly must have received relevant information pertaining to the choices at hand.

The Tri-Council Policy Statement (1998, Article 2.4) specifies that free and informed consent must be voluntarily given, without manipulation, undue influence or coercion. In other words the participate must choose to participant without pressure from the researcher, members of the research team, family, practitioner or others. In addition, the participant must not be led to feel that he/she is obligated to participate, it must be clear that whatever he/she chooses is acceptable and will not affect the quality of their present or future medical care. The freedom to choose is the cornerstone of informed consent, since it maintains the autonomy of each individual.

Obviously, all of the elements in the informed consent process (disclosure of information, comprehension, voluntariness) explained above are closely related

and interdependent since informed consent is valid only if "*one is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention*" (Beauchamp and Childress, 1994, p. 145).

As evidenced above, disclosure of information, comprehension and voluntariness are key concepts being studied within this project. For the purpose of this study each of these concepts are defined as follows:

Disclosure of Information: is defined as the amount of information regarding the purpose of the study, the possible harms and risks, the potential benefits as well as the possible alternatives provided to potential participants during the informed consent process in order for that individual to make a choice regarding whether he/she wishes to participate in the study.

Comprehension: is defined as the individual's (potential participant) understanding the information provided to him/her during the informed consent process in order for a decision to be made regarding his/her participation in clinical trial research.

Voluntariness: is defined as the individual's right to choose and exercise a free choice regarding his/her participation in a clinical trial. A choice that is free from coercion, manipulation and controlling interference from others. It also entails the freedom to refuse, to accept now and withdraw later without prejudice.

Role of the Nurse in the Informed Consent Process

Historically, as evidenced by the Declaration of Helsinki (1964), the physician, principal investigator, was responsible for ensuring adequate disclosure of information to potential research participants and responsible for obtaining informed consent prior to enrolling participation in the experiment. With time, other professionals became involved in the research process and what used to be "a one man show" turned into a "team effort". In accordance with the *Good Clinical Practice: Consolidated Guidelines* (Health Canada, 1997), this team is lead and the research project is executed under the authority of a principal investigator (usually a physician). This investigator is responsible for the quality and integrity of the research activities undertaken within the project. Under the responsibility of the investigator also lies the security and well being of all whom voluntarily participate as research participants (Deschamps et al., 1995). Clearly, the responsibility of the study lies squarely on the principal investigator, and the courts have consistently placed this responsibility on them (McLean, 1996). However, it is common practice for the investigator to delegate this responsibility partially or totally to the clinical trial nurse (Arrigo et al., 1994; Barnes et al., 1998; Berry et al., 1996; Cassidy & Macfarlane, 1991; Davis, 1989; Davis, 1988; Deschamps et al., 1995; Johnson, 1986; Lynch, 1988; McEvoy et al., 1991; McLean, 1996; Sadler et al., 1999; White-Hershey & Nevidjon, 1990).

Reflective of this common practice of delegating responsibilities to others within the research team, is the most recently revision Declaration of Helsinki

(October, 2000) which addresses and targets, for the first time in its history, not only physicians, but all those who play a part in medical research involving human subjects. Accordingly, those working in collaboration with a physician must adhere to the ethical principles described in the Declaration to guide research involving human participants.

Although the literature suggests that clinical trial nurses are involved and participating in the informed consent process (Arrigo et al., 1994; Barnes et al., 1998; Berry et al., 1996; Davis & Underwood, 1989; Davis, 1988; Lynch, 1988; McEvoy et al., 1991; McLean, 1996; Sadler et al., 1999; Wager et al., 1995), little empirical data is available regarding the number of nurses who actually take part in this process, how they are involved, the extent of their involvement, and the ethical implications arising from this involvement. This is probably attributable to the fact that the role of the nurse in this process has long been an object of controversy (Davis, 1989). There are two existing paradigms, one that argues that the principal investigator is legally responsible for obtaining the informed consent and it is a personal duty and responsibility that may not be delegated to another (Declaration of Helsinki, 1964; Nuremberg Code, 1947; Smith, 2000). The other asserts that indeed informed consent is the principal investigators' responsibility, but the nurse has an *ethical duty* and/or *moral responsibility* to ensure the participant's understanding of the consent process (Barnes et al., 1998; Berry et al., 1996; Canadian Nurses Association, 1991; Cassidy & Macfarlane, 1991; Davis, 1989; Hubbard, 1982; Johnson, 1986; Keatings & Smith, 1995; Lynch,

1988; McLean, 1996; Sadler et al., 1999; Wager et al., 1995). Some go as far as to declare that the nurse, whether or not this responsibility is delegated to him/her, is at least as responsible as the physician in obtaining consent and have the obligation to provide information to the potential participant in collaboration with the physician (Berry et al., 1996; Cisar & Bell, 1995; Melink, 1989; Sadler et al., 1999).

The *Code of Ethics for Nurses* (Canadian Nurses Association, 1997) lists and describes several value statements that express the broad ideals of the nursing profession. Of interest are "*respect for needs and values of clients*" (Value I) and "*respect for client choice*" (Value II). These values are both derived from the principle of respect for autonomy. The first value, respect for needs and values of clients, obliges the nurse to treat the client with respect and in accordance with their individual needs and values. The second value, respect for client choice, emphasizes the need to respect the client and his right to choose and control his/her own care as fundamental, and stresses the significance of informed choice. The obligation of the nurse professional, abiding to the ideals of the nursing profession, is truthful disclosure of information, assessment of the understanding of clients about their care, providing information as required, and finally, ensuring that force, coercion and manipulative tactics were not used in the obtaining of consent (Canadian Nurses Association, 1997). Once again one could appreciate the relation between the obligation of the nurse described above and the key concepts of this study: disclosure of information, comprehension, and

voluntariness. Accordingly, when nurses enter the profession, they commit to the rules, values and obligations described in the professional codes. Therefore, the clinical trial nurse governed by these value statements must ensure that the individuals needs and values are being respected both in clinical practice and in the research setting. In order to do so, the nurse must assess the individual's knowledge regarding the purpose, risks, benefits and alternatives relating to the study, and must ensure that the participant was not coerced into participating. Clearly, the value statements described above make explicit the requirement for informed consent. Not doing so would not only violate these basic nursing values but in addition violate the participant's rights. Moreover, in Quebec, health care professionals are required by law to ensure that participants understand the nature of the treatment, the need for the treatment, the risks and the benefits of the treatment in order to obtain fully informed consent (Keatings & Smith, 1995).

As well, the International Council of Nurses (1996) published guidelines entitled, *Ethical Guidelines for Nursing Research* which emphasize that all nurses have the *ethical responsibility* and *duty* to ensure protection of patients, be they research participants or not. In fact, the nursing goal in clinical trials is to protect the participant and as such the nurse should pay special attention to the consent form as a tool for protecting the participant (Johnson, 1986). Finally, in order to minimize undue influence, where the research participant is also in a relationship of dependency with the investigator, such as patient/doctor relationship, caution is required (Smith, 2000). In this regard, the Medical Research Council of Canada

(1987) suggests that in order to decrease the probability of conflict of interest, it would be prudent for principal investigators to delegate the obtaining of consent to other health professionals, especially if the investigator is also the treating physician. The question that arises is whether obtaining consent should be delegated to the clinical trial nurse.

According to Lynch (1988) nurses receive education and training in the principles of client teaching, communication, and interpersonal relationships. This together with the fact that they are the professionals with more frequent and close contact with the participant, places nurses in a central position in the ongoing process of informed consent. Conversely, McLean (1996) cautions nurses who take on the role of obtaining consent for research purposes. McLean (1996) asserts that prudence is required and this responsibility should not be assumed unless the nurse is at the very least, knowledgeable about and familiar with the research protocol, the condition being investigated, the screening criteria and process, the potential risks and benefits, the legal and ethical issues involved. Furthermore, McLean (1996) heeds nurses to be familiar with the proper procedures for the delegation of medical functions to nursing within their institution, and knowledgeable about the institution's policies and procedures governing the informed consent process for research purposes.

Arrigo and colleagues (1994) executed a European study in order to identify nurses' involved in clinical trials and describe the extent of their

involvement. A questionnaire was designed, tested, edited and 312 questionnaires were distributed to fifteen European countries, of which 120 were returned. The analysis demonstrated that of these 120 nurses, 73 % reported that they participated in patient information, while 56 % reported participating in obtaining informed consent. Interestingly, the most common activity amongst this group was supplying information to nursing colleagues (77%). These findings demonstrate that indeed nurses are participating in obtaining informed consent either directly (53%) or indirectly (73%). However, the extent of their involvement, such as what their involvement entails, at what point in the process they became involved, as well as any problems or ethical implications they may have encountered in this process, are not explored in this study.

In an earlier study by Davis (1988), the role of the nurse in the informed consent process was investigated. Twenty-seven nurses participated in semi-structured interviews to determine whether nurses were in anyway involved in informed consent and if so how? These nurses reported that they had taken part in the informed consent process involving research as often as they had in the process of consent for treatment. Their involvement was often almost immediately after the first interaction focused on obtaining informed consent. The central functions of the nurse involved in this process, as viewed by these nurses, was to reinforce, repeat and deal with the participants' questions that arose at different stages of their involvement in research (Davis, 1988). They assisted in the process of informed consent by deepening the participant's understanding of

the options and responding to specific questions. Often, they explained meaning of words that appeared on consent forms or that the physician had used. Interestingly, the nurses reported that in some research situations, their lack of information regarding the protocol had hampered them in carrying out these functions. Davis (1988) described five main roles played by the CTN in the informed consent process: watchdog, advocate, resource person, coordinator, and facilitator. The role of the *watchdog* is to monitor informed consent situations. As evidenced by this study (Davis, 1988), the CTN often accompanied the participant to witness the consent. In fact most nurses preferred to act as a witness because it made their later involvement in the ongoing process of informed consent easier, in addition by witnessing the consent they could report what they saw as violations of the consent process. The *advocate* is a role enacted by the nurse in order to mediate on behalf of participants. Given the lack of role boundaries, nurses often found themselves acting as the participants advocate by default since they were the most available and usually the professional with most details about the participant and his/her health status. As *resource person*, the nurses collected, dispensed, and reported information about all alternatives available, guided participants regarding their informational needs, and clarified features of consent that were misunderstood or overlooked. The *coordinator* role functioned to preserve an open, friendly atmosphere. The nurse explored and observed direct or indirect effects on the participant and their family and ensured necessary time for working through any issues that might arise. Finally, the role of *facilitator* where the nurse acts to clarify and validate differences in views and

opinions between parties involved in informed consent and assume responsibility of getting the team together to discuss aspects of specific situations that raise issues to be discussed.

Interestingly, in the examples provided by Davis (1988), nursing involvement occurred only after informed consent had already been obtained from the participant by the principal investigator. However in certain circumstances nurses are responsible for obtaining consent (Barnes et al., 1998). In fact certain authors describe a sharing in the responsibility of informed consent by the principal investigator and the clinical trial nurse, underlining a collaborative effort in the process of informed consent between the physician and the clinical trial nurse (Berry et al., 1996; Cisar & Bell, 1995; Sadler et al., 1999). Berry and colleagues (1996) specify that usually the physician discusses standard therapies versus entering a clinical research trial and leaves the "details" up to the nurse once the potential participant expresses desire to participate in the trial. Others describe a less direct involvement of the nurse who contributes to the process by: answering questions regarding the protocol, helping to determine the extent of the participants comprehension, providing additional and ongoing review of information, and describing treatment schedules, related symptoms and management (McEvoy et al., 1991; McLean, 1996; White-Hershey & Nevidjon, 1990).

The study by Davis (1989) reported that one of the major dilemmas confronting clinical trial nurses participating in the informed consent process was an undefined role for themselves, leading them to experience confusion regarding their functions and ethical obligations. Congruently, a study by Johnson (1986) demonstrated that nurses in this position often experienced conflicts between loyalty to the investigator, their responsibility to the sponsoring companies and their primary responsibility to protect the participant's interests. The problems nurses encountered when participating in the informed consent process were related to situations where consent was not truly informed, and when the nurse perceived a conflict of interest between the importance of the research and the best interest of the participant (Davis, 1989). According to Berry and colleagues (1996), in order to decrease the likelihood of conflicts experienced by the nurse regarding the study or the principal investigators intentions, principal investigators should in the earliest steps of the informed consent process formally involve the clinical trial nurse.

In addition to the above-mentioned conflicts and dilemmas, the situation in which CTN are employed may contribute to the experience of conflicts and dilemmas. In conformity with the regulations set forth in the *Good Clinical Practice: Consolidated Guidelines* (Health Canada, 1997), the investigator, and not the institution, is responsible for hiring qualified personnel required to collaborate in the research study, therefore the nurse working in this setting does not hold a hospital position and is under the authority of the principal investigator

(Deschamps et al., 1995). These circumstances under which CTNs are employed and functioning may foster the potential for financial, employment and professional conflicts. For example, the nurse employed by the principal investigator is subject to his/her authority has the potential of resulting in an employment conflict of interest; the fact that CTNs are dependent on research grants to pay for his/her salary reflects a potential for a financial conflict of interest; and finally, the very dynamic of the principal investigator also being the employer places the nurse in a situation where he/she may potentially have to choose between trying to protect the research participant and being loyal to the principal investigator and/or the research study (professional conflict interest). What further contributes to the potential for financial conflicts of interest is the fact that several sponsoring companies pay the principal investigator per subject recruited from which the salary of the clinical trial nurse comes from in most cases. As a result the CTN who is dependent on this money for his/her salary is placed in a situation where he/she has vested interest in recruiting as many participants as possible. The aforementioned conflicts are defined as follows: (a) financial conflict of interest refers to the potential for personal financial gain from taking part in activities of research; (b) employment conflict of interest which makes reference to potential conflicts that may occur in relation to the position of employment held; and (c) professional conflict of interest which refers to situations in which objectivity would pose a problem due to one's professional role (International Council of Nurses, 1996).

Ethical dilemmas arise when ethical reasons both for and against one or more courses of action are present and choices must be made (Canadian Nurses Association, 1997). As mentioned earlier, previous studies suggest that CTN participating in the informed consent process are experiencing both conflicts and dilemmas. Are clinical trial nurses in Quebec meeting their obligation vis-à-vis the informed consent process? If so, are they experiencing conflicts and what ethical dilemma's, if any, are they experiencing?

As evidenced in this chapter, clinical trial nurses exist, and are actively involved in research involving human subjects. In Quebec, there appears to be no empirical data available regarding this role. It is the aim of this study to explore this area and document the role played by the clinical trial nurse in the informed consent process. In addition, it aims to determine the ethical issues that are experienced by these nurses, if any, in the performance of this expanded role. The key concepts being studied in this project with regard to the ethical issues surrounding the informed consent process are: *conflict of interest* and *ethical dilemma*. For the purpose of this study the concepts are defined as follows:

Conflict of Interest: refers to situations where the clinical trial nurse's expertise, financial compensation, professional affiliation, position, or knowledge in any way compromise his/her objectivity in exercising his/her responsibilities in the informed consent process.

Ethical Dilemma: refers to situations where the clinical trial nurse involved in the informed consent process finds himself/herself in a position where

no easy answer can be made since ethical reasons for and against one or more courses of action are present.

Chapter III

Method

This method chapter includes a description of the design or general strategy for conducting the study, the population from which the sample was selected, the criteria for selection of subjects, the setting and procedure of the study, the method of measuring, collecting data, and the ethical considerations.

Study Design

This study is based on a descriptive design. This choice was made in light of the fact that little data is available regarding the role of the clinical trial nurse in the informed consent process.

Study Population and Target Population

The study population consisted of a sample of registered nurses working in clinical trial settings in Quebec. The target population consisted of all nurses working in clinical trial settings with a physician as principal investigator within four McGill University affiliated Hospitals: the Jewish General Hospital, the Montreal General Hospital, the Royal Victoria Hospital, and St. Mary's Hospital.

Sampling Procedure

The sampling was of the convenience type. Given the fact that there are no registries or records available identifying clinical trial nurse's names or work place, it was necessary to use the networking technique in order to identify potential participants. The Research Ethics Office coordinators network was used, since they are aware of research taking place within the Hospital and are

familiar with the nurses working in clinical trial settings. Key nurses working in the clinical trial setting were identified and introduce to the recruiter and a collaborative alliance was created. Through this network, potential participants were presented to the recruiter, who presented other nurses and so on. Each potential participant was told about the aims of the study, what participation entailed, the possible risks and benefits, his/her right and freedom to choose to participate or not, and how anonymity would be protected. Those who were interested in participating were handed the questionnaire (Appendix I), the accompanying explanatory letter (Appendix II), a self-addressed envelope, and instructed to complete the questionnaire and to return it via the internal mail using the self-addressed envelope supplied for them.

A letter (Appendix III) reminding them to complete and mail the questionnaire was sent four weeks after the initial contact. Included in this package were, the reminder letter, the information sheet and the questionnaire. The letter addressed all potential participants, thanking those who already completed the questionnaire and asking those who had not yet completed the questionnaire to please do so now. Given the anonymous nature of the participants, sending this letter to all potential participants was the only way, therefore the reminder packages were mailed to all those who were originally given a questionnaire to complete. Within the McGill University affiliated Hospitals it was estimated that the accessible population consisted of approximately one hundred nurses. Ninety-five nurses meeting the inclusion

criteria were invited to participate. Sixty completed questionnaires were received via mail (63,2% response rate). From the second mailing, five more questionnaires were received, for a total of sixty-five participants, reflective of a 68,4% response rate.

Inclusion Criteria:

1. Member of the Ordre des Infirmières et Infirmiers du Québec (OIIQ)
2. Able to read and understand English.
3. Part of a clinical trial research team where the principal investigator is a physician
4. Part of a clinical trial research team involving competent adults.

Sample

Table I presents the study populations demographic information. The age of the participants ranged from 25 to 60 years for a mean of 39.5 years with a standard deviation of 7.9. The nurses in this population had an average of 5 years experience in the clinical trial setting, with a standard deviation of 4.6. The highest level of nursing education for the majority of respondents was a Bachelor Degree (44.6%), followed by a Diploma of Collegial Studies (DEC) (35.4%), an undergraduate certificate in Nursing (13.8%) and finally a Masters Degree (6.2%). Of the sixty-five participants, twenty-three (35%) indicated that their highest level of education was in a field other than Nursing, such as for instance,

Community Health (19%), Business Administration/Management (14.2%) and Health Science (14.2%).

Table II shows that the majority of participants (66.2%) indicated having received some education in research ethics; either during their nursing studies (26.2%), on the job training when they were hired (20%) or after completion of their studies and before taking on this position (6.2%). Six participants received training both during their nursing studies and on the job, one participant reported having received training during his/her nursing studies and also prior to taking on the position, while one participant indicated having received training prior to taking on the position as well as on the job training. Only one participant indicated having received training at all three points, during his/her nursing studies, after the completion of their studies and on the job training. In terms of the amount of training during their nursing studies, seven respondents received 45 hours or more, seven others reported having received between 12 to 30 hours and six respondents between 2 to 6 hours. All those who received training before taking on their position but after the completion of their nursing studies did so through a 45 hours undergraduate course. Finally for those who were trained on the job, 40% indicated that their training was between 6 and 24 hours. Noteworthy is the fact that on the job training was given by the nurse he/she was replacing (42.9%), by the principal investigator (28.5%), or by the sponsoring company (28.5%). Fully, 33.8% of nurses in this population working in the clinical trial setting had not received any form of research ethics education when

they began working in this position. Eight participants have since received some research ethics education, but nonetheless, 14 participants (21.5%) are practicing in this field with little if any knowledge in research ethics.

When asked about their job description less than half (41.5%) of the study respondents had one, and of the 27 participants who reported having a job description, only 12 knew who had formulated it. Seven nurses indicated they themselves had written their own job description, while three specified that it was the principal investigator. The sponsoring company and the institution were each named by one participant as writers of their job description. With regard to their current "title", 32.3% "Research Coordinator", 32.3% "Research Nurse" and 30.8% used "Study Coordinator". "Clinical Trial Nurse" (13.8%), "Study Nurse" (6.2%) and "Research Study Coordinator" (4.6%) are titles less frequently used by this population. Of interest is the fact that 15.4% of respondents reported using more than one title interchangeably.

Table I

Distribution of the Clinical Trial Nurse's Demographic Characteristics (N=65)

Characteristics		n	%	$\bar{X}$	Sd
Gender					
	Female	63	96.9		
	Male	2	3.1		
Age				39.5	7.9
	25-34 years	21	32.3		
	35-44 years	30	46.2		
	45-54 years	9	13.8		
	over 55 years	4	6.2		
	not given	1	1.5		
Highest Level of Nursing Education					
	Bachelor	29	44.6		
	DEC	23	35.4		
	Certificate	9	13.8		
	Masters	4	6.2		
Highest Level of Education (non-nursing)		23			
	DEC	7	30.4		
	Bachelor	13	56.5		
	Masters	3	13.0		
Years of Clinical Trials Experience				5	4.6

Table II

Distribution of the Respondent's Education in Research Ethics (N=65)

EDUCATION	n	%
Training in Research Ethics		
YES	43	66.2
NO	22	33.8
During Nursing Studies	17	26.2
On the Job	13	20.0
After Completion of Nursing Studies	4	6.2
More than one of the above	9	13.8

Data Collection

The questionnaire (Appendix I) was developed by the present author and her director based on the available literature (Declaration of Helsinki, 2000; Tri-Council Policy Statement, 1998), as well as on the validated questionnaire (Question 18 & 19) used by Arrigo and colleagues (1994). It was intended to be self-administered and consisting of a 50 item questionnaire of mainly closed-ended questions. The type of questions were most commonly of the Likert type, with the possible response consisting of either 1=never, 2=rarely, 3=sometimes, 4=often, 5=always or a Likert scale ranging from 1 to 4, where 1=strongly disagree, 2=disagree, 3=agree and 4=strongly agree. Also used in the questionnaire were questions of the yes/no type and the select from the

alternatives type. Of note is the fact that a third of the questions were open-ended, where the respondent could specify or explain in writing their answer. This questionnaire required approximately fifteen minutes to complete, as was determined in the pilot study explained below.

The elaborated questionnaire was submitted to three experts within the field for evaluation. This step was incorporated within the design to test the reliability and face validity of the questionnaire. The comments from this panel were incorporated into the protocol and the questionnaire was revised. The revised questionnaire was then administered to a small group of clinical trial nurses for testing. This pilot study was conducted in order to refine the questionnaire, and to determine the length of time needed for its completion. The pilot group consisted of four clinical trial nurses each working at different institutions and ranging in age and years of experience. The data collected from this pilot group indicated that the responses received were congruent with what the questions were trying to ask. In other words the clarity of the questionnaire was tested and certain words and questions were re-worded in order to enhance clarity. A final draft was then developed and distributed to the convenience sample of potential participants; those participating in the pilot group were not part of the final study.

Through the use of the SPSS computer program, the data from the questionnaire were entered into a data sheet by the author. In order to minimize

errors in data entry, limits were set in the SPSS program for each cell. Furthermore, the spreadsheet was then crosschecked with the data from the questionnaires for quality assurance before initiating the analysis.

Variables and Measures

The concepts being studied in this research project include, disclosure of information, comprehension, voluntariness, conflict of interest and ethical dilemma. The conceptual definitions as well as the operational definitions will be presented below for each of the aforementioned study variables. As well, the items used to measure these variables will be noted.

Disclosure of information is defined as the amount of information provided to potential participants about the purpose, possible harms and risks, potential benefits and possible alternatives during the informed consent process in order for that individual (potential participant) to autonomously choose a course of action. This study seeks to determine the role played by the clinical trial nurse in disclosing information to the potential participant during the informed consent process. As such three questions were formulated, question 24, 25 and 30, in order to ascertain information regarding whether or not clinical trial nurses provided information to potential participants, the amount of information they provided, and the extent of their involvement (total, partial, none) during the informed consent process. The first question consisted of a Likert type (1=never, 2=rarely, 3=sometimes, 4=often, 5=always), and the other two questions were of

the select from the responses type, with an option for the responder to fill in their answer if they felt the need. This provided an open-ended aspect to the close-ended questions.

Comprehension is defined as the individual's (potential participant's) understanding of the information provided to him/her during the informed consent process in order to allow that individual the possibility to make an autonomous choice. Three items, questions 26, 27 and 29, were formulated in order to determine whether clinical trial nurses were involved in assessing participant's understanding of the study, the alternatives available, as well as the extent of their involvement (total, partial, none) during the informed consent process. The first question was of the select from the possible responses type, with the possibility of specifying in writing their response, and the other two questions were of the Likert type (scale 1 to 5, same as above).

Voluntariness is defined as the individual's (potential individual's) right to choose and exercise an autonomous choice regarding his/her participation in research. A choice that is free from coercion, manipulation and controlling interference from others. It also entails the freedom to refuse, to accept now and withdraw later without prejudice. In order to explore the clinical trial nurses involvement in assessing the participant's willingness to participate in clinical trials as well as to determine their role in ensuring that the participant is participating voluntarily without undue pressure, three items were formulated,

question 28, 31 and 32. All of which were close-ended questions of the Likert type (scale 1 to 5).

Conflict of interest refers to situations where the clinical trial nurse's expertise, financial compensation, professional affiliation, position or knowledge compromise in any way his/her objectivity in exercising his/her responsibilities in the informed consent process. In order to determine whether clinical trial nurses were being confronted with conflicts during their involvement in the informed consent process, a question of the Likert type, from 1 to 5 where 1=never (2=rarely, 3=sometimes, 4=often) and 5=always was formulated (Question 33). In addition, an open-ended question inviting respondents to explain and describe their experience was used. Furthermore, in order to identify the types of conflicts (financial, employment, professional) three additional questions were posed, consisting of the same Likert scale mentioned above (Questions 42, 43, 44).

Ethical Dilemma refers to situations where the clinical trial nurse involved in the informed consent process finds himself/herself in a position where no ready-made easy answer is available and thoughtful consideration is required since ethical reasons for and against one or more courses of action are present. In order to evaluate whether clinical trial nurses were experiencing ethical dilemmas as well as the cause of the dilemma, 6 items were created, question 34, 35, 36, 37, 38 and 39. Most of these questions (35 to39) aimed to identify the cause of the perceived experience of dilemma and were of the Likert type, with a 1 to 4 scale,

where 1=strongly disagree (2=disagree, 3=agree) and 4=strongly agree. The other item (Question 34) consisted of a Likert scale of 1 to 5, aimed to determine the frequency at which nurses participating in the informed consent process experience dilemmas.

Human Subjects

The Research Ethics Committee at l'Université de Montréal and at McGill University reviewed and approved this project. As well, each Hospital's Research Ethics Committee approved the project as required by their institutional regulations.

Potential participants were informed that their participation was entirely voluntary and that they were free to choose to participate or not. As well, a full disclosure of the aims, risks and benefits were explained to all. Moreover, in order to ensure confidentiality, the study was conducted in an anonymous manner, meaning the questionnaire was and still is unlinkable to the participant. There is no way of knowing the identity of those who completed the questionnaire, hence the participant's identity will remain unknown and untraceable at all times.

Chapter IV

Presentation of Results

This chapter will present the statistical analysis of the results regarding the role of the clinical trial nurse in the informed consent process as well as the ethical implications of this role. The results will be presented in the form of answers to the research questions raised by this project and are of the descriptive type, in the form of frequencies, percentages, means, and standard deviations.

Role of the CTN in the Informed Consent Process

Table III outlines the functions performed by the clinical trial nurse relating to the informed consent process within this study population. All the respondents (100%) indicated that they participated in providing information to the participant, and 98.5% indicated having participated in educating the participant and their family. Almost all (95.4%) specified that answering the participant's questions was their responsibility. Furthermore, a large majority of respondents (96.9%) indicated actually participating in obtaining informed consent. Indeed, the information provided above indicates that nurses are participating in the informed consent process, however what remains unclear is at what point they become involved in the process, the extent of their involvement and what ethical issues, if any, they encountered from this role.

Table III

Distribution of the Functions Undertaken by the Clinical Trial Nurse

FUNCTIONS	n	%
Participating in informing the participant	65	100
Participating in participant/family education	64	98.5
Participating in obtaining informed consent	63	96.9
Responding to participants questions	62	95.4
Conducting follow-up phone calls with participants	62	95.4

Disclosure of Information

The results show that all respondents (n=65) indicated that they in one capacity or another provide information to the research participant. As illustrated in the bar chart below (Figure 1), 56 CTNs reported often taking part in providing information to the potential participant (86.2%), 6 sometimes (9.2%), 2 rarely (3.1%) and 1 always (1.5%).

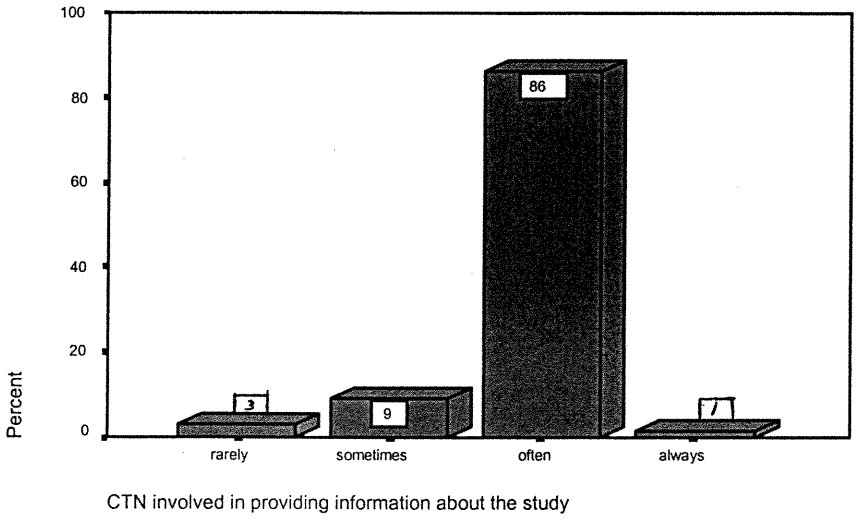

Figure 1 – *Distribution of the Nurses' Involvement in Providing Information to Participants about the Study (N=65):*

Data also indicated that in many cases both the CTN and the principal investigator shared the responsibility of providing information to the research participant. As shown in Table IV, the majority of respondents indicated that the role of explaining the purpose of the study (74.5%), the risks involved (67.3%), the potential benefits (69.1%) and alternatives available (65.5%) was a collaborative one shared by the nurse and the principal investigator.

Table IV

Distribution of Information Disclosed by the CTN, the PI or Both during the Informed Consent Process (N=55)

	Nurse Only		PI Only		Both PI & Nurse	
	n	%	n	%	n	%
Purpose	13	23.6%	1	1.8%	41	74.5%
Risks	15	27.3%	3	5.5%	37	67.3%
Benefits	14	25.5%	3	5.5%	38	69.1%
Alternatives	8	14.5%	11	20.0%	36	65.5%

Comprehension

Figure 2 shows that a little over half (56%) of the respondents indicated that it is both the principal investigator's and the nurse's responsibility to assess the participants' understanding of the study prior to the consent being obtained. Data collected also demonstrated that twenty-two nurses reported this was solely their responsibility (40%). Only one participant indicated that no one assessed the participant's understanding and finally one nurse indicated that this was solely the principal investigator's responsibility. With regard to clarifying the participants' understanding of their options, out of fifty-five respondents, almost all (n=53) indicated that they were involved either always (48.2%), often (30.4%), or sometimes (16.1%).

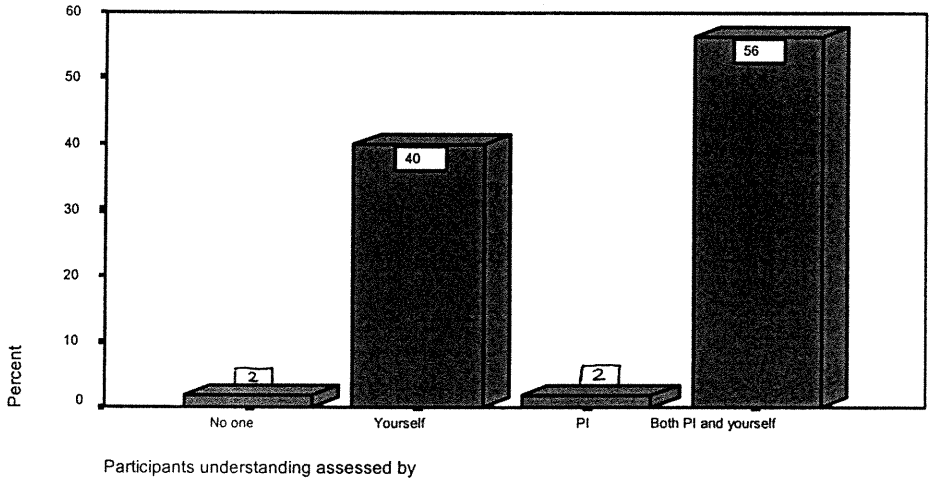

Figure 2 – *Distribution of Whom Assess Participants Understanding of the Study Before the Consent is Signed (N=55)*

Voluntariness:

The majority of CTN (92.3%), as illustrated below (Figure 3), indicated they assess the participant's willingness to participate. From these, 72.3% responded they assessed it always, often (12.3%) or sometimes (7.7%). Only a small percentage of nurses reported having never or rarely assessed whether the participant was truly volunteering without undue pressure. Congruently, almost all the nurses (93.8%) reported verifying the participant's willingness to continue to participate throughout the study, 45 of which indicated doing it always (69.2%), 9 often (13.8%), and 7 sometimes (10.8%). In fact, the study population demonstrated a strong knowledge base relating to this concept (voluntariness). This was evidenced by the fact that all the respondents indicated that the participant had the right to withdraw from the study at any time, even after having signed the consent form.

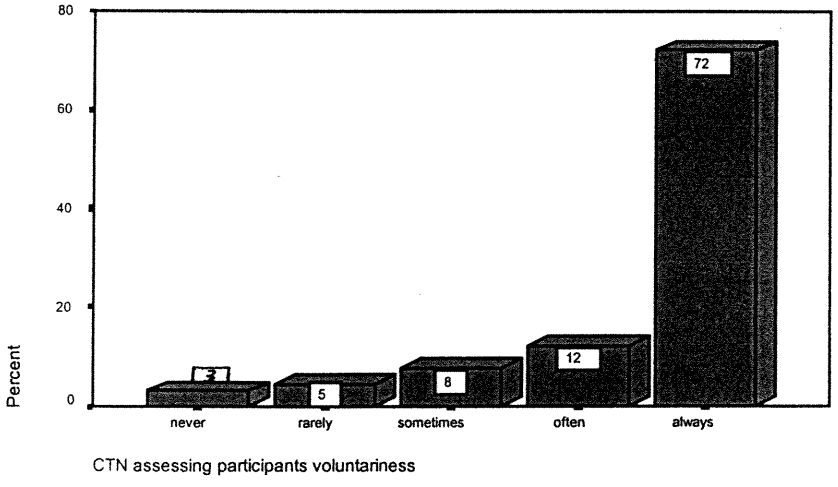

Figure 3 - *Clinical Trial Nurses Assessment of Participant's Voluntariness (N=65)*

Extent of CTNs Involvement in the Informed Consent Process

In order to determine whether CTN's are delegated the responsibility of obtaining consent from the potential participants, the questionnaire was designed to include two sections: (a) questions intended for nurses who participate in the process and obtain the consent, and (b) questions addressing only those nurses who participate in the process but do not obtain consent. Question 28, 29 and 30 were specifically for nurses not responsible for obtaining consent. Thirty-seven nurses responded to these questions suggesting that 56.9% of nurses are not responsible for obtaining consent. However, this assumption would be inaccurate since 28 of the 37 nurses completed both sections, the one that was to be completed by those responsible for obtaining consent as well as the one reserved for those not responsible for obtaining it. Therefore, we can only be certain that 9 of the respondents (13.8%) are not responsible for obtaining consent but do participate in the process.

At What Point do Nurses Become Involved in the Informed Consent Process?

As presented in Table V, a large percentage (75%) of nurses are involved before, during and after the informed consent is obtained. Eight nurses reported being involved only before consent is obtained, 3 only after, and 4 only before and during. These findings suggest that 23% of the population do not perceive the informed consent as a "process" but rather as a "moment in time". With regard to nurse's perception of informed consent, as noted in Figure 4, a large

majority (97%) indicated that they do not perceive the consent as simply the formality of a signature.

Table V

Distribution of When Clinical Trial Nurses Became Involved in the Informed Consent Process (N=64)

TIME OF INVOLVEMENT	n	%
Before, During & After	48	75.0
Only before consent is obtained	8	12.5
Only Before & During	4	6.3
Only after the consent is obtained	3	4.7
Only During & After	1	1.5
Only during the time consent is being obtained	0	0

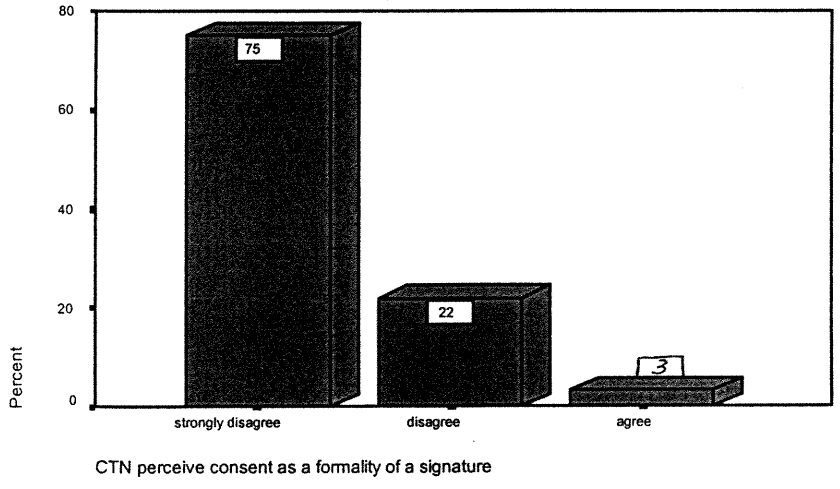

Figure 4 - *CTN's Perception of the Informed Consent as a Formality of a Signature (N=65)*

Ethical Issues that Arise from this Role

What are the ethical issues that arise from the nurse's role in the informed consent process? This question is answered by referring to key variables identified and defined in this study: conflicts of interest and ethical dilemmas.

Conflicts of Interest

As noted in Figure 5, 37 nurses (56.9%) reported having experienced conflicts between their obligation to the participant and their obligation to the research while 28 (43%) reported having never experienced this. Of those who did experience conflicts (37 nurses), the frequency at which they occurred were rarely (29.2%), sometimes (26.2%) or often (1.5%). With regard to the types of conflicts experienced by the 37 nurses, only 21 (56.8%) went on to describe them.

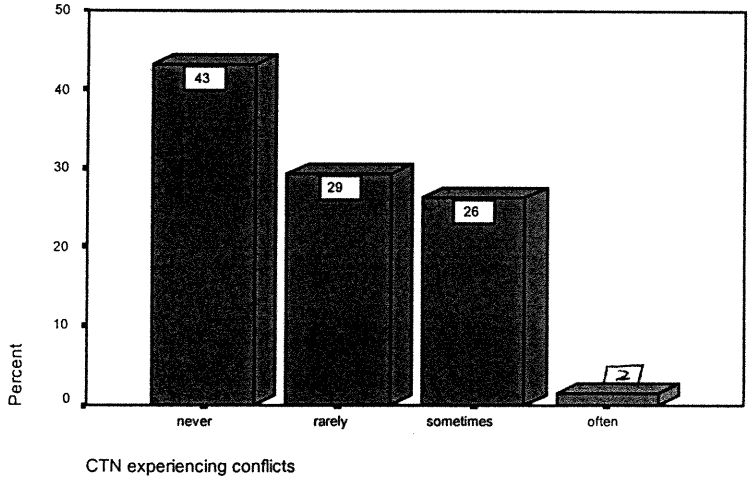

Figure 5 - *Distribution of the Experience of Conflicts by the CTN in the Informed Consent Process*

The nurses were asked to describe in writing their "lived experience" with regard to the experience of conflicts during their participation in the informed consent process. The method of Van Kaam (1966) was used for analysis of this phenomenological data (Beck, 1994). The data were classified and ranked according to the frequency of occurrence. The most frequently experienced conflict, as described by ten nurses, occurred when the participant did not fully understand the implications of the study or lacked knowledge regarding the purpose of the research. The second most commonly experienced conflict, as explained by four nurses, occurred when the alternatives available were not offered to the participant. This placed them in what they perceived as a conflict of interest. One noted that the alternatives were not offered to participants, because the sponsor of the study was also paying for the nurse's, therefore they enrolled the patient even though better treatment was available (financial and professional conflict of interest). A minority of nurses (n=2) described experiencing conflicts when they were asked to approach potential participants at a time they felt was inappropriate for recruitment due to the vulnerability and serious illness of the patient. As well, two nurses admitted that they felt conflicts and feelings of guilt when the participants were not benefiting from the study and yet were not withdrawn from the study (professional conflict of interest). Other situations, as described by a few nurses, that provoked conflict were when the participant refused to read the consent form and simply signed the form because they trusted the doctor, when the participants were not aware of the voluntary nature of the study and finally, when the participant did not meet the inclusion criteria but the

principal investigator insisted on enrolling the participant into the study (employment conflict of interest).

Professional conflicts of interests seem to be the most frequently experienced types of conflicts, since 38 nurses indicated having experienced a situation where the subject did not appear to understand the implications of their participation but yet had signed the consent form; with 30.8% reporting rarely, 24.6% sometimes and 3.1% often. Of note is the fact that from the possible choices in the Likert type scale (1 to 5) "always" was never selected by this study population in the conflicts of interest section of the questionnaire.

Ethical Dilemma

Approximately two-thirds of respondents (42 nurses) reported having experienced some level of ethical dilemma from their role in the informed consent process; 33.8% rarely, 26.2% sometimes, 1.5% often and 3.1% always (Table VI). The most common causes of ethical dilemmas as identified by the respondents were either due to the lack of clear policies and guidelines regarding this role (27%), or due to the fact that their employer was also the principal investigator of the research (23.8%), or due to the lack of a job description (22.3%). Lack of information and lack of education were the least common causes for ethical dilemmas faced by the clinical trial nurse when participating in the informed consent process. Respondents indicated that they always (92.3%) or often (6.2%) had access to the research protocol. In fact, 95.4% of respondents reported

reading the protocol. Also, the majority of respondents (67.7%) always had their questions regarding the protocol answered by the principal investigator, either often (18.5%) or sometimes (11.7%). Only one nurse reported never receiving answers from the principal investigator. Of note is the fact that 98.5 % of respondents indicated that if they had not had access to the research protocol, this would have hamper their ability to carry out their responsibilities.

With regard to lack of education, it did not appear to pose dilemmas for most of the respondents since 35.4% rated their knowledge of the informed consent process as excellent, 38.5% very good, 21.7% as good and only 4.6% as poor. Nevertheless, half of the study population (50.8%) reported the need for more education in this process. Specifically, 30.8% wanting education on the legal implications and obligations of the clinical trial nurse involved in obtaining consent as well as the liability issues regarding this role. The other 20% wanting more education on the actual informed consent process.

A Posteriori Analysis

During the analysis phase of this study, it became evident that two groups naturally formed within this study population: those experiencing conflicts and ethical dilemmas while participating in the informed consent process and those who did not. Although it is not the purpose of this study to determine the relationship between variables, it seemed interesting and useful to look more closely at these two groups. This section will therefore examine the relationship

between the two key concepts: conflicts of interest, ethical dilemmas and other variables, such as age, work experience, job description, and amount of training in research ethics.

As noted in Table VI, 37 nurses (56.9%) reported having experienced conflicts during their participation in the informed consent process while 28 (43.1%) indicated having never experienced them. Similarly, with regard to the experience of ethical dilemma, 42 (64.6%) reported having experienced ethical dilemmas during the informed consent process while 23 (35.4%) indicated having never experienced them.

Prior to testing for association between the key concepts (conflict of interest, ethical dilemma) and the variables mentioned above, the items were added resulting in a single global score for each of the key concepts. This allowed an increase in the power and for more discrimination of the study population. The regrouping was deemed necessary since the answers provided by the respondents for these specific variables were poorly dispersed.

The creation of new variables was possible since the variables were oriented in the same way and since they generated good alpha coefficients. Tests of Cronbach Alpha were performed to ensure that the variables were consistent: conflict of interest (Q33, Q42, Q43, Q44): N=58; alpha 0.74 and ethical dilemma

(Q34, Q35, Q36, Q37, Q38, Q39) N=57; alpha 0.85. The results supported the regrouping of the variables, below (Table VII) are the global scores.

Table VI

Distribution of Clinical Trial Nurses Experiencing Conflicts and Ethical Dilemmas (N=65)

EXPERIENCED		n	%
Conflicts of Interest			
NO		28	43.1
YES		37	56.9
	Rarely	19	29.2
	Sometimes	17	26.2
	Often	1	1.5
Ethical Dilemmas			
NO		23	35.4
YES		42	64.6
	Rarely	22	33.8
	Sometimes	17	26.2
	Often	1	1.5
	Always	2	3.1

Table VII

Global Score of the Study Variables, Conflict of Interest and Ethical Dilemma:

Global Score	N	Min	Max	Mean	Sd
Conflict of Interest	63	4,00 (4,00-20,00)	13,00 (4,00-20,00)	7,1	2,6
Ethical Dilemma	62	6,00 (6,00-25,00)	20,00 (6,00-25,00)	10,9	3,7

In order to determine whether a relationship exists between the key concepts (conflict of interest, ethical dilemma) and age, as well as years of experience, Pearson's correlation tests were used since both these variables are continuous. As shown below (Table VIII), the longer the nurses were involved in clinical trials the more they experienced conflicts (r=0.32, $p<0.05$). There was no significant relationship for the age variable ($p<0.05$). With regard to job description, a t-Test was used to compare the mean score of two groups, those with a job description and those without a job description, in order to determine whether having a job description or not had an influence on the experience of conflicts and ethical dilemmas. As illustrated in Table IX, there was no significant difference ($p>0.05$) between those with a job description and those

without one. This result suggests that this variable has no significant relation with the experience of conflicts and ethical dilemmas. Finally, with regard to the amount of training received in research ethics, in order to determine whether a relationship exists between the key concepts and the amount of research ethics training, Pearson's correlation tests were performed since the hours of training is a continuous variable. As evidenced above (Table VIII), the amount of hours of training received by the nurse in research ethics was significantly related to the experience of conflicts ($p<0.05$) but not to the experience of ethical dilemmas ($p>0.05$).

Table VIII

Pearson's Correlation Between Key Concepts (Conflict & Dilemma) and Age, Years of Experience and Research Ethics Training

	Conflict	Dilemma
AGE	0,16	-0,08
YEARS OF EXPERIENCE Mean= 5.1 Sd=4.7	0,32*	-0,21
HOURS OF TRAINING IN RESEARCH ETHICS	0,262*	0,177

* Correlation is significant at the 0,05 level (2-tailed)

Table IX

Mean Score of Two Groups, Those with a Job Description and Those Without

		CONFLICT		p		DILEMMA		p
Job Description	n	Mean	Sd	0.278	n	Mean	Sd	0.320
YES	26	7,5	2,5		27	11,4	3,8	
NO	37	6,8	2,6		35	10,4	3,7	

Chapter V

Interpretation and Discussion of Results

The goals of this study were to explore and describe the role of the clinical trial nurse in the informed consent process as well as the ethical implications that may accompany this role. The results regarding the two research questions will be discussed in this chapter as well as the similarities and differences between these results and those reported in the literature. Finally, the study's methodological limits will be underlined, and recommendations will be made.

Role of the Clinical Trial Nurse in the Informed Consent Process

The results of this study demonstrate that a large majority of clinical trial nurses are participating in the informed consent process of research participants (autonomous persons) either partially or totally. The framework guiding this study, the principle of "*respect for autonomy*", tells us that in order to respect an autonomous person, one must allow that person the right to hold views, the right to make a choice and the right to take actions based on personal values and beliefs (Beauchamp & Childress, 2001). Therefore, respect for autonomy obliges professionals, such as the CTN, to communicate information, assess and ensure understanding, assess and ensure the willingness of the participation and provide adequate time for decision-making. According to this study's findings, it would appear that clinical trial nurses are meeting their professional obligations of disclosure of information, comprehension and voluntariness and this regardless of whether obtaining consent is their responsibility or not.

Disclosure of Information

Similar to what was reported by other authors (Berry et al., 1996; Cisar & Bell, 1995; Sadler et al., 1999), the results indicate that the disclosure of information about the purpose of the study, the risks involved, the potential benefits and the alternatives available, is the shared responsibility of the principal investigator and the clinical trial nurse. With regard to providing information regarding possible alternatives, this responsibility was the least delegated to the nurse and commonly a shared responsibility or that of the principal investigator. Of note is the fact that one third of nurses from this study population are totally delegated the responsibility of providing information to the patient regarding the purpose of the study as well as the risks and potential benefits. These findings are consistent with Barnes and colleagues (1998) that noted in certain circumstances nurses themselves are solely responsible for obtaining consent. These results are also congruent with other authors (Arrigo et al., 1994; Berry et al., 1996; Cassidy & Macfarlane, 1991; Davis, 1989; Davis, 1988; Deschamps et al., 1995; Johnson, 1986; Lynch, 1988; McEvoy et al., 1991; McLean, 1996; Sadler et al., 1999; Wager et al., 1995; White-Hershey & Nevidjon, 1990) who suggested that it was common practice for the principal investigator to delegate these responsibilities partially or totally to the clinical trial nurse.

The results demonstrate that CTNs are indeed involved in the informed consent process and are taking on significant responsibilities with little or no educational preparation. Nevertheless, in compliance with the regulatory

guidelines (Civil Code of Quebec, 1991; Declaration of Helsinki, 2000; Tri-Council Policy Statement, 1998), and the literature (Belmont Report, 1982; Grady, 1991; Haddad, 1996; Speck, 1996; Tranter, 1997), all nurses in this study population reported participating in providing essential information required in order for a potential participant to make an informed choice. This demonstrates that CTN are participating in the autonomous choice process in giving the participant the opportunity to provide free and informed consent. With regard to the role played by the CTN in the informed consent process, and in accordance with Davis (1988), one of the roles played by the CTN is that of a "*resource person*". This role as defined by Davis (1988) involves collecting, dispensing and reporting information, guiding participants regarding their informational needs, and clarifying features of the consent that were not understood or overlooked. As reported earlier, it appears that the results of this study support the above and demonstrate that nurses are playing the role of *resource person* in the informed consent process. The definition provided for resource persons amalgamates the role of the nurse in disclosure of information and that of ensuring comprehension suggesting that providing information and ensuring comprehension go hand in hand.

Comprehension

The findings suggest that a collaboration exists between the principal investigator and the clinical trial nurse with respect to assessing the participants understanding of the study prior to obtaining consent. Nevertheless, two thirds of

the CTNs were totally delegated this responsibility. This suggests twice the number of nurses are solely responsible to assess comprehension of the information compared to the actual disclosure of information. This demonstrates that assessing participant's understanding is a responsibility that is more commonly delegated to the clinical trial nurse than is disclosure of information. These findings are in agreement with the paradigm that asserts that informed consent is the principal investigators responsibility, but the nurse has an *ethical duty* and/or *moral responsibility* to ensure the participant's understanding of the consent process (Barnes et al., 1998; Berry et al., 1996; Canadian Nurses Association, 1991; Cassidy & Macfarlane, 1991; Davis, 1989; Hubbard, 1982; Johnson, 1986; Keatings & Smith, 1995; Lynch, 1988; McLean, 1996; Sadler et al., 1999; Wager et al., 1995).

Voluntariness

Assessing the participant's willingness to participate and ensuring that their participation is truly voluntary is a role that appears to be totally delegated to the CTN. In fact almost all nurses (92.3%) in this study indicated that this was their responsibility. As described in the Nuremberg Code (1947), the Declaration of Helsinki (2000), the Tri-Council Policy Statement (1998, Article 2.4), and the Civil Code of Quebec (1991), in order for consent to participate in research to be valid, it must be voluntary. Nurses in this study population are ensuring that these regulations are being followed. Therefore, in addition to the role of "resource person", the CTN plays an important role of ensuring that the participant's rights

are not violated. In Davis' (1988) terms, this would be the role of "watchdog" and "advocate" played by the clinical trial nurse in the informed consent process. Davis defines "watchdog" as the role of monitoring the informed consent process and "advocate" as a role enacted by the nurse in order to mediate on behalf of the participant. With regard to the role of the nurse as "watchdog", Davis puts the emphasis on the role of the nurse as a witness, whereas, in this study as evidenced by the results, the CTN role of "watchdog" takes on a more global and active meaning, encompassing the CTNs role in ensuring that the participants rights are respected, by making sure the participant has received a full disclosure, has comprehended the information and is freely making a choice. This role is tied into the "advocate" role since the nurse plays a role of ensuring the participant's rights. As evidenced in this study and reported elsewhere (Beauchamp & Childress, 2001; Belmont Report, 1982; Deluca et al., 1995; Haddad, 1996; Harth & Thong, 1995; Lynch, 1988; Tranter, 1997; Veatch & Fry, 1987; Watts, 1997) the CTNs role includes ensuring that the participant's right to refuse to participate and/or freedom to withdraw at anytime without prejudice are respected.

This investigation added to the knowledge base by providing information as to when the clinical trial nurse becomes involved in the informed consent process. The "when" was unclear in the literature (Arrigo et al., 1994; Barnes et al., 1998; Sadler et al., 1999), the findings demonstrate that a large majority (75%) of this population were involved before, during and after the informed consent was obtained. It would therefore appear that nurses are involved from the

beginning and throughout the participation. Interestingly, these results differ from those reported by Davis (1988) insomuch as nurses in this study reported participating before, during and after the consent was obtained instead of only after the consent was obtained as was the case in Davis's study population. The results suggest that approximately 20% of the study population do not perceive the informed consent as a "process" since their involvement ceases the moment the consent is given. We can conclude that in accordance with the literature (Beauchamp & Childress, 2001; Davis, 1989; Deluca et al., 1995), and the regulations (Tri-Council Policy Statement, 1998), the majority (75%) of clinical trial nurses in this population perceive the informed consent as a process that lasts throughout the study.

Ethical Issues Accompanying this Role

With regard to the experience of conflicts and ethical dilemmas, this study population seems to experience them less than previously reported in the literature (Davis, 1989; Johnson, 1986). However what may be interesting to note is that the types of conflicts and dilemmas are very much the same.

Conflict of Interest

Contrary to what was reported by Davis (1988) and Johnson (1986), nurses in this study population did not often experience conflicts when participating in the informed consent process, and in fact experienced them rarely or sometimes. These findings may be related to the fact that these nurses became

involved in the process at an earlier stage in comparison to the previously reported studies, which according to Berry and his colleagues (1996) results in a decline in the perception of conflicts. Interestingly, although the frequency of the experience of conflicts differs, the type of perceived experienced conflicts are consistent with those experienced by the nurses in Davis' (1988) study. Conflicts occurred mainly in situations where consent was not truly informed due to lack of knowledge regarding the purpose or the implications of the research, and when the CTN perceived a conflict of interest between the importance of the research and the best interest of the participant. Other respondents described conflicts related to the financial, organizational and professional structure. For instance, nurses experienced financial conflicts of interests in situations where alternatives were not offered to participants because the sponsor of the research was also the provider of nursing support. Other conflicts issued from situations where the principal investigator asked the CTN to approach a potential participant they felt was inappropriate or even more serious, asked to enroll a participant that did not meet the inclusion criteria; these are obviously employment and professional conflicts of interest due to the structural organization that places the nurse in the employment and under the direct authority of the principal investigator. Johnson's (1986) study demonstrates that nurses in this position experience conflicts between loyalty to the investigator, their responsibility to the sponsoring companies and their primary responsibility to protect the participant's interest. These findings are consistent with the results of this study, suggesting that the role of "advocate" (protecting the participants needs and rights) has a direct impact on

the experience of conflicts and dilemmas. Nurses in this role have an unclear definition of their role and boundaries resulting in situations where nurses find themselves acting as the participants advocate by default and in doing so are finding themselves experiencing conflicts (Davis, 1989).

Ethical Dilemma

As described elsewhere (Davis, 1989: Davis 1988; Johnson, 1986), the three most common causes of ethical dilemma for CTNs participating in the informed consent process are: (a) the lack of clear policies and guidelines defining their role, (b) the lack of a job description, and (c) the fact that their employer is also the principal investigator of the study. Obviously, the lack of standard practical and ethical guidelines governing the practice of clinical trial nurses is at the heart of the experience of ethical dilemmas and is what has further exacerbated the uncertainty in this role (Deschamps et al., 1995; Johnson, 1986). As a result CTN are finding themselves questioning what their duties and moral obligations are, as well as what their responsibilities entail (Davis, 1989: Davis, 1988; Johnson, 1986). Interestingly, the results indicate that lack of education is not a cause of clinical trial nurses dilemmas. However, the findings with regard to education are at odds within this very population. At the beginning of the questionnaire the results indicated that few received research ethics education or training for their position however, when asked to rate their knowledge of the informed consent process most indicated that it was excellent or good. Nevertheless, when asked whether they felt they needed education regarding the

informed consent process most indicated that they did. Obviously, these results are difficult to interpret since they are inconsistent.

A Posteriori Analysis

The years of experience of the clinical trial nurse has a significant relationship, at a 5% level, with the perceived experience of conflict of interest. This is logical, for those with more experience have been in this setting longer and therefore have had more opportunity of experiencing conflicts than those who have been in the setting for less time. Conversely, it is also possible that those who have been in the setting longer are more knowledgeable and therefore are more aware of the potential conflicts and as a result perceive and report these experiences.

Interestingly, Johnson (1986) suggests that the lack of educational preparation contributes to the experience of moral and ethical conflicts. The author postulates that this lack of education may be the very reason for which there is a low prevalence of nurses experiencing conflict within this population. If you have little or no education in research ethics, as has been determined in this study population, then how does one recognize a dilemma and a conflict if one does not know what either of them entails? In order to determine whether this hypothesis is correct, the association between hours of training in research ethics and the experience of conflicts and or dilemmas was tested. The statistical analysis demonstrates that those with more hours of education had an increased

tendency to report conflicts. Therefore, these findings support the proposed hypothesis, education in research ethics has a significant relation to perceived conflicts of interest since the individual has been sensitized to the potential conflicts and dilemmas and therefore is aware of them when they occur and is therefore potentially better equipped to deal with them.

Methodological Limits

The non-random sample (N=65) consisting only of McGill affiliated nurses will affect the validity of the study and limits the generalizability of the results. This limit is related to lack of both financial and human resources. It would have been ideal to recruit all nurses working in the Province of Quebec; this would have provided a more accurate picture. This was not feasible due to the lack of both financial and human resources.

Based on the results of this study, it is obvious that certain areas could now be examined more specifically in order to determine more about the role of the nurse in the informed consent process. For instance, more specific questions regarding the actual role of the nurse in collaboration described by this sample regarding disclosure of information and comprehension could be examined. As well, how the nurse assesses the participant's comprehension, or how voluntariness is assessed and ensured could be determined. However, this was not explored in this study since the level of participation and involvement of the CTN in this process was still unclear.

With regard to the reliability and validity of the questionnaire, this could only be determined through the use of the questionnaire in future similar studies where the consistency in time could be tested.

Finally, another limit of the study results from the fact that the research is limited to include nurses involved in research involving competent adult participants only. This limit decreased the number of potential nurses participating in this study. It is important to note that nurses in this setting are involved in research involving incompetent or minor participants, however, they are small in number in my experience as the coordinator of a research ethics office. This limit could not have been avoided for the principle of respect for autonomy described by Beauchamp and Childress (2001), the framework guiding this study, is based on this limit.

Nursing Implication

This study identifies the role of the clinical trial nurse in the informed consent process. Accordingly, this study has several practical implications for nurses working in this setting. It allows nurses in this field to understand the important and critical role of the nurse as well as the professional obligation involved in taking part in the informed consent process. In addition, nurses will be able to address perceived conflicts and ethical dilemma that may accompany this role and potentially may explore these concerns.

In addition, this research may contribute to nurses' awareness of the importance and necessity of well defined roles and proper educational preparation. This may promote nurses demands for proper training in order to take on this position. This study also underlines the central role played by the nurse in the informed consent process and underlines the fact that nurses are often the first and sometimes the only contact for participants of clinical trials. This means that nurses have both an ethical and moral duty to ensure that the participants are informed, comprehend the information and are aware of the voluntary nature of their participation.

Finally, this research provides baseline data about the role of the clinical trial nurse in the informed consent process here in Quebec as little empirical data is available about this role.

Recommendations

Recommendations for Research:

Future studies examining the collaborative relationship between the clinical trial nurse and the principal investigator in the informed consent process are needed. The extent of the nurse's involvement in this collaboration remains unclear. Does the principal investigator discuss the standard therapies versus entering the study and leaves the details up to the clinical trial nurse? Do the principal investigator and the clinical trial nurse present the study to the

participant together, or does the nurse complement the process by answering the questions and then obtains consent?

Regarding comprehension and voluntariness, future studies are needed to determine how comprehension and voluntariness are assessed by the nurse. This information was not attained by this study since it was not the aim of it. Nevertheless the results demonstrate that nurses are delegated this responsibility, information about how nurses are fulfilling this responsibility is now warranted. Now that the concepts have been identified, a qualitative methodology involving interviews would provide clarifications about this role.

Additional studies regarding the ethical implications, such as how the lack of clear policies and guidelines, as well as the lack of a clear job description influences the experience of conflicts and dilemmas, and how nurses deal with these dilemmas. The dilemmas that result from the experience of conflicts also need to be studies, for example the fact that the principal investigator is also the CTN's employer resulted in nurses experiencing financial, professional and employment conflicts of interest and also resulted in nurses experiencing ethical dilemmas. An explorative qualitative approach would provide information regarding these ethical implications and would provide insight on how these issues are handled which potentially would trigger the development of an ethical framework specific for nurses in this role.

Recommendations for Education:

The role of the clinical trial nurse as well as the ethical implications of such a role must be part of the nursing program curriculum. Given that almost half of the study population's level of nursing education was a Bachelors, it would seem most appropriate for the curriculum to include research ethics courses. Nurses must be sensitized to the importance of such a role and its legal and ethical implication. Also of importance is the development of a standardized minimal training program that would be mandatory for all nurses wanting to work in such a setting. The MSSS together with the FRSQ should elaborate this training program in collaboration with the OIIQ. Leaving it up to the sponsoring companies and the principal investigator is not appropriate because of the potential conflicts that have been underlined in this study, secondly because the fundamental philosophy of nursing must be at the foundation of this training program necessitating nurses input, not other disciplines. Allowing other disciples to define a nursing role is unacceptable.

Recommendations for Practice:

One of the ways to eliminate or decrease the incidence of perceived ethical dilemmas and conflicts of interest is to define the role of the clinical trial nurse through the elaboration of norms, standards and ethical guidelines. The nurse would be better positioned to advocate for his/her clients in a systematic and logical manner through the use of a standardized framework guiding the nurse in dealing with the conflicts and dilemmas they are experiencing.

Nurses are taking on this role and are fulfilling their duties as described in the existing ethical and practical guidelines. However, these guidelines do not address the specific needs of this group of nurses and specific guidelines would provide a much needed framework. The OIIQ must work towards providing these guidelines for their members.

Additional Recommendations:

Clinical trial nurses must take a greater role in advocating for and being involved in the development of both practical and ethical guidelines regarding their role in research teams. Also, they must demand training when they take up this role for there are many ethical and legal implications accompanying this role.

Conclusion

The purpose of this study consisted of examining and documenting the role played by the clinical trial nurse in the informed consent process as well as exploring the ethical implications that accompany this role. The results of this study provide very much needed empirical data regarding the role of the clinical trial nurse in the informed consent process, since very little empirical data was available in the literature. Guiding this study, the principle of *respect for autonomy* as defined by Beauchamp and Childress (2001) was used, with additional support from the professional and ethical codes governing the nursing practice (Canadian Nurse Association, 1997; International Council of Nurses, 1996). Accordingly, two research questions were formulated in order to help attain the purpose of the study.

Analyses conducted during this research disclosed that a large majority of CTNs in this study population are participating and playing an important and significant role in the informed consent process. This role includes being the "resource person", the "watchdog" and the "advocate". As the "resources person" CTNs are disclosing information, assessing participant's understanding and providing information as required. As the "watchdog", CTNs are ensuring that force, coercion and manipulative tactics are not used in the obtaining of consent. As evidenced by the results of this study, it is common practice for these functions to be carried out in collaboration with the principal investigator. Nonetheless, one-third of the study population were delegated the responsibility

of disclosing information, two-thirds the responsibility of assessing participant's comprehension and almost all indicated that voluntariness was their responsibility. Given the above we can conclude that CTN's have taken a central position in ensuring that the participants' rights are respected, by making sure that they have received a full disclosure, have comprehended the information and are participating freely.

Indeed nurses have a critical role to play, but little if any have received educational preparation for this role. One third of this study population had no training in research ethics when they took on this position, in fact, 14 nurses in this study sample have yet to receive any training in research ethics. Of those who did receive training, it commonly was given by the principal investigator or the sponsoring company, which underlines the fact that other disciplines are defining this critical and vital role.

Fully, the results indicate and point to the need for the formulation of standard ethical and practical guidelines defining and guiding the clinical trial nurses role in the informed consent process. Especially since this void is what is enforcing situations where these nurses are experiencing ethical dilemmas and conflicts. The conflicts were most commonly due to the structural organization involving the principal investigator as the employer of the CTN. With regard to ethical dilemmas, the causes were most commonly due to the lack of policies, guidelines, and a clear job description.

Empirical data collected here confirms what has been reported in the literature, clinical trial nurses do play an important and critical role in the informed consent process and are experiencing conflicts and dilemmas. The time is here for the profession of nursing (OIIQ) to formulate clear ethical and practical guidelines governing the role of the clinical trial nurse in the informed consent process, leaving it to the discretion of other disciples is unacceptable.

Furthermore, the need for standardization of educational preparation or training for nurses working in this setting has also been underlined by the result of this study. The Deschamps Report (1995) recommended that the OIIQ work towards the development of an educational program since nurses in this setting were poorly prepared. Seven years have gone by since that recommendation, yet as evidence by this study population not much has changed with regard to education and training for the clinical trials nursing role.

The results of the study make evident that this area of nursing is a highly specialized one, yet, there are no standards regarding the training that should be received by nurses taking on this role, no norms or ethical guidelines, nor is this role recognized as a specialty. It has been argued that clinical trial nurses are not participating in research that will contribute to the advancement of nursing knowledge, and perhaps is the reason that this role is undefined and not recognized by the profession. However, nurses in this setting are playing a

critical role in advocating for research participants, in teaching and educating the participant and the family, as well as providing holistic care for those participating in research. Although this may not be contributing to the advancement of nursing knowledge this role is contributing to the well being of participants. Nurses receive training in the principles of communication and interpersonal relationships and are in a central position for the ongoing process of informed consent since they are the professionals with more frequent contact with the participant. As a result, this role has developed and grown over the years. Clinical trial nurses not only exist, but play a critical role in this research team. Nurses have pioneered and made a place for themselves within research teams, the nursing profession must know recognize this fact and provide these nurses with boundaries and direction as a well as education in order to protect the public and nurses themselves.

Reference List

Annas, G.J. & Grodin, M.A. (1992). The Nazi doctors and the Nuremberg Code: Human rights in human experimentation. New York : Oxford University Press.

Appelbaum, P.S., Lidz, C.W., & Meisel, A. (1987). Informed consent: legal theory and clinical practice. New York : Oxford University Press.

Arrigo, C., Gall, H., Delogne, A., & Molin, C. (1994). The involvement of nurses in clinical trials : Results of the EORTC oncology nurses study group survey. Cancer Nursing, 17 (5), 429-433.

Barnes, D.M., Davis, A.J., Moran, T., Portillo, C.J., & Koenig, B.A. (1998). Informed consent in a multicultural cancer patient population: Implications for nursing practice. Nursing Ethics, 5 (5), 412-423.

Baudouin, J.L. (1981). L'expérimentation sur les humains: un conflit de valeurs. McGill Law Journal, 26, 809-846.

Baudouin, J.L., & Parizeau, M.H. (1987). Réflection juridiques et éthique sur le consentement au traitement médical. Médecine/Sciences, 3, 8-12.

Beauchamp, T.L., & Childress, J.F. (2001). Principles of biomedical ethics (5th ed). Oxford (New York) : Oxford University Press.

Beauchamp, T.L., & Childress, J.F. (1994). Principles of biomedical ethics (4th ed). Oxford (New York) : Oxford University Press.

Beauchamp, D.E., & Steinbock, B. (1999). New ethics for the public's health. New York : Oxford University Press.

Beck, C. T. (1994). Reliability and validity issues in phenomenology. Western Journal of Nursing Research, 16 (3), 254-267.

Beecher, H.K. (1970). Research and the individual human studies. Boston : Little, Brown and Company.

Berry, D.L., Dodd, M.J., Hinds, P.S., & Ferrell, B.R. (1996). Informed consent: Process and clinical issues. Oncology Nursing Forum, 23 (3), 507-512.

Brewin, T.B. (1982). Consent to randomized treatment. Lancet, 2 (8304) 919-921.

Canadian Nurses Association. (1983). Ethical guidelines for nursing research involving human subjects. Ottawa, Canada: Author.

Canadian Nurses Association. (1997). Code of ethics for registered nurses. Ottawa, Canada: Author.

Cassidy, J., & Macfarlane, D.K. (1991). The role of the nurse in clinical cancer research. Cancer Nursing, 14 (3), 124-131.

Cassileth, B.R., Zupkis, R.V., Sutton-Smith, K., & March, V. (1980). Informed consent: Why are its goals imperfectly realized? New England Journal of Medicine, 302, 896-901.

Chell, B. (1998). Competency: What it is, what it isn't, and why it matters. In J.F. Monagle & D.C. Thomasma (eds.), Health care ethics-critical issues for the 21st century (p. 117-127). Gaithersburg, Maryland : Aspen Publishers, Inc.

Cisar, N.S., & Bell, S.K. (1995). Informed consent: An ethical dilemma. Nursing Forum, 30 (3), 20-28.

Davis, A.J. (1988). The clinical nurse's role in informed consent. Journal of Professional Nursing, 4 (2), 88-91.

Davis, A.J. (1989). Informed consent process in research protocols: Dilemmas for clinical nurses. Western Journal of Nursing Research, 11 (4), 448-457.

Davis, A.J., & Underwood, P.R. (1989). The competency quagmire: Clarification of the nursing perspective concerning the issues of competence and informed consent. International Journal of Nursing Studies, 26 (3), 271-279.

Deschamps, P., Vinay, P., & Cruess, S. (1995). Rapport sur l'évaluation des mécanismes de contrôle en matière de recherche clinique au Québec : Ministère de la Santé et des Services sociaux du Québec, Canada.

Deluca, S.A., Korcuska, L.A., Oberstar, B.H., Rosenthal, M.L., Welsh, P.A., & Topol, E.J. (1995). Are we promoting true informed consent in cardiovascular clinical trials? Journal of Cardiovascular Nursing, 9 (3), 54-61.

Faden, R., & Beauchamp, T.L. (1986). A history and theory of informed consent. New York: Oxford University Press.

Giertz, G. (1980). Ethics of randomized clinical trials. Journal of Medical Ethics, 6, 55-57.

Gouvernement du Québec. (1994). Nurses Act, R.S.Q., c. I-8. Québec, Canada : Éditeur officiel du Québec.

Gouvernement du Québec. (1993). Professional code of Quebec, C-26. Québec, Canada: Publications du Québec.

Gouvernement du Québec. (1993). Code of ethics of nurses, I-8,r.4. Québec, Canada: Éditeur officiel du Québec.

Gouvernement du Québec. (1991). Code civil du Québec, c.64. Québec, Canada: Auteur.

Grady, C. (1991). Ethical issues in clinical trials. Seminars in Oncology Nursing, 7 (4), 288-296.

Gross, J. (1986). Clinical research in cancer chemotherapy. Oncology Nursing Forum, 13, 59-65.

Haddad, A. (1996). Acute care decisions: Ethics in action. R.N. March :17-19.

Harth, S.C., & Thong, Y.H. (1995). Parental perceptions and attitudes about informed consent in clinical research involving children. Social Science Medicine, 41 (12), 1647-1651.

Health Canada. (1997). Good clinical practice; Consolidated guidelines. Ottawa, Canada: Minister of Public Works and Government Services Canada.

Hubbard, S.M. (1982). Cancer treatment research: The role of the nurse in clinical trials of cancer therapy. Nursing Clinics of North America, 17, 763-783.

International Council of Nurses. (1996). Ethical guidelines for nursing research. Geneva, Switzerland: Author.

Johnson, J.M. (1986). Clinical trials: New responsibilities and roles for nurses. Nursing Outlook, 34 (3), 149-153.

Keatings, M., & Smith O. (1995). Ethical and legal issues in Canadian nursing. Toronto: W.B. Saunders Canada.

Levine, R.J. (1986). Ethics and regulation of clinical research (2nd ed). Baltimore: Urban and Schwarzenberg.

Luker, K.A. (1999). The dilemma concerning the nurse's role in a multidisciplinary research agenda. Nursing Research, 4 (2), 85-86.

Lynch, M.T. (1988). The nurse's role in the biotherapy of cancer: Clinical trials and informed consent. Oncology Nursing Forum, 15 (6), 23-27.

Mariner, W.K. (1997). Public confidence in public health research ethics. Public Health Reports, 112, 33-36.

McEvoy, M.D., Cannon, L., & MacDermott, M.L. (1991). The professional role for nurses in clinical trials. Seminars in Oncology Nursing, 7 (4), 268-274.

McLean, P. (1996). Biomedical research and the law of informed consent. The Canadian Nurse, 11, 49-50.

Medical Research Council of Canada. (1987). Guidelines on research involving human subjects. Ottawa, Canada : Ministre des Approvisionnements et Services Canada.

Melink, T.J. (1989). Phase I Trials: Role of the nurse investigator. Cancer Treatment and Research, 98, 842-846.

Ministère de la Santé et des Services sociaux. (1998). Plan d'action ministériel en éthique de la recherche et en intégrité scientifique. Quebec, Canada : Gouvernement du Québec

Monagle, J.F. & Thomasma, D.C. (1998). Health care ethics-critical issues for the 21st century. Gaithersburg, Maryland : Aspen Publications.

O'Connor, K.F. (1996). Ethical/moral experiences of oncology nurses. Oncology Nursing Forum, 23 (5), 787-794.

Papakonstantinou, C., Panarello, L., Sulpizio, M., Senosier, M., Cantini, F., & DiMatteo, M. (1997). A collaborative effort sets precedence : Introducing experience with clinical trials to nursing students. Canadian Oncology Nursing Journal, 7 (4), 194-195.

Quinn, H.R. (1990). Treating the patient with cancer: A trial of chemotherapy in small cell carcinoma of the lung. In A. Faulkner (ed.), Excellence in Nursing, the Research Route (p. 9-23). London: Scutari Press.

Rusnak, E. (1996). Safeguarding human subjects of medical research. Research Nurse, 2 (3), III.1-III.9.

Sadler, G.R., Lantz, J.M., Fullerton, J.T., & Dault, Y. (1999). Nurses' unique roles in randomized clinical trials. Journal of Professional Nursing, 15 (2), 106-115.

Saunders, C. (1995). From involuntary subjects to invited participant: The evolving consent process. Research Nurse, 1 (6), III.21-III.28.

Schloendorff V. Society of New York Hospital, 211 N. y. 125, 105 N. E. 92,95 (1914)

Shafer, A. (1982). The ethics of the randomized clinical trial. New England Journal of Medicine, 307, 719-724.

Shuster, E. (1997). Fifty years later: The significance of the Nuremberg code. The New England Journal of Medicine, 337 (20), 1436-1440.

Silva, M.C. (1995). Ethical guidelines in the conduct, dissemination, and implementation of nursing research. Washington, DC : American Nurses Association.

Silva, M.C., & Sorrell, J.M. (1984). Factors influencing comprehension of information for informed consent: Ethical implications for nursing research. International Journal of Nursing Studies, 21 (4), 233-240.

Silva, M.C., & Sorrell, J.M. (1988). Enhancing comprehension of information for informed consent: Review of empirical research. IRB, 10 (1), 11-15.

Smith, P. (2000). Issues in consent. NCERH Communiqué, 10 (2),5-9.

Speck, P. (1996). Consideration of consent in clinical research. Palliative Medicine, 10, 163-164.

Spivey, W. (1989). Informed consent for research in the emergency department. Annual Emergency Medicine, 18, 766-771.

Three Canadian Councils of Canada. (1998). Tri-council policy statement : Ethical conduct for research involving humans. Ottawa, Canada : Author.

Tranter, J. (1997). The patient's rights in clinical research. Professional Nurse, 12 (5), 335-337.

Sadler, G.R., Lantz, J.M., Fullerton, J.T., & Dault, Y.D. (1999). Nurses' unique roles in randomized clinical trials. Journal of Professional Nursing, 15, (2), 106-115.

United States Government. (1949). Trials of war criminals before Nuremberg military tribunals (Nuremberg Code). Control Council Law, 2 (10), 181-182.

Van Kaam, A. L. (1966). Existential foundations of psychology. Pittsburgh: Duquesne University.

Veatch, R.M. & Fry, S.T. (1987). Experimentation on human beings. In R. Veatch & S. Fry (ed.), Case Studies in Nursing Ethics (p. 231-258). Philadelphia: J.B. Lippincott Company.

Veatch, R.M. & Fry, S.T. (1987). Consent and the right to refuse treatment. In R. Veatch & S. Fry (ed.), Case Studies in Nursing Ethics (p. 259-277). Philadelphia: J.B. Lippincott Company.

Wager, E., Tooley P.J.H., Emanuel, M.B., & Wood, S.F. (1995). Get patients' consent to enter clinical trials. British Medical Journal, 311, 734-737.

Watts, D.D. (1997). Informed Consent in Emergency Research: What every emergency nurse should know. Journal of Emergency Nursing, 23 (1), 70-74.

White-Hershey, D., & Nevidjon, B. (1990). Fundamentals for oncology nurse/data managers: Preparing for a new role. Oncology Nursing Forum, 17 (3), 371-377.

World Medical Association. (2000). Declaration of Helsinki VI, revised in Edinburgh, Scotland : Author.

World Medical Association. (1964). Declaration of Helsinki. In J. Katz (ed.), Experimentation with human beings: The authority of the investigator, subject, professions, and state in the human experimentation process (p. 312-313). New York : Russell Sage Foundation.

Yeo, M., & Moorhouse, A. (1996). Concepts and cases in nursing ethics (2nd ed.). Ontario, Canada: Broadview Press Peterborough.

Yeo, M. (1991). Nursing ethics. Peterborough,Canada: Broadview Press Ltd.

Appendices

Appendix I

*Code#*_____

Questionnaire

For each of the following, please circle your response.

1. Sex: 1. Female
   2. Male

2. Age: ____

3. Highest Level of Completed Nursing Education:
   1. DEC
   2. Certificate
   3. Bachelor
   4. Masters
   5. PhD

4. Highest Level of Education other than Nursing:
   1. DEC
   2. Bachelor
   3. Masters
   4. PhD

   Please specify:_____
   _____

5. Did you receive any formal teaching on Research Ethics during your Nursing education? Yes No

6. If you answered yes to question # 5, approximately how many hours of teaching did you receive?
   _____

7. Following completion of your Nursing studies and **before** taking on a position in research, did you take any courses or training in Research ethics? Yes No

8. If yes, please specify_____

_____

9. When you began to work in your current position, did you receive any training in Research Ethics? Yes No

If no, go to question # 12

10. If yes, specify from whom you received this training.
    a) received training from the principal investigator
    b) received training from the sponsoring company
    c) received training from the nurse you replaced
    d) other, please specify_____

    _____

    _____

11. How long did your training last?
    a) Less than 1 day
    b) 1 to 3 days
    c) 4 to 7 days
    d) more than 7 days
    e) If more than 7 days, please specify_____

12. Have you taken any courses/training in Research Ethics since you acquired this position? Yes No

13. If yes, please specify the number of teaching hours received.

    _____

    _____

    _____

14. How many years have you worked in the clinical trial setting (including previous settings)?

    _____

15. What is your current official title?
    a) Study Coordinator
    b) Research Coordinator
    c) Research Nurse
    d) Clinical Trial Nurse
    e) Study Nurse
    f) Other, please specify_____

16. Do you have a job description? Yes No

17. If yes, who wrote this job description?
    a) the principal investigator
    b) the sponsoring company (pharmaceutical)
    c) yourself
    d) the institution (Hospital)
    e) other, please specify_____
    f) I have no job description

18. What activities related to clinical trials are you involved in?

a.	Participating in writing the protocol	Yes	No
b.	Participating in scientific review	Yes	No
c.	Participating in ethical review	Yes	No
d.	Participating in informing the participant	Yes	No
e.	Participating in obtaining informed consent	Yes	No
f.	Introducing/supplying information to other Nursing colleagues that may be involved	Yes	No

g. Other activities, specify:_____
_____
_____
_____

19. What other nursing tasks do you perform within the clinical trial setting?

a.	Basic patient care	Yes	No
b.	Drug preparation	Yes	No

c. Drug administration Yes No

d. Monitoring of toxicities Yes No

e. Organization of follow-up Yes No

f. Data management Yes No

g. Participant/family education Yes No

h. Other, specify:_____
_____
_____

20. Do you perform other nursing functions within the clinical trial setting?

a. Responding to participants requests for advice/information regarding health problems? Yes No

b. Conducting scheduled follow-up visits? Yes No

b. Conducting follow-up phone calls with Participants? Yes No

d. Conducting physical exams? Yes No

e. Conducting blood work? Yes No

Using the scale below, please circle the number that best describes your involvement.

21. Are you involved in identifying potential study participants (recruitment)?

1	2	3	4	5
never	rarely	sometimes	often	always

22. Once a potential study participant is identified, who is the first to approach the individual about the study?

a) Yourself (Nurse)
b) Principal Investigator
c) Co-Investigator
d) Clinical Research Associate (CRA)
e) Other, specify: _____

23. When do you become involved in the informed consent process? (You may check more than one answer)
    a) Before the consent is obtained
    b) During the time consent is being obtained
    c) After the consent is obtained
    d) All of the above

24. Are you involved in providing information to the participant about the study?

1	2	3	4	5
never	rarely	sometimes	often	always

If it is your responsibility to obtain consent from research participants, please answer questions # 25, 26, 27, otherwise go to question # 28.

25. In the table below, please indicate for each question your response by placing check mark (✓) in the appropriate column.

Before the consent is signed, who explains the following:

	Yourself	Principal Investigator	*Both*	*Other*
a) The purpose of the study				
b) The risks involved in Participating				
c) The benefits in Participating				
d) The alternatives available				

26. Before the consent is signed, who assesses the participants understanding of the study?
    a. No One
    b. Yourself
    c. Principal Investigator
    d. In Collaboration (both yourself and the P.I.)
    e. Other, please specify,

    _____

The next series of items are statements about the role of the nurse. Please indicate to what extent, "never", "rarely", "sometimes", "often", or "always" that this happens as part of your work.

27. Does your involvement include clarifying the participants' understanding of their options?

1	2	3	4	5
never	rarely	sometimes	often	always

If obtaining consent is your responsibility, please go to question #31.

28. My role involves "witnessing" the consent process.

1	2	3	4	5
never	rarely	sometimes	often	always

29. My role includes assessing the participant's understanding of the study, after the consent is obtained.

1	2	3	4	5
never	rarely	sometimes	often	always

30. I clarify the participant's understanding of the study by answering questions.

1	2	3	4	5
never	rarely	sometimes	often	always

31. I assess if the participant is truly participating voluntarily (no undue pressure).

1	2	3	4	5
never	rarely	sometimes	often	always

32. I ensure that the participant's willingness to participate has not changed.

1	2	3	4	5
never	rarely	sometimes	often	always

33. Have I experienced conflict between my obligation to the participants and my responsibility to the research protocol?

1	2	3	4	5
never	rarely	sometimes	often	always

If so, describe your experience_____

_____

_____

_____

_____

_____

_____

34. Participating in the informed consent process presents ethical challenges (dilemmas) for me.

1	2	3	4	5
never	rarely	sometimes	often	always

Please read the following statements and indicate whether you "strongly disagree", "disagree", "agree", or "strongly agree".

35. The ethical challenges (dilemmas) I experience are because I do not have a clear job description.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

36. The ethical challenges (dilemmas) I experience are because there are no clear policies and guidelines to consult.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

37. The ethical challenges (dilemmas) I have to face are related to the lack of information transmitted to me about the study.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

38. The ethical challenges (dilemmas) that I experience are related to a lack of information and education about the informed consent process.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

39. The ethical challenges (dilemmas) that I experience occur because my employer is the principal investigator of the study.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

40. I feel that the consent is simply the formality of a signature.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

41. I feel that the participant has the right to withdraw from the study even after he/she has agreed to participate and signed the consent.

1	2	3	4
strongly disagree	disagree	agree	strongly agree

Please read the following statements and indicate to what extent, "never", "rarely", "sometimes", "often", or "always" has this occurred to you in your work.

42. The structure of financial compensation (an amount of money per participant recruited) has influenced how I recruit participants into the study.

1	2	3	4	5
never	rarely	sometimes	often	always

43. I have experienced situations where the principal investigator has requested that I obtain consent from a participant that I felt should not be approached.

1	2	3	4	5
never	rarely	sometimes	often	always

44. Have I been aware of a situation where the participant has signed the consent form however, it appeared that the participant did not understand the implications of participation.

1	2	3	4	5
never	rarely	sometimes	often	always

45. I have access to the research protocol.

1	2	3	4	5
never	rarely	sometimes	often	always

46. If I did not have access to the protocol, this would hamper my ability to carry out my responsibilities?

1	2	3	4	5
never	rarely	sometimes	often	always

47. I read the research protocol.

1	2	3	4	5
never	rarely	sometimes	often	always

48. I have an opportunity to have my questions about the protocol answered by the principal investigator.

1	2	3	4	5
never	rarely	sometimes	often	always

49. Please rate your knowledge of the process of informed consent.

1	2	3	4
excellent	very good	good	poor

50. Do you feel you are in need of further education regarding the informed consent process? Yes No

Specify topics of interest: _____

_____

_____

_____

_____

Thank you for taking the time to complete this questionnaire, it is very much appreciated. Please place it in the envelope provided and mail it today.

Appendix II

Participants' Information Sheet

Title of Research: Research Ethics and the Role of the Clinical Trial Nurse in the Informed Consent Process.

Principal Investigator: Ms. Franca Cantini (Masters Student)
[redacted]

Dr. Jocelyn St-Arnaud (Supervisor)
Université de Montréal
(514) 343-7619

Dr. Jack Mendelson
McGill University

Purpose of the Study:

The purpose of this study is to identify and document the role of the clinical trial nurse in the informed consent process within five McGill affiliated hospitals. Furthermore, it is to identify the ethical issues experienced by these nurses in this role.

Little documentation is available regarding the role of the nurse in the informed consent process and the ethical implications of such a role. This study will provide us with this important information and provide insight into the ethical conflicts and dilemmas experienced by nurses involved in the informed consent process.

Objectives:

- To describe the role of the clinical trial nurse in obtaining informed consent.
- To explore the ethical issues that arise from this role.

Conditions of Participation:
In order to participate in this study you must be:

- Registered Nurse with the OIIQ
- Able to read and understand English
- Working in the clinical trial research setting in collaboration with a physician (principal investigator)
- Working in research involving competent adults

Advantages:

In participating in this study, you will help in the furthering of nursing knowledge and contribute to the eventual development of ethical guidelines for nurses working in this specific specialized area.

Risks:

There are no anticipated risks in participation.

What does participation entail?

Completing a questionnaire consisting of 50 questions that will take approximately 15 minutes of your time. We do not want to know your name, all we need are you honest answers to the questions.

Secondly, it requires that you enclosing the completed anonymous questionnaire in the envelope provided, seal it, place the sealed envelope in the inter-hospital envelope also provided for you and mail via the inter-hospital mail.

Confidentiality:

All information will be treated in a strictly confidential manner. In order to ensure this, the questionnaire does not include questions that require you to give us information that would allow you to be identified. It is anonymous, meaning there is no way for us to identify you. Therefore, your identity will remain unknown and untraceable at all times.

Participants Rights:

Your participation is entirely voluntary. If you wish to participate you simply complete the questionnaire and mail it anonymously to us, in the envelope provided.

Questions:

If you have any questions regarding the study, you may contact the principal investigator, Ms. Franca Cantini at [redacted]
Should you have any questions regarding your rights as a research participant, you may contact a member of the Research Ethics Committee, Ms. Francine Gratton at (514) 343-5946 or the ombudsman, Ms. Marie-José Rivest at (514) 343-2100.

Thank you for taking the time to read about this important study, please fill in the questionnaire and send it today.

Appendix III

February 2, 2002

Subject: Project entitled, "The Role of the Clinical Trial Nurse in the Informed Consent Process"

Dear Colleagues:

Several weeks ago I met with most of you in order to explain the purpose and importance of the above-mentioned project. I am in the process of working on a Masters in Nursing and this project is what my thesis is based on. Several of you completed the questionnaire and mailed it back to me, and for this I thank you. However 40% did not respond. Since this study is anonymous, there is no way for me to know who responded and who did not, therefore, I am sending this letter and package to all the nurses I met.

If you have already completed the questionnaire and mailed it to me, I thank you for your support in this very important study. If you are amongst those who either completed the questionnaire and never mailed it, or simply misplaced the questionnaire, or never got around to completing the questionnaire, please take the time to do so now. This is very important since I want my results to reflect the reality in which nurses in this setting are practicing, as it stands I can only describe what 60% of you are living and I am really interested in learning about the experiences of those who have not responded as yet.

If you are unsure or are reluctant to respond, please contact me and I can answer any of your concerns or questions. You can contact me, Franca Cantini at 340-8222 ext 2445.

The information sheet and questionnaire are attached to this letter, please complete the questionnaire and mail it to me via the envelope I have provided for you. Remember this study is anonymous, I am only interested in information not your identity.

Thank you

Sincerely,

Franca Cantini