University of Alberta

PATIENTS' PERCEPTIONS OF PARTICIPATION IN CLINICAL RESEARCH

BY

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DEDICATION

Although there turns out to be only one name on this thesis, work of this undertaking is a collaborative effort, and that is monumentally true of this one. Without the continued support and encouragement of key people in my life, my husband Barton, my son Carson, and my parents Andrew and Emilie Horboway, this endeavor would never have been accomplished. Thank you for staying the course with me.

ABSTRACT

Participation in clinical research is not clearly understood. As the number of eligible subjects for clinical research is commonly limited, researchers can gain from understanding individuals' perceptions about their willingness to participate. A descriptive survey was used to: (1) gain an understanding of the knowledge, attitudes, and beliefs that underlie decisions to either participate or not participate in clinical research; (2) describe the advantages and disadvantages that were perceived to be associated with participating or not participating in clinical research; and (3) explore the relationships between these perceptions and reported interest in future clinical research participation. Of the 152 respondents to the questionnaire, Perceptions of Participation in Clinical Research (PPCR), 123 were participant subjects and 29 were nonparticipant subjects in cardiology clinical research trials. Various factors were identified which influenced participation and nonparticipation in clinical research, specifically the knowledge, the attitudes and beliefs, and the perceived advantages and disadvantages of clinical research. The findings from this study can be used to assist researchers to develop more targeted recruitment strategies, and optimize retention and compliance interventions.

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Chapter 1

Introduction

Little is known about what motivates people to enroll in a research study and to remain in a study, often for many years. Participation in a study imposes many requirements on a subject. Depending on the study design, subjects may be asked to comply with a prescribed regimen, to accept treatment assignment by randomization, to undergo additional laboratory tests, physical examinations, interviews, and in a blinded trial, to remain unaware of what treatment they are receiving for the duration of the study. The idea is not new that individuals participating in research, particularly behavioral research, may not be representative models for the study of human behavior in general. Anthropologists, economists, political scientists, psychologists, sociologists, and statisticians are now well aware of the problem of participation bias (Rosenthal & Rosnow, 1975; Hunninghake, Darby, & Probtsfield, 1987; Hudmon & Kinney, 1995) Volunteer bias in the literature is defined as individual or situational factors that might differentiate participants/volunteers from individuals found in the natural setting (Kruglanski, 1973; Spilker & Cramer, 1992). The concern over volunteer bias has led to the development of strategies for reducing bias, or unrepresentativeness of volunteer samples (Rosenthal & Rosnow, 1975; Agras, Bradford, Hunninghake, Knoke, & Marshall, 1983; Hudmon & Kinney, 1995).

Ways for optimizing recruitment, long-term retention, and compliance of subjects are discussed in the literature. However, little information was found about subjects' point of view on the balance between the advantages and disadvantages of research participation.

Although much anecdotal information about subjects' reactions to the research experience has been acquired by researchers and research assistants, few systematic studies have been carried out that look at the attitudes of current and potential subjects toward investigative treatment, their views of the purpose, importance, and appropriateness of clinical research, and their reasons for participating or not participating in research.

Purpose of the Study

The purpose of this study was to gain an understanding of the knowledge, attitudes, and beliefs that underlie decisions to either participate or not participate in clinical research. As well, the advantages and disadvantages that were perceived to be associated with participating or not participating in clinical research were identified. The relationships between these perceptions and reported interest in future clinical research participation were explored. The specific questions addressed were:

1. What are subjects' knowledge of clinical research?
2. What are subjects' attitudes and beliefs regarding clinical research?
3. What advantages do subjects perceive from clinical research?
4. What disadvantages do subjects perceive from clinical research?
5. What factors influence the subjects' participation or nonparticipation in clinical research?
6. What are the characteristics of participants versus nonparticipants in clinical research?
7. What is the relationship between the subjects' perceptions of participating or not participating in clinical research and reported interest in future clinical research participation?

Definition of Terms

The term '**participant**' is taken to assume eligible subjects who chose to take part in a research protocol. The term '**nonparticipant**' describes eligible subjects who chose not to take part in a research protocol.

Significance of the Study

As the number of eligible subjects for clinical research is commonly limited, researchers can gain from understanding individuals' perceptions about their willingness to participate. Information obtained from clinical trial participants can provide researchers with information that can be applied to strengthen recruitment messages for future trials by identifying key areas that former participants express as important trial-related advantages. Researchers also can increase participant satisfaction by helping to decrease perceived disadvantages for participants while enrolled in the study. As well, researchers can better inform potential participants of the disadvantages they could expect to encounter if they decide to enroll. Perceptions are commonly influenced by beliefs, values, knowledge, and past experience, but often can be changed by prospective interventions, such as education about clinical research (Hudmon, Stolzfus, Chamberlain, Lorimor, Steinbach, & Winn, 1996). The initial step is the careful assessment and description of these relevant factors. Identification of subject characteristics that are associated with specific perceived advantages and disadvantages of participation will permit researchers to develop more targeted recruitment and optimize retention and compliance interventions.

Chapter 2

Review of the Literature

Accrual of sufficient numbers of subjects is one critical prerequisite for a successful, randomized clinical study. Very little work has been done to determine why subjects agree or decline to enroll. Some researchers have undertaken to elicit attitudes toward participating in clinical research from participants (Mattson, Curb, & McArdle, 1985; Goodman & Black, 1986; Arnold, Johnstone, & Stoskopf, 1989), while others have surveyed subjects not enrolled in studies (Ho, Atwood, & Meyskens, 1987; Cassileth, Lusk, Miller, & Hurwitz, 1982; Saubrey, Jensen, Rasmussen, Gjoruup, Guldager, & Riis, 1984). As some of the literature on the participant/nonparticipant in research is dated, it is important to incorporate and review current publications to gain a better understanding.

The objectives of this literature review are first, to describe the problems and strategies used by researchers in the process of recruitment of subjects into studies; second, to assess the characteristics, attitudes and beliefs of the participant/nonparticipant regarding study involvement; third, to describe the problems and strategies used with participants that affect the retention of subjects in studies; fourth, to describe the problems and strategies that are identified in the literature that affect subjects' adherence and compliance to a study protocol; and finally, to discuss the consequences of these outcomes.

Recruitment of Study Subjects

The study of the complexities and difficulties of the recruitment process, which have often been underestimated by researchers, is becoming an established area of inquiry. Effective recruitment is an important element in the successful conduct of a study (Spilker

& Cramer, 1992). Failure to reach recruitment goals can compromise statistical power and decrease the likelihood of detecting a treatment effect, if one exists (Hunninghake, Darby, & Probstfield, 1987). A review of the developing literature concerning recruitment reveals many concerns (Agras & Bradford, 1982).

In the literature, there have been ten major recruitment problems identified that have had an important impact on the recruitment process. These include: prolonged recruitment time, recruitment of insufficient number of subjects, miscalculations of the number of eligible subjects, intersource variability, intercenter variability, variation in subject approach, inconsistencies in message content to potential subjects, variation in participation level of investigators and research staff, differing views of the process of informed consent, and lack of published information on recruitment. These problems have lead to other potential consequences to recruitment which include: increased costs, uneven workload, and morale problems for subjects and research staff.

Recruitment Problems

Many clinical trials and population-based studies have been conducted, but the amount of information that has been published regarding recruitment is limited. Most of the information has been described during the past two decades and primarily relates to large multicenter clinical trials.

Prolonged Recruitment Time. Recruitment of the requisite number of subjects within the expected duration of time does not occur often (Hunninghake et al., 1987). The Aspirin Myocardial Infarction Study (AMIS) is only one example found in the literature, of a clinical trial that completed its recruitment efforts on time (Schoenberger, 1979). In

the Coronary Primary Prevention Trial (CPPT), recruitment took more than twice as long as initially planned (Agras & Bradford, 1982). Similarly, in the National Cooperative Gallstone Study (Croke, 1979), and the Coronary Drug Project (Schoenberger, 1979), recruitment was slower than was planned. In the Coronary Drug Project, only 23% of the entry goal had been achieved midway through the recruitment phase (Schoenberger, 1979). Lee (1983) identified that prolonged recruitment during the initial phase of a study usually results in failure to meet the recruitment goal at the end. One of the reasons for this inability to meet recruitment goals is that subjects cannot be accessed and recruited until the study is about to begin. This often accounts for an underestimation of time needed to attract subjects.

Recruitment of Insufficient Numbers of Subjects. Insufficient numbers of subjects is another extremely common recruitment problem. In the literature, of the ten Veterans Administrative Collaborative studies, only two reached the initially estimated sample size, only one of these closed recruitment on schedule, and three studies were terminated because of inadequate recruitment (Collins, Bingham, Weiss, Willford, & Klett, 1984). Similar problems have been reported in a review of oncology clinical trials; 2 of 39 studies achieved the desired number of subjects within two years (Pocock, 1978). Even, if the original sample size is in fact attained, recruitment often took longer than anticipated. Moussa (1984) comments that the reasons researchers do not obtain their initially estimated sample size is that often they do not estimate sample size. Instead, the number of subjects available to the researcher during a given time frame determines the sample size of the study. Moussa (1984) contends sample size requirements need to be carefully

determined; otherwise, the results will lack the power to detect a statistically significant difference.

A second reason for this inability of researchers to obtain their estimated sample size was commented on by Charlson and Horwitz (1984). They found that if the researchers did not screen a large number of subjects (i.e. twice as many as needed), often achievement of required sample size did not occur. To determine the amount and source of pre-randomization losses in clinical trials, Charlson and Horwitz (1984) investigated 41 clinical trials. They reported that 66% of the 41 clinical trials reviewed never achieved their projected sample size. Charlson and Horwitz (1984) reported that one third of the clinical trials they reviewed did not use screening logs and 57% failed to collect any data on eligible patients who were not entered.

Miscalculations of the Number of Eligible Subjects. Another recruitment problem related to insufficient number of subjects that has emerged in the literature is the fact that when researchers do estimate their sample size, they miscalculate the number of eligible subjects in the total population. There is a misconception that the total population of eligible subjects will correlate with the number of individuals who enter a study. Williford, Bingham, Weiss, Collins, and Rains (1987) found that in eight of nine multicenter clinical trials conducted within the Veterans Administrative Cooperative studies, the original recruitment projections were overrated. Different researchers use different methods, sometimes individual to their own practice, to complete their calculations. A frequently quoted statement is that the exclusion criteria and willingness to participate will reduce the enrolled population to less than 10% of the original expected number (Ederer, 1975;

Hunninghake et al., 1987). Ederer (1975) suggests that if planning for recruitment does occur, it generally defines only the population of eligible subjects without taking into account other variables.

In the literature, one reason for the overly optimistic projection of available numbers of subjects to enroll that is made in almost all research, is so widespread and well known, is found in a general principle known as "Lasagna's law". Most researchers know this effect to be true from their own experience, but there are few studies that have evaluated this issue. Lasagna's law means that at the initiation of a study and also at the completion of a study, there is a high availability of suitable subjects to be enrolled in a study. It is during the middle of the study that there is a low availability of suitable subjects to be enrolled into a study (Spilker, 1991).

Intersource Variability. A problem that contributes to the difficulties in the recruitment process is the variations in the yield of subjects (both volume and efficiency) from different types of recruitment sources. For example, physician referral is an efficient method of obtaining subjects, because initial screening has already been accomplished. However, it is also a low volume source (Agras & Bradford, 1982). In both the CPPT (Agras, Bradford, Hunninghake, Knoke, Marshall, & McKeown,1983), and the Coronary Drug Project (1979), the yield from physician referral was so much lower than anticipated that sources with a higher volume but lower efficiency, such as mass media strategies and mass screening, were added to the recruitment campaign. The CPPT (Agras et al., 1983) has provided the most extensive data regarding recruitment sources. The recruitment sources varied in terms of yield, the time necessary to acquire eligible subjects, and the

time that a given source continued to yield subjects. Subjects obtained in the Lung Heart Study (LHS) through referrals (physicians and pulmonary function labs) were in such small numbers that the approach was thought not to be useful (Connett, Bjornson-Benson, & Daniels, 1993). This was similar to results reported by several cardiovascular disease prevention trials where recruitment by referrals was ineffective largely due to unacceptable low rates of accrual (Bradford, 1987; Schoenberger, 1987; Buchwald, Matts, Hansen, Long, Fitch, & the POSCH Group, 1987). In contrast, in the Nocturnal Oxygen Therapy Trial (NOTT), 78% of the enrolled subjects were referrals from physicians (Williams, Snedcor, DeMets, & the NOTT Research Group, 1987). However, 58% of the referrals were from the NOTT study physicians themselves, which is a different situation than relying on referrals from the community and other sources. The high failure rate in the Veterans Administrative collaborative studies (Collins et al., 1984) may have been the result of an exclusive reliance on these referrals, rather than using mass screening procedures in appropriate populations.

Hunninghake et al. (1987) concluded that mass screening (including worksite and public site screening) produced the lowest yield of enrolled subjects per number screened but did offer access to the largest pool of screenees. The experience in the Lung Heart Study was that offsite mass screening was only moderately successful (Connett et al., 1993). Both public site and worksite screening were less effective than mail/phone or media methods, in part because contact was made with a large number of subjects who tended to be less motivated to undergo later screening or to participate in the study. A

somewhat similar experience was reported for the CPPT, which turned to other recruiting sources when recruitment by referrals was insufficient (Bradford, 1987).

Mass mail and media recruitment were reported by Hunninghake et al. to have an intermediate yield (1987). These approaches, with mass mail augmented by telephone follow-up, produced the best yield in the Lung Heart Study (Connett et al., 1993). However, the CPPT (Agras et al., 1983), the AMIS (Schoenberger, 1987), and POSCH (The Program on Surgical Control of the Hyperlipidemia) had varying levels of success with these methods of direct appeal to screenees. The AMIS, targeted to subjects with a previous myocardial infarction, found it most efficient to review hospital records and then make a direct appeal to those who were eligible; relying solely on volunteer response to mass media appeals resulted in many ineligible screenees (Schoenberger, 1987). The strongest conclusion that can be made is that no systematic knowledge exists about the effectiveness of various recruitment sources across specific areas of research (Holden, Rosenberg, Barker, Tuhrim, & Brenner, 1993).

Intercenter Variability. There is considerable variation in the efficiency of recruitment and entry rate into studies among centers. Collins, Bingham, Weiss, Willford, and Kuhn (1980) stated that even using a single source, such as mass mailing in the National Diet-Heart Study, there was more than a twofold difference among the five participating centers in the number of men entered, and a threefold difference in the proportion of initial contacts proceeding to entry. Differences are suggested to be due to: variation among centers in the size of the eligible population, organizational differences

among centers, and different methods of approach to sources and potential subjects (Collins et al., 1980; Croke, 1979).

Variation in Approach to Subjects. There is little information shared or documented amongst researchers regarding the various ways in which researchers can approach potential subjects. The personality of the recruiter affects success of recruiting (Kaye, Lawton, & Kaye 1990). More personal contact with potential subjects increased the likelihood of participation. In one center of the CPPT study (Agras et al., 1983), it was found that a letter appealing to volunteers to contact the center yielded a 10% participation rate, while telephone contact resulted in a 54% rate of participation (Hunninghake, Peterson, LaDouceur, Knoke, & Leon, 1982). Even higher participation rates have been reported from face-to-face contact involving home visits, with up to 90% participation in some studies (Epstein, Ostrander, Johnson, Payne, Hayner, Keller, & Francis, 1965; Norton, Breitner, Welsh, & Wyse 1994). However, Agras and Bradford (1982) comment that telephone contact and home visits may not be cost-effective for large-scale studies. With lack of documentation by the researchers of how subjects are recruited initially by them, reasons regarding why different approaches are used have not been commented on in the literature.

Variable Message Content. The content of messages directed to potential subjects has been documented as having an effect on the volume of contacts elicited from a given pool of potential subjects. Fear-arousing is associated with lower response rates than appeals emphasizing positive benefits of the study. In a study by Kirscht, Haefner, and Eveland (1975), fear-arousing appeals yielded a 27% rate of appointments, of which 70%

were kept, compared with 36% and 90% for positively oriented appeals. This difference was accounted for by the differential response of women to these two types of messages. Brevity, simplicity, and clarity are important aspects of any message, which may be supplemented by other motivational factors (National Diet-Heart Study, 1968).

Participation Level of Investigators and Research Staff. Active participation is needed to achieve enrollment of potential subjects. Physicians may be willing to allow their patients to participate in studies but they may not have the time or energy to identify eligible subjects (Martin, Henderson, Zacharski, Rickles, Forman, Cornell, Forcier, Edwards, Headley, & Kim, 1984; Pocock, 1978; Schoenberger, 1979; Taylor, Margolese, & Soskolne, 1984). A survey of research support staff found there was great enthusiasm and participation of the investigators at the initial onset of a study to enroll potential subjects, but that enthusiasm declined rapidly after a study had been going on at a center (Diekman & Smith, 1989). Reasons identified by investigators for the inability to keep up the participation level was that other research projects were being developed that needed their input, and that they felt confident in their research staff members to continue recruitment (Taylor et al., 1984). Researchers need to actively search medical records for eligible subjects and to persist in follow-up efforts to locate potential subjects.

Process of Informed Consent. In a study done by Taylor, Margolese, and Soskolne (1984), obtaining informed consent was cited as a reason not to enter eligible subjects in clinical trials by 38% of physicians. The physicians maintained that informed consent is a labor intensive task that is far in excess of what is appropriate. Kopelman (1983) notes that some physicians view consent requirements to be so restrictive and idealized that true

consent is unrealistic and thus results in few patients qualifying or agreeing to enter randomized clinical trials. Others believe that the process of obtaining informed consent places unwarranted stress on the potential subject (Nobel, 1985).

Studies examining how informational and situational factors influence an informed consent procedure between physicians and subjects have been increasing in recent years. Many studies of informational factors have examined how formats and content of informed consent forms influence subjects' comprehension (Bergler, Pennington, Metcalf, & Freis, 1980; Epstein & Lasagna, 1969), while research with clinical volunteers has indicated that reinforcement from a significant other (Hassar & Weintraub, 1976; DeLuca, Korcuska, Oberstar, Rosenthal, Welsh, & Topol, 1995) and a desire to comply with a physician's request (Schultz, Pardee, & Ensinck, 1975), were prominent situational influences. Bergler et al. (1980) found that 75% of the hypertensive subjects participating in a drug study would have been willing to participate without having received the information provided in the informed consent form. Although informed consent is desired by subjects, Bergler et al. (1980) believe that the personal trust and confidence placed in the physician may be more important to having subjects participate in research.

There are many previous studies in the literature that have raised questions about the ethics of informed consent (Ingelfinger, 1972; Caplan, 1982). It is understood that differences exist between the amount and type of information subjects want to receive and what physicians think subjects should receive (Strull, Lo, & Charles, 1984; Mark & Spiro, 1990). The literature brings forward the idea that researchers often misperceive subjects' comprehension of the information provided in the consent form (Boritz-Wintz, 1992;

Perrin, 1992). In spite of this, factors predicting a subject's successful signing of the informed consent form remain unclear. The results of a recent study suggest that subjects who were better educated (college and graduate school), were encouraged to participate by a significant other (spouse or family member), were given adequate time to decide (4.5 hours), or initially approached by a physician were more likely to consent (DeLuca et al., 1995).

A previous study (Sherlock, 1986) on subject decision making showed that only 10% of the subjects in inpatient and cardiology wards wanted to participate in shared decision making about treatment. Subjects were willing to agree with the researcher's opinions, with little regard for the idea of informed consent as viewed by the researchers (DeLuca et al., 1995; Sherlock, 1986).

Furthermore, it is interesting to note that 30% of subjects stated that they did not read the consent form (DeLuca et al., 1995) in spite of surveys indicating that "people have a universal desire for information, choice, and respectful communication about decision" (Caplan, 1982, p. 165). Lidz, Meisel, and Osterweis (1983) state that subjects rarely want information to direct their treatment. The most common reasons subjects want information are for compliance, as a courtesy, and to be able to veto a treatment decision. Therefore, despite the nature of the researcher-subject relationship, to protect subject autonomy, Kemperman (1984) suggests that it remains the responsibility of researcher to give the subject the initial information needed for making decisions, even though the subject may later delegate the decision.

Lack of Published Information. Finally, it appears that a major problem in recruitment efforts is related to the lack of published information regarding recruitment (Newburg, Holland, & Pearce, 1992). Many clinical trials are conducted by researchers who have no experience in clinical trials, and limited documented experience from which to benefit (Hunninghake et al., 1987). Potential recruitment problems are not anticipated, and no ready reference is available for solutions if problems arise. The Veterans Administrative Collaborative studies (Collins et al., 1984) excluded previously unsuccessful clinical researchers, because the record of a researcher in a clinical trial was a predictor of recruitment in future clinical trials. Experienced researchers also have accounted for successful and timely recruitment in AMIS (Schoenberger, 1979).

The available information in the literature indicates that recruitment has almost always been a greater problem than was anticipated (Hunninghake et al., 1987). Complete, comprehensive, and standardized reporting of all recruitment information for studies of all sizes is needed. This may lead to many of the problems associated with recruitment being minimized by careful designing and planning of recruitment strategies.

Consequences of Recruitment Problems. Delays in the recruitment process result in increased costs for recruitment and for the entire study. The duration of the study has to be extended or the power of the study is reduced because of fewer subject observations (Hunninghake et al., 1987). Failure to recruit a sufficient number of subjects could result in financial consequences as a result of a shortfall in entry rates (Croke, 1979; Schoenberger, 1979; Hudmon & Kinney, 1995), and in some studies, participating centers have to be closed or replaced (Collins et al., 1980; Croke, 1979). In addition, protocol

changes are likely to be made when recruitment in unexpectedly difficult (Collins et al., 1980; Croke, 1979; Schoenberger, 1979; Morgan, Wardell, Weintraub, Mazzullo, & Lasagna, 1974). It is difficult to predict how changes to the inclusion or exclusion criteria of a study will influence the final outcome. Changes do influence the population entered into the study, which could subsequently affect many variables within the study (Hunninghake et al., 1987).

Another consequence related to recruitment delays is an uneven workload. In many studies, a late surge of recruitment results in an uneven rate of entry of subjects, which in turn creates an uneven workload. The uneven workload increases staffing requirements for a clinic and creates administrative problems. Hunninghake et al. (1987) comment that an uneven workload can create a risk that resources will be diverted to the recruitment effort and that other study functions will suffer.

Prolonging the recruitment phase can also have an adverse effect on the subjects. When a study is prolonged, subjects can become increasingly more reluctant to adhere to the protocol, or the duration of the study may be extended beyond the time originally specified in the consent form. The resultant increase in workload and the need for scientific compromise may affect the morale of staff which, in turn, may further affect a deteriorating recruitment picture (Agras & Bradford, 1982).

Recruitment Strategies

There are many varied and different strategies reported in the literature that address the before mentioned recruitment problems. Agras, Marshall, and Kraemer (1982) state that the most important issue with regards to increasing recruitment of subjects is to

develop a strategy that involves multiple stages. If initial efforts fail to enroll sufficient numbers of subjects, then further efforts need to be rapidly implemented. If the reasons for low enrollment can be determined, then specific efforts need to be used in order to see changes in the enrollment numbers.

Stage Development Techniques. The initial step with regards to recruitment of potential subjects is to determine whether the central problem of recruitment relates to: 1) subjects, 2) researchers, 3) protocol requirements, 4) other factors, or 5) a combination of two or more of these factors (Spilker, 1991).

The next step is to identify the specific causes as well as possible solutions. Spilker (1991) suggests that prior to the study it is useful to develop a series of alternative techniques to attempt to increase enrollment if the rate of subject recruitment becomes a problem. These techniques include: 1) loosening the inclusion/exclusion criteria; 2) loosening the demands of the protocol; i.e., eliminating some or all disagreeable tests; 3) speaking informally to additional colleagues directly or by telephone to request referrals; 4) speaking formally/informally at professional meetings to request referrals; 5) writing letters to colleagues and request referrals; 6) putting notices in places for colleagues and or subjects to observe; 7) printing pamphlets and distribute directly to potential subjects; 8) advertising in local or regional sources (i.e., newspapers, TV, radio); 9) contacting subjects directly at health fairs, or by radio, and TV appearances; 10) increasing or initiating payment or other benefits to patients (i.e. include payment for transportation and/or meals); 11) increasing the time of the study's duration; 12) hiring additional personnel to help recruit patients; 13) determining which techniques are working best at

sites with high recruitment rates and utilizing those techniques at sites with lower recruitment rates (Spilker, 1991).

If recruitment strategies are not successful, then it may be necessary to decrease the number of subjects in the study (Spilker, 1991). The new number chosen should be reached in collaboration with a statistician. Although a lowering of the required sample size is usually accompanied by a decrease in the power of the study, it is sometimes possible to decrease the sample size without compromising the results (Biles, 1995). For example, consideration of a secondary hypothesis may be dropped, or different statistical tests may be found to be more appropriate for analyzing the data (Spilker, 1991).

Methods to increase subject enrollment are not always the problems of recruitment. Sometimes the researchers must be convinced of the importance and reasonableness of entering certain types of subjects. Reasons for low subject enrollment that relate to the views of the researcher are discussed by Taylor, Margolese, and Soskolne (1984). Some researchers may have discomfort with: 1) inclusion of a placebo, 2) size of the group given placebo, 3) randomization process, 4) informed consent procedures, 5) restricted eligibility requirements, 6) excessive time required to care for subjects, 7) administrative requirements of completing data collection, 8) perceived conflicts between care offered to subjects in usual treatment versus that required by protocol, or 9) the overall value of the trial (i.e., additional information may have been obtained since the study started, or preference for one treatment).

Recruitment strategies suggested in the literature are extrapolated from the results of the Coronary Primary Prevention Trial (Agras et al., 1983), as it is the most

comprehensive description of a recruitment process for a large major multicenter trial that has devoted an entire monograph to describing its recruitment efforts (Agras & Bradford, 1982). Recommendations from the CPPT (Agras et al., 1983) and the National Cooperative Gallstone study (Croke, 1979) are applicable to both single and multicenter research efforts (Dunbar & McKeown, 1982). More recently, the Lung Health Study (Connett et al., 1993) published their experiences in recruitment of subjects.

Relaxation of Inclusion Criteria. It is an accepted generalization that in most research situations subject recruitment becomes progressively easier as the admission criteria of a study ease. This was confirmed when Croke (1979) observed that the ability of ten centers to recruit participants was increased by loosening the criteria admission into the clinical trial. This change had a great impact on the enrollment rate of subjects than did any of the other methods used to increase subject enrollment at the different sites. Spilker (1991) believes the trend described by "Lasagna's law" occurs primarily because admission criteria prevent many subjects from enrolling that the researcher initially considered as viable subjects for the study. Lasagna's law may be countered in several ways, one of which involves modifying the admission criteria. However, Spilker (1991) warns that it is important to determine whether the admission criteria can be modified without affecting the study's integrity.

Accurate Determination of Sample Size. The number of subjects required for a study refers to the number of subjects who finish a study rather than then number that enter (Spilker, 1991). Therefore, in planning a study, the definition of a `completed' subject is important to establish, as is the expected rate of subject dropouts and

discontinuers. Clinically experienced researchers previously estimated the number of subjects to include in a study based on their judgement and clinical expertise. "Guesstimates" of sample size are absolutely invalid and scientifically unacceptable in research, no matter how experienced the guessers (Spilker, 1991). For most studies, the required sample size is determined on the basis of: 1) the magnitude of the effect expected (or desired), 2) the variability (often estimated) of the variables being analyzed, and 3) the desired probability (power) of observing that effect with a defined significance level (Polit & Hungler, 1987; Cohen, 1988). A power of 0.80 is usually chosen for most studies, although some experimental designs require a higher power. To estimate the number of subjects for a study, Erderer (1975) suggested using Muench's third law, which states that the number of subjects required for a study must be divided by a factor of at least 10. Two other postulates also apply to recruitment: 1) the more common the disease and the less stringent the criteria, the more subjects will be available to enter a study; and, 2) the longer the follow-up period, the more visits there are, and the more measurements taken at each visit, the fewer subjects the researcher can handle (Collins et al., 1984).

Identification of Additional Sources of Subjects. More often than not, subjects are often recruited for clinical trials from the medical practice of a researcher, but there are numerous occasions when this is either not possible or is not the sole source of subject recruitment. The strategies used in the Coronary Primary Prevention Trial (CPPT) (Agras & Bradford, 1982), the National Cooperative Gallstone Study (Croke, 1979), and the Lung Health Study (Connett et al., 1993) could be used to provide a framework for planning overall recruitment strategies. Even though the strategies cannot be directly

transferable to all studies, it is a beginning to document a recruitment plan. As more data regarding recruitment for clinical trials becomes available, it will be possible to identify and specify more precisely the important variables and parameters involved in such efforts, and therefore, enhance planning for future research.

Blood Banks. In the CPPT, (Agras et al., 1983), blood banks represented a recruitment source with relatively high volumes of initial contacts and entries, a low ratio of entries to initial contacts and a relatively low effort level requirement for the recruitment team. Blood banks provided 26% of initial contacts and 15% of first protocol visits and entries. The most critical determinant of a successful collaboration was the early negotiation with the blood bank director. Several features seemed to characterize successful blood bank collaborations: Blood banks were willing to release names and addresses, provided staff support, did not request monetary reimbursement, and agreed sometimes enthusiastically, to participate in joint media campaigns tended to produce the most referrals. The blood banks were well adapted to identify healthy, asymptomatic men with an abnormal laboratory finding identifiable by a blood test for the CPPT (Stern, 1982).

Shared Referrals. The shared use of resources from several large clinical trials has not previously been reported as a recruitment strategy. This strategy could, in the future, provide an enriched sample of potential subjects (Hunninghake et al., 1982). Referrals from related clinical studies represent a recruitment source with a relatively low volume of initial contacts, moderate volume of interviews, a high ratio of entries to initial contacts, and a low effort level requirement for the recipient recruitment team. For the

CPPT, (Agras et al., 1983), this strategy provided an overall 1% of initial contacts, 9% of first protocol visits, and 11% of entries. Referrals were obtained from three major clinical studies. Approximately two-thirds of the total entries from this source were derived from the Multiple Risk Factor Intervention Trial 1982 (MRFIT) and almost three-fourths of these were accounted for by the Minnesota LRC Prevalence study. Recruitment costs are usually low with this strategy. The combination of low costs and high efficiency make study subject referrals attractive. Hunninghake et al. (1982) suggest that such referrals may not always be available, but if they are, every effort should be made to maximize their use.

Community Screening. Mass screening linked to an event, location, or organization represents another recruitment strategy with a relatively high volume of initial contacts and entries, a low ratio of entries to initial contact, and a relatively high effort level requirement for the recruitment team. In the CPPT, (Agras et al., 1983) community screenings provided 21% of initial contacts and 14% of first protocol visits and entries. Screening is costly and involves careful planning and implementation of complex arrangements. Screening of community locations was better than events or organizations, primarily because of the greater proportion of age-eligible men relative to the total screened and the higher volume of initial contacts (Melish, 1982).

Screening of Entire Communities. Refers to targeting the effort on the entire community, with screening at one site over a short period of time, using various community resources to facilitate the process arose out of the demographic characteristics of the area served by Iowa in the CPPT (Agras et al., 1983). The process included three

components: access to names and addresses of age-eligible persons who could be contacted through a direct-mail announcement of the screening program; support of local media and community leaders; and effective on-site screening teams. Responses to direct mailings were enhanced by a coordinated mass media campaign, in which print media was more effective than radio or television. The likelihood of an age-eligible man participating in the initial contact screening for the CPPT was greater for residents of smaller than larger communities (Schrott & Merideth, 1982).

Mass mailings. This recruitment strategy represents a moderate-volume, low-efficiency with a relatively moderate volume of initial contacts and low volume of entries, a low ratio of entries to initial contacts, and a relatively moderate effort level requirement for the recruitment team. In the CPPT, (Agras et al., 1983), this source provided 6% of initial contacts, 7% of first protocol visits, and 6% of entries. Mailings were sent to those identified through voter registration and driver licensee lists, group-membership and direct-mail services firms. Variable responses were obtained, with voter registrants yielding the highest level. Unwillingness to participate at the first protocol visit excluded only one-third as many participants from this source as was observed among all sources. Costs were significantly reduced by the availability to the center of computerized mailing lists, as well as the adoption of automated data processing procedures in conducting the mailings and follow-up phases (McDearmon & Bradford, 1982).

Mass Communication Methods. This strategy played a main role in the overall recruitment effort of the CPPT (Agras et al., 1983). Use of the mass media represents a recruitment strategy with a relatively moderate volume of initial contacts and entries, a

moderate ratio of entries to initial contacts, and a relatively moderate effort level requirement for the recruitment team. In the CPPT, media sources accounted overall for 4% of initial contacts, 11% of first protocol visits, and 11% of entries. The media also served in an add on role to other recruitment strategies. The yield from television and newspaper messages was generally better than that from radio. The flow of response varied appreciably among these types of media. Only one-fourth as many subjects recruited through this strategy were excluded due to unwillingness to proceed at the first protocol visit as was observed among all sources (Levenkron & Farquhar, 1982).

Medical Referrals. This was another strategy that played a main role in recruitment efforts of the CPPT (Agras et al., 1983). Little (1982) believes that most large clinical trials can benefit from careful explanation first to the medical community and then to the public, both during the initiation of recruitment and periodically during the conduct of the trial. The potential subjects need accurate information about the problem under investigation. The subject should get the same message from the researcher and personal physician. Therefore, recruitment should start with explanations to the medical community (Little, 1982). Medical referrals represent a recruitment source with a relatively low volume of initial contacts and entries and a high ratio of entries to initial contacts. This source requires a low effort for the recruitment team. In the CPPT (Agras et al., 1983), this strategy provided 3% of initial contacts, 8% of first protocol visits, and 10% of entries. Low yields preclude reliance on these sources for any but the smallest clinical trial (Little, 1982).

Computer Networks. More recently computer networks have offered a viable alternative for subject recruitment through the use of on-line bulletin boards and support groups for many health-related issues (Wilmoth, 1995). With increasing access to the Internet system, 1.5 million Canadian households (13%) now have access to the Internet (Statistics Canada, 1997). A researcher who has access to one of the networks has therefore, access to a large pool of potential subjects. Advantages of this method include: 1) increased generalizability of research findings due to wide geographical distribution of on-line members; and 2) the ease and low cost of accessing large numbers of potential subject in a relatively short period of time. Disadvantages include: 1) the need to have access to a personal computer and membership in an on-line network: 2) possible skewing of demographic data as subjects are assumed to have higher education or financial status; and 3) access and recruitment limited to studies using mailed questionnaires or telephone interviews (Wilmoth, 1995).

Motivation of Research Staff. The Lung Heart Study (Connett et al., 1993) recruiters considered the following to be important staff-related principles: 1) experienced staff, though expensive, is cost effective, 2) staff members should be encouraged to be creative and flexible in their approach to recruitment, 3) team work and regular meetings of the entire recruitment staff are essential, and 4) acceptance by staff of the required degree of uniformity in training, and adherence to the protocol by all clinical centers is necessary for a well run clinical trial (Connett et al., 1993)

Spilker (1991) suggests informing researchers in a study of how well they themselves are doing compared with other researchers. Friendly competition among

researchers to enroll subjects is encouraged, but keeping in mind that enthusiasm should not lead to enrolling ineligible subjects. With regards to improving staff members motivation, Taylor et al. (1984) explain that the more feedback received about the study and the status of the subjects they have enrolled, will continue to encourage subject enrollment. Dunbar and McKeown (1982) suggest that keeping a core staff intact through out recruitment and the subsequent phases of a study can have a very positive effect on morale.

Enhancement of Study Comprehension. The role of the researcher includes assessing subjects' and significant others' understanding of the plan of study treatment, as well, the psychological, sociocultural, economic and quality-of-life issues that may affect participation. Awareness of possible obstacles, such as comprehension, need to be dealt with. DeLuca et al. (1995) suggest that to enhance comprehension, the readability testing of the consent form must be done. Ideally, subjects should be taught about a study over several sessions. This gives subjects the time to comprehend information, ask questions, and consult with others before decisions are made. A study performed at the University of Rochester demonstrated that allowing subjects to take the consent home before signing resulted in greater acquisition of information in most every required area of informed consent (Hutson & Blaha, 1991). These same researchers also found that conducting a teaching session for informed consent, followed by a tutoring session, helped to recall the important elements of the consent. Previous research also demonstrated that increased comprehension of the informed consent was found if the subjects were instructed to write and speak about the information they were given (Sorrell, 1991).

Structured Documentation. Hunninghake et al. (1987) suggest that all future trials should carefully document and report their recruitment efforts. The use of standardized terminology, data collection, and reporting of results would enhance researcher's knowledge and facilitate obtaining solutions to many recruitment problems. The most revealing information can be obtained by first documenting how many eligible participants refuse, followed by calculating the rate of refusal for each study and comparing reasons for refusing to reasons for agreeing to participate (Caplan, 1992; Spilker, 1991; Hinds, Quargnenti, & Madison, 1995). A common theme that is running through the literature on strategies for recruitment is that recruitment strategies need to be tailored to accomplish a specific study's recruitment goal within a prescribed period of time. There is a strong belief that increased efforts are needed in the planning of recruitment prior to the start of a study and in monitoring recruitment during the study (Hunninghake et al., 1987; Young & Dombrowski, 1989; McBride, Massothe, Underbakke, Solberg, Beasley, & Plane, 1996). The Lung Heart Study (Connett et al., 1993) experience in recruitment suggests that recruitment is time consuming, expensive, and requires creativity and resourcefulness. Inexperienced researchers often underestimate the magnitude of the task. Additionally, some apparently sound plans for recruitment may turn out to be ineffective or unrealistic. It is unwise to rely on one or two untested strategies. Multiple approaches and the ability to shift emphasis dynamically are important. Lastly, timely and regular monitoring of recruitment results for each strategy is essential. Frequent communication and sharing of experiences can help researchers learn which methods are effective and which should be abandoned (Connett et al., 1993).

Characteristics of Participants and Nonparticipants

There is growing suspicion among researchers that subjects who find their way into the role as a research subject may not be entirely representative of the population in general (Rosenthal & Rosnow, 1975; Hudmon & Kinney, 1995; Cronan, Durkin, Groessl, & Tomita, 1997). This problem has been of great interest to behavioral researchers and has been in the psychological literature as a topic of interest since 1944 (Cochran, 1963; Deming, 1944; Hansen & Hurwitz, 1946).

Participation in a research study in not a purely random event. If it was, there would be no relationships between participation and various personal characteristics (Rosenthal & Rosnow, 1975). The purpose of the paragraphs to follow will be to describe the characteristics that serve to differentiate participants in behavioral and allied health research from nonparticipants and to examine in some detail what is known about the attitudes and beliefs of these two groups. The interpretation of the data and the generalizability of the study results depends on the characteristics of the subjects who actually completed the study as compared to the characteristics of those who did not. It is important to understand how the data obtained may have differed if the nonparticipants had entered or remained in the study. Spilker (1991) reported that interpreting data and extrapolating from the study findings are dependent on the characteristics of the participants, nonparticipants, and those who began but did not finish the clinical trial.

The rates and reasons for refusals are not usually reported in research studies, despite that such information would expand the understanding of how eligible participants view certain concepts and research processes. It would describe study samples accurately

and identify study designs that have excessive demands on participants or in other ways discourage participation. Such information is helpful in designing studies that facilitate participation and maintain scientific rigor (Hinds et al., 1995).

Spilker (1991) has described various types of subjects. A number of subjects usually decide on their own not to enter a study at one of several stages prior to its initiation (designated subject refusers). Alternatively, subjects may be told that they do not qualify for a study because of failure to meet one or more inclusion criteria (nonqualified subjects). Other subjects who enter a study decide themselves to drop out (subject dropouts) or are discontinued by the researcher before the study is completed (subject discontinuers). Those who complete a study are designated subject completers.

It has become readily apparent that there are few characteristics that unequivocally differentiate participants from nonparticipants. An example of this, sex of the subject, will serve as an illustration. There are studies showing that females volunteer more than males (Pucel, Nelson, & Wheeler, 1971; Rosnow, Holper, & Gitter, 1973; Sheridan & Shack, 1970); there are studies showing that males volunteer more than females (MacDonald, 1979; Wilson & Patterson, 1975); and there are studies showing no difference between the sexes in their likelihood of participation in studies (Diamant, 1970; Francis & Diespecker, 1973). A review of the recent literature in the allied health database in the area of characteristics of the participant/nonparticipant subject and their attitudes and beliefs regarding their participation in studies revealed that there are three approaches to explaining this phenomenon: 1) surveys of attitudes towards participation in clinical trials among subjects and public; 2) assessment of characteristics of those who participate in

screening programs and prevention studies; and 3) surveys that address the perceptions about advantages and disadvantages of clinical trial participation. Several of the published studies included information about the demographics of the participants.

It was Rosenthal and Rosnow (1975) initially, that investigated many of the behavioral studies regarding the question of how participants, differ from nonparticipants. These authors described the characteristics of the participant. Rosenthal and Rosnow (1975) list the characteristics of the participant by the degree of confidence they are associated with participating in the study. To qualify for "maximum confidence," a relationship had to be based on a large number of studies, of which a majority significantly favored the conclusion and of which the majority of just the significant outcomes favored the conclusion drawn. Therefore, the conclusions warranting maximum confidence are: 1) participants tend to be better educated than nonparticipants; 2) participants tend to have higher social class status than nonparticipants; 3) participants tend to be more intelligent than nonparticipants; 4) participants tend to be higher in need for social approval than nonparticipants; and, 5) participants tend to be more sociable than nonparticipants (Rosenthal & Rosnow, 1975). Conclusions warranting considerable confidence are: 6) females are more likely than males to participate for research in general; 7) participants tend to be less authoritarian than nonparticipants; and, 8) participants tend to be less conforming than nonparticipants.

Rosenthal and Rosnow (1975) have also identified variables that tend to increase or decrease the rates of participation by identifying certain situational determinants, again based on examination of many behavioral research studies. Conclusions warranting

maximum confidence include; 1) subjects more interested in the topic under study are more likely to participate; and, 2) subjects with expectations of being more favorably evaluated by the researcher are more likely to participate. Conclusions warranting considerable confidence according to Rosenthal and Rosnow (1975) include: 3) subjects perceiving the research as more important are more likely to participate; 4) subjects' feeling states at the time of the request for participation are likely to affect the probability of participation. Subjects made to "feel good" or to feel competent are more likely to participate, and 5) subjects offered greater material incentives are more likely to participate.

In a clinical trial related to the prevention of heart disease, participants tended to be older, of higher socioeconomic status, with more dependants, and more likely to routinely use medical services than the general population (Greenlick, Bailey, Wild, & Grover, 1979). Similarly, participants in the Hypertension Detection and Follow-up Program (HDFP) were more likely than nonparticipants to be employed, married, white, and have attained a higher education level (Hypertension Detection and Follow-up Program Cooperative Group, 1978). In a case-control study of thyroid cancer in women, participants were younger, better educated, and less likely to have smoked than nonparticipants (McKeown, 1982). Data collected on participants and nonparticipants at a breast cancer screening clinic indicated that those who attended were likely to be of higher socioeconomic level, to be married, and to have a family history of breast cancer (French, Porter, Robinson, McCallum, Howie, & Roberts, 1982). In a survey of a sample of subjects who attended a cancer screening examination and risk assessment, those

participants most interested in participating in cancer prevention research were more likely to be younger, be better educated, have higher family incomes, use vitamins regularly, have greater awareness of the possible link between dietary practice and cancer risk, be more concerned about getting cancer, and believe than changes in dietary practices can decrease cancer risk (Mettlin, Cummings, & Walsh, 1985).

Overall, the participant is generally younger (Mettlin et al., 1985; McKeown, 1982), has a higher socioeconomic status, uses medical services more routinely (Greenlick et al., 1979; Mettlin et al., 1985; French et al., 1982; Cronan et al., 1997; Larsen & McQuire, 1990; Norton et al., 1994), married and Caucasian (HDFP, 1978; French et al., 1982), better educated (Mettlin et al, 1985; DeLuca et al., 1995; HDFP, 1978; McKeown, 1982), report more positive attitudes about participating in research (Kaye et al., 1990) and is less likely to smoke (McKeown, 1982).

In contrast, a nonparticipant tends to be older, of lower socioeconomic status or have less education, more often to be male, to smoke, to live in large urban areas, have fewer healthcare contacts, have increased mortality rates, poor physical health, and comorbid conditions (Romans-Clarkson, Walton, Herbison, & Mullen, 1988; Wilhelmsen, Ljungberg, Wedel, & Werko, 1976; Barton, Bain, Hennekens, Rosner, Belanger, Roth, & Speizer, 1980; Janzon, Hanson, & Isacsson, Lindell, & Steen, 1986; Forthofer, 1983; Cronan et al., 1997; Colsher & Wallace, 1989).

Little is known about how individuals perceive research (Hudmon et al., 1996). Thousands of clinical trials have been conducted in recent years, yet relatively few studies assessing subjects' perceptions of these clinical trials have been reported (Cassileth et al.,

1982; Kemp, Skenner, & Toms, 1984; Mattson et al., 1985; Tangrea, Adrianza, & Helsel, 1992; Nasco & Leonard, 1994; Sutherland, Carlin, Harper, Martin, Greenberg, Till, & Boyd, 1993; Henzlova, Blackburn, Bradley, & Rogers, 1994; Kusek, Lee, Faulkner, Levell, Milligan, & Norris, 1996; Schron & Pressel, 1995). Hudmon et al., (1996) reported that seven such studies described the perceptions of actual participants: randomized trials testing the effects of cardiovascular drugs (Mattson et al., 1985; Nasco, & Leonard, 1994; Henzlova et al., 1994; Kusek et al., 1996; Schron & Pressel, 1995), a dietary intervention for the prevention of breast cancer (Sutherland et al., 1993), and a chemoprevention agent to prevent the recurrence of basal cell carcinoma (Tangrea et al., 1993).

The value of clinical trials and other research to the advancement of knowledge for the researcher may not be understood by the public. Little systematic inquiry has been undertaken regarding how much the public understands regarding the need for rigorous scientific study of new treatments and the role that participants play in this effort.

There is also little direct information about the attitudes of the public towards clinical trials (Cassileth, et al., 1982; Kemp, et al., 1984; Saubrey, et al., 1984); however, three published surveys suggest that clinical trials are viewed as ethical and important by the public. Despite support for the general concept of clinical trials, all of these studies suggest that there are segments of the population who have reservations about participation in clinical trials.

Cassileth et al. (1982) administered a self-report questionnaire to 104 patients with cancer and 84 cardiology patients, plus 107 members of the public. Although, the

demographic characteristics of the three groups of subjects were different, there were no significant differences in opinion among the three groups, therefore, the responses were merged. Seventy-one percent of the participants believed that patients should serve as research subjects, and most subjects (69%) thought that the most important reasons to participate were the benefit to society and the increase in medical knowledge. Only 3% believed that patients should not be used as guinea pigs. An additional important observation from the study was that 36% of the participants thought that patients receiving treatment recommended by a physician received better care than patients who participated in medical research (13%) or that investigative and physician-directed treatment were equal (25%). Kemp et al. (1984) had a related questionnaire response that found 70% of subjects thought that "doctors know privately which one of the investigated treatments is best" or were uncertain about this possibility. However, these researchers used multiple choice and open-ended questions to characterize attitudes about clinical trials in general, rather than presenting detailed and explicit information about actual study protocols to participants who would find the problem noticeable.

Mattson, Curb, McArdle, AMIS Research Group, and BHAT Research Group (1985) used open-ended questions to assess the attitudes of subjects in two large cardiac clinical trials (AMIS and BHAT) towards the advantages and disadvantages of clinical research participation. The results of this work indicated that the overall perceived disadvantages of participation were low; however, Mattson et al. acknowledge that the opinions of the patients surveyed may not be representative of patients who refused trial entry in the first place.

Surveys were completed among participants in the Beta-Blocker Heart Attack (BHAT, 1985) and the Aspirin Myocardial Infarction Study (AMIS, 1985) to obtain data on the subjects' point of view of participation in a clinical trial. In AMIS to obtain data on these perceptions, a questionnaire partially based on hypotheses generated in AMIS was mailed out. Results from the two studies suggested that subjects in both clinical trials felt that the additional medical monitoring, the opportunity for a "second opinion," and the reassurance received were more important benefits than actual physical improvement. Altruistic motivations were high in both studies. Frequency of perceived disadvantages was low, centering mainly around transportation problems and clinic waiting time. The large majority of subjects indicated that they would volunteer for similar research in the future (Mattson et al., 1985). Other clinical trials that reported on the perceived advantages and disadvantages of participation in clinical trials from a patient's point of view include: the studies of Left Ventricular Dysfunction (SOLVD) trial, the Stroke Prevention in Atrial Fibrillation (SPAF II) study, and the Systolic Hypertension in the Elderly Program (SHEP) (Kusek et al., 1996).

Barofsky and Sugarbaker (1979) examined the reasons for patient nonparticipation in randomized clinical trials for the treatment of sarcomas. Qualitative data collected from 32 nonparticipators in five protocols indicated that patients' beliefs about the effects of the treatments upon their functional abilities and quality of life were the primary determinants of the decision to refuse enrolment or to withdraw from these trials. Barofsky and Sugarbaker's (1979) study, although old, highlights the need to develop quantitative

methods that would allow such data to be collected in a systematic manner that is also flexible enough to adapt to the unique characteristic of different protocols.

The limited amount of studies done in the area of attitudes of the public towards participation suggest that the concerns of participants and public need to be addressed if studies are to be successful in recruitment of adequate numbers of participants. There is a need for more research to determine if a difference between the attitudes held by those subjects who agree and those who would refuse to participate in a study. If differences do exist, this may have implications for the process of obtaining informed consent and for the generalization of the results of a clinical trial (Llewellyn-Thomas, McGreal, Thiel, Fine, & Erlichman, 1991).

Several themes recur in the literature regarding participants' perceptions of being involved in research. The most commonly cited benefit of participation in three clinical trials (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Leonard, 1994; Aby, Pheley, & Steinberg, 1995) was related to close medical follow-up and learning more about the illness and medications for treatment. Henzlova et al. (1994) and Ross, Jeffords, and Gold, (1993) concluded that the main reason given for participation was the advice received from primary care physicians. Money was the primary motivator among young participants in Phase I trial participation (Kirkpatrick, 1991). Altruism was suggested in six studies (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Leonard, 1994; Sutherland et al., 1993; Henzlova et al., 1994; Schron & Pressel, 1995; Kirkpatrick, 1991; Newburg et al., 1992; Aby et al., 1995). Souder (1992) identified eight motivators for elderly subjects:

altruism, interpersonal contact, free care motivators like documentation, second opinions, reassurance about their condition, hope, novel experiences, and scientific involvement.

Disadvantages associated with participation commonly were related to transportation and parking for clinic appointments (Mattson et al., 1985; Nasco & Leonard, 1994; Henzlova et al., 1994; Kusek et al., 1996; Schron & Pressel, 1995). Tangrea et al. (1992), however, reported that the main disadvantage of participation in a chemoprevention trial was the amount of time spent in the clinic, followed by side effects of the study drug. In each study for which investigators have asked study participants about their interest in joining future clinical trials, over two-thirds have indicated an interest (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Pressel,1994; Henzlova et al., 1994; Schron & Pressel, 1995; Ross et al., 1993; Hudmon & Kinney, 1995). This would seem to indicate that study participants enrolled in studies indicate a high level of satisfaction with regards to participation. No studies were found that related prospective studies of factors associated with enrollment, adherence, and attrition.

Attrition of Participants

Once a participant has consented to be in a study, the goal for the researcher is to retain the subject until the completion of the study. However, research populations often do not conform to the rules desired of them by researchers. For example, eligible subjects will often either decline participation in a study, or drop out once the study is under way. Sample attrition poses a problem frequently found by clinical researchers, but is rarely discussed in the literature. Attrition of subjects (those subjects who fail to complete the study following enrollment (Given, Keilman, Collins, & Given, 1990) poses a serious

problem for researchers by introducing bias (Howard, Krause, & Orlinsky, 1986; Flick, 1988). Attrition can threaten both internal and external validity (Flick, 1988; Brink & Wood, 1989; Wilson, 1989). Research methods currently detail study samples and settings. The problems being that current acceptable methods of reporting provide only part of the information needed to assess one aspect of external validity, the descriptive accuracy of the sample (Hinds et al., 1995). Descriptive accuracy is enhanced by comparing the characteristics of eligible subjects who refuse to participate with those who consent. Individuals from both groups share the characteristics that make them eligible to participate, but their choices (consent or refusal) could indicate differences that are important to the results of the study (Hinds et al., 1995). Little attention has been paid in the literature to practical methodological strategies to minimize attrition (Clinton & Beck, 1986; Flick, 1988; Given et al., 1990).

It is interesting to note that most basic research textbooks (Wilson, 1989; Shelley, 1984; Brink & Wood, 1989; Polit & Hungler, 1987) and clinical trial textbooks (Spilker, 1991) will only briefly mention that a loss of subjects from a study can be a threat to the validity of the study results. Moreover, there is an omission of the strategies to minimize this from occurring.

Wilson (1989) states, "little can be done about differential loss of subjects except to document it as a potential limitation of a study when it occurs and try to prevent it by making every ethical effort to enable willing subjects to continue participating in the study" (p. 158). Polit and Hungler (1987) state that attrition is problematic for the researcher because those who drop out of the study may differ in important respects from

the individuals who continue to participate, therefore, the generalizability of the findings may be impaired. Refusing is rarely a rejection of a study's worth or of the researcher. Refusal is more likely to occur in studies where eligible participants consider the demands, the risks, or both to outweigh the benefits and value (Hinds et al., 1995).

Only recently has there been published articles on strategies to minimize subject attrition (Given et al., 1990; Flick, 1988). Adequate preparation and supervision of data collectors is primary in maintaining subject participation. Data collectors should have skills that: 1) enhance the desire of subjects to participate, 2) reflect knowledge and importance of the study, 3) reflect excellent communication skills, and 4) demonstrate enthusiasm and commitment to the project. Given et al. (1990) believe these skills may help to reduce subject reluctance and discomfort of ongoing participation and encourage accuracy and candour in their responses (Bradburn, 1983; Collins, Given, Given, & King, 1988). Also, participants need to become committed to active participation in a study. Suggestions are to design a logo or theme to be used to establish association with a study. This logo would be used on letters, certificates, questionnaires, newsletters, and with all communication with the study participants (Flick, 1988). Questions or concerns about the credibility of the study or data collectors would therefore be limited. Subject identification with the study would serve to establish trust and credibility.

Howard et al. (1986) suggest open, ongoing communication by the researchers with subjects to enhance retention and active participation. Expectations of frequency, duration, and extent of participation should be explained to each participant at the start of

the study. Sharing these expectations enables subjects to make an informed decision about participation.

Creation of a positive interpersonal environment and rapport between the data collectors and each subject is crucial to retention (Woodward, Chambers, & Smith, 1982). Given et al. (1990) reveal that where attrition is a major problem, lack of continuity of interviews may be an issue. Continuity increases the likelihood of trust between the subject and data collectors, which can also enhance the quality and completeness of the data collected. This can be achieved by newsletters to participants outlining current information about the study, or having access and availability of the research staff to participants through a toll-free number if needed. Contacts from participants should be responded to promptly (Given et al., 1990).

Respect for participants' time and schedules minimizes attrition (Flick, 1988). Flexibility in scheduling appointments, including evenings and weekends to allow subjects to attend their appointments. Follow-up by data collectors immediately after a missed appointment conveys concern for missing an appointment and to reschedule.

Appreciation of extensive time, effort required, and positive regard for each individual needs to be conveyed to participants (Flick, 1988). Given et al. (1990) suggest to demonstrate appreciation for the participant's involvement, gifts can be given. Gifts would include coffee mugs, desk calendars, clocks, pens with the logo and theme of the project embossed on them. Given et al. (1990) suggest gifts instead of money as an incentive, as money is spent without any evidence of study participation. At the completion thank-you notes or personalized certificates of appreciation for participation

can be mailed out to the participants. Some authors discourage the use of money as a reward. Given et al. (1990) emphasized the importance of "mementoes" rather than money as appreciative gestures because mementoes are enduring, whereas money is spent quickly. However, no empirical data exist to support this view. Diekmann and Smith (1989) described payment as a incentive although the authors do not state whether payment is effective in retaining participants. Nieswiadomy (1987) believed that researchers should not give monetary compensation to research participants.

Incentives have the ability to influence a person's willingness to become involved in a study and to stay involved over an extended period of time. Diekmann and Smith (1989) examined three incentives: free heath assessment, medical care, and money. Money was seen to have the greatest influence on participation compared to intangible incentives. Money is the easiest and most widely used incentive for increasing subject recruitment and retention, and some researchers believe it increases compliance (Rudy, Estok, Kerr, & Menzel, 1994). Monetary payment of subjects is complicated by questions related to the morality of payment and to the reasonable amount of payment that subjects should receive. In experienced healthy volunteers financial reward was the main reason to participate (90%) followed by curiosity (6.3%). Financial reward was generally considered to be well balanced for inconvenience (time) and for the perceived risk (discomfort) (Bigorra & Banos, 1990). Polit and Hungler (1991) and Woods and Catanzaro (1988) stated the financially poor subject is more likely coerced with a large sum of money. The coerciveness of money should be evaluated by the researcher and the institutional review committee with regards to the context of each research study. Drawing a distinction

between money as a legitimate incentive and money as excessive persuasion is difficult (Wineman & Durand, 1992).

Psychology and marketing research has examined the importance of giving money in exchange for the research participant's time and effort to offset any inconvenience. Bellizzi and Hite (1986) found that initial face-to-face contact and a monetary incentive significantly improved retention of subjects when compared to the study that offered no incentive. The belief was that once money was accepted, subjects felt a commitment to participate. If the money was taken but the subject did not follow through, cognitive dissonance was experienced. To avoid this uncomfortable feeling, subjects participated. This was also found by Wiseman, Schafer, and Schafer (1983), which documented that shoppers were significantly more likely to complete an initial 20-minute questionnaire as well as a follow-up interview when financial incentives were given. Weltzien, McIntyre, Ernst, Walsh, and Parker (1986) reported similar results for individuals who received a questionnaire on satisfaction with mental health treatment. Thus, the combination of tangible and intangible rewards and incentives, including money, is likely to be most effective in recruiting subjects and minimizing attrition. The exact combination needs to be tailored to the particular research study (Wineman & Durand, 1992).

Large multicenter clinical trials rarely report attrition rates or explain the affect of the attrition rate of their results. There appears to be poor documentation and description in clinical trials of attrition rates. Monitoring the rates and reasons for refusals could help researchers identify systematic and random influences on study outcomes. There is also a need to develop strategies that can be used in research to minimize attrition. Although

there are strategies in the literature to improve attrition rates, these strategies have received little rigorous evaluation. Specifically, two issues lacking are the efficacy on retention of using incentives (i.e. money) to decrease attrition, and the need to evaluate behavioural strategies.

Participant Compliance

After enrollment of participants is complete, the success of a study is dependent upon the study protocol. Poor adherence affects the sensitivity of a study to detect treatment effects, and necessitates increasing the sample size, which in turn increases the cost of completing a study (Schron, Brooks, Gorkin & Kellen, 1996). Compliance is defined simply as the extent to which a subject's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with prescribed medical or health advice (Haynes, Taylor, & Sackett, 1979). The term 'adherence' may be used interchangeably with 'compliance'.

Once subjects consent to participate in a research study they must comply with the researcher's instructions by taking the recommended number of medications at the designated times, come to the clinic as directed, be cooperative and honest with the staff who are conducting the study, and adhere to all other aspects such as, avoiding certain medications, following a certain diet, or exercise program. Spilker (1991) states it is usually assumed that patients who take their study medication as prescribed are also compliant with other aspects of a protocol. It is also known that compliance decreases over time (Crammer & Russell, 1988).

Subjects who are noncompliant with the study protocol often withdraw from a clinical trial. If patients from different treatment groups withdraw from a study at variable rates, results may be affected (Spilker, 1991). Poor compliance that is undetected in a study may result in: 1) invalid results, and 2) treatment that is actually effective for certain populations (under certain condition) being labelled as ineffective, a Type II error (Spilker, 1991; Rudd, Byyny, Zachary, LoVerde, Titus, Mitchell, & Marshall, 1989).

Much research has been devoted to identifying the determinants of subject compliance. In the literature there are four main reasons for poor subject compliance (Spilker, 1991; Feinstien & Ransohoff, 1976; Eraker, Kirscht, & Becker, 1984). They include: 1) disease-related reasons which occur when few symptoms are present for a subject, such as elevated cholesterol or a terminal illness that is known to a subject, especially when accompanied by physical debilitation; 2) patient-related reasons which include forgetfulness, lack of complete belief in the value of the treatment, unpleasant taste of the medicine, size of the tablets, cost of therapy, adverse reactions, safety containers, mental illness, lack of understanding of terms used (i.e., take with meals may mean before, during, or after meals), anger at or dissatisfaction with, researcher or staff, incomplete understanding of how to be compliant with the protocol; 3) clinical trial or medical practice related reasons which include the number of pills required to ingest at each dosing, number of times a day the medicine must be taken, large number of medications prescribed, medication regimens that tend to be confusing or complex, requirements of protocol may be too painful, stressful, or demanding, long duration of therapy; and, 4) investigator-related reasons which include long time period from referral to appointment,

subject is kept waiting a long time by researcher, failure of researcher to keep the appointment, poor physician-subject relationship.

Numerous studies have attempted to identify compliers and noncompliers based on personality traits and behavior (Davis, 1968; Schwartz & Griffin, 1986), but the results of such studies are mixed and universal generalizations have not emerged. Some patient behaviors required for compliance include: visit physician or clinic, answer questions about their medical history honestly, cooperate with testing, particularly when a voluntary effort is requested, allow required tests to be performed, purchase or obtain medicines prescribed, take medicines as prescribed in terms of doses and timing, adhere to appointment schedule, and adhere to advice or requests regarding diet, exercise, relaxation, or other aspects of behavior (Davis, 1968; Schwartz & Griffin, 1986; Spilker, 1991). A recent study, the Cardiac Arrythmia Suppression Trial, (CAST) described subject characteristics that predict medication adherence after a myocardial infarction. It was found that subjects with at least a high school education, who were married, older in age (over 60) along with better mental health, had less stress, and worse physical functioning (angina or history of myocardial infarction) tended to adhere to the study protocol (Schron et al., 1996).

Strategies to Enhance Compliance

There are numerous strategies to enhance compliance in the literature, but few have been systematically assessed, and most represent a common-sense approach (Peck & King, 1982). Some of these strategies include: 1) simplifying the demands of the protocol on subjects; 2) simplifying the instructions of how to follow the protocol or how to take

the medications; 3) minimizing the number and duration of unpleasant or painful tests; 4) maintaining relatively frequent contact with subjects, contact the subject before scheduled visits; 5) providing the subject with appropriate information on the research trial and striving for a positive researcher subject relationship by having have subjects see the same researcher each time, providing positive feedback to subjects about their performance, preparing subjects for expected adverse reactions in order not to become upset and discontinue therapy; 6) planning visits at a mutually convenient time and ensuring that the subject has a minimal delay in waiting to see the researcher; 7) involving the subject's spouse, family, support group in the research study; and, 8) using informational materials in the language that the subject speaks or provide pictorial instructions (Spilker, 1991; Blackwell, 1972; Hussar, 1980; Peck & King, 1982; Morrow & Rabin, 1966).

A consequence of noncompliance is that the subject does not receive the full benefit of treatment. Another consequence involves the interpretation of findings from clinical trials (Feinstein & Ransohoff, 1976). For example, if there is only half of the research subjects taking as little as 80% of prescribed medications, there is a large increase in the number of subjects needed to show a treatment is efficacious (Goldsmith, 1979). Some investigators have proposed that clinical trials should not be published without an adequate assessment of compliance (Soutter & Kennedy, 1974). The importance of compliance in the design, analysis, and interpretation of clinical trials has only rarely been addressed in the literature. Goldsmith (1976) illustrated that incomplete compliance in clinical trials can have a substantial effect, both upon the sample size requirements for showing real differences between treatment and control groups and upon the ability to

conclude that treatments have clinically significant effects. Feinstein and Ransohoff (1976) also stated the impact of noncompliance on data analysis and the manner in which differences in compliance can affect appraisal of a therapeutic regimen's efficacy and safety.

Comparisons of clinical compliance and adherence rates in different clinical trials should be made with caution (Bell, Curb, Friedman, McIntyre, Payton-Ross, & the BHAT Research Group, 1985). Operational definitions of compliance differ between clinical trials and are often not well documented (Goldsmith, 1976). In addition, the evaluation of compliance is often neglected in the analysis of data from clinical trials (Feinstein & Ransohoff, 1976). Even in studies where reports are available, comparisons are difficult to make because of differences in research methods. There are differences in measures of adherence used as well as in definitions of the various measures (Bell et al., 1985).

Consequences to Study Outcomes

A review of the literature concerning recruitment reveals many problems. An apparent lack of published and standardized reporting regarding recruitment efforts means that potential recruitment problems are not anticipated. Documentation would greatly enhance knowledge, as well as save time and resources for future trials, and eventually facilitate obtaining solutions to many recruitment problems.

Failure to reach recruitment goals due to delays in recruitment or insufficient number of subjects being enrolled can compromise statistical power of a study and the sample size. These factors contribute to increased costs, changes in workload, and morale problems for subjects and staff. As well, decreasing the likelihood of detecting a treatment

effect, if one exists. Much of the literature reviewed suggested that it is important to accurately estimate the number of eligible, attainable participants and outline an effective recruitment plan. Careful monitoring of the recruitment process throughout the study is also needed.

Such monitoring consists of systematic documentation of the characteristics of study participants and eligible subjects who decline study participation. Otherwise, researchers are unable to assess the representativeness of their study population. Factors that are not significantly associated with enrollment provide evidence for the generalizability (external validity) of the study's results, by demonstrating that the enrolled population is representative of the recruited population with respect to the assessed factor. In contrast, if participants and eligible nonparticipants differ on factors related to the main outcomes of a trial, the external validity of the trial results will be compromised. Knowledge of systematic differences, particularly if identified prior to a study's conclusion can provide investigators with a direction for focusing recruitment efforts during the remainder of the recruitment period; to enhance generalizability, these efforts would focus on under represented groups. The need for identification of factors associated with enrollment and knowledge of reasons for not participating in a study can assist in the development of recruitment interventions.

There is confusion and little documentation, as to the point in the enrollment process when an individual becomes a participant in a research study. There is even less clarity of what characterizes a nonparticipant subject. Few studies have systematically evaluated the attitudes and perceptions of current and potential research subjects to

investigation of their views of the research purpose, importance and appropriateness of research, and their reasons for participating or not participating. As well, little information is available from the subject's point of view, on the balance between the advantages and disadvantages of study participation. Reviews of study participants in various research studies have tended to look at subject accession problems centering on the physician and study site characteristics, and only subject data on sociodemographic and disease-related factors.

Rarely discussed in the literature is the problem of sample attrition. Few researchers report sample attrition rates and few explanations are given regarding the effect of the attrition rate on the results of the study. Valuable information related to external and internal validity could be captured from the inclusion of refusal rates and reasons in research outcomes. Knowing what factors participants consider when deciding to participate or not will help researchers in making accurate projections regarding sample size and accrual time. There appears to be little attention given to strategies to minimize attrition, as well as the evaluation of such strategies.

The issue of compliance and adherence in research has also rarely been addressed in the literature. Operational definitions of compliance differ among studies. Most often, the evaluation of compliance is neglected in most research studies. This can effect the sensitivity of a study to detect a treatment effect. Compliance and adherence strategies related to research participation appear to be frequently stated in the literature, but few are systematically assessed.

In conclusion, four points will be made. First, there is a need for researchers to quantify the magnitude of nonparticipant subjects in research. Second, an opportunity to study the participant/nonparticipant subject's attitudes and perception regarding study participation arise in every research study, but is rarely done. Methods for increasing participation as well as clarifying the effect of sample bias on the generalizability of results are required. Third, while a goal of complete participation is unrealistic, a variety of techniques for decreasing attrition and increasing compliance need to be systematically assessed and further investigation done if the representativeness of sample is to be improved. Fourth, there is the need to have complete, comprehensive, and standardized reporting of all recruitment information, as well as monitoring of the recruitment process throughout the study to help facilitate obtaining solutions to many recruitment problems.

At the present time, more research is needed to broaden the understanding of the multiple factors related to enrollment in research studies. Studies of enrollment bias could be incorporated as a part of future clinical trial protocols without excessive burden to staff or participants. It is also important to strike a balance between protecting research subjects' rights and the need to advance knowledge. Public concern about confidentiality may produce increased difficulties in conducting research including that aimed at understanding the nonresponse phenomenon. The sample of a study also has important implications in judging the clinical significance of research findings.

Chapter 3

Method

A descriptive survey was used to (1) examine the participants' and nonparticipants' knowledge of clinical research; (2) elicit participants' and nonparticipants' attitudes and beliefs about clinical research; (3) describe the advantages and disadvantages of participating in clinical research; (4) identify the factors that influence the decision to either participate or not participate in clinical research; and, (5) determine the relationship of study variables to the potential future participation in clinical research of participants and nonparticipants. A review of the literature indicated little prior knowledge of the subject's point of view on the balance between the advantages and disadvantages of research participation.

Sample

Individuals who were approached to participate in Cardiology Clinical Trial/s X (Appendix A) were the convenience sample for this study. After each individual had made his/her decision to either participate or not participate in Cardiology Clinical Trial/s X, the research nurse for Cardiology Clinical Trial/s X compiled a list of potential subjects to be contacted by the investigator. The investigator remained blinded to the decision as to whether the individual decided to participate or not participate in Cardiology Clinical Trial/s X.

Instrument

Data were collected by means of the survey questionnaire, "Perceptions of Participation in Clinical Research" (PPCR) (Appendix C). The questionnaire was

developed based on current clinical experience, the Canadian Nurses Association (CNA) ethical guidelines for nursing research (1994), and a review of the literature. Questions were based on information in the literature that was identified as being important to the topic of subject participation/nonparticipation in clinical trials. The items in the PPCR are related to factors of participation and nonparticipation in clinical trials and are separated into areas of knowledge, beliefs and attitudes, advantages and disadvantages, factors of influence and demographic data. The first section is comprised of 22 items which address subjects' knowledge of clinical trials by using a false/true/unsure response set. The second section consists of 21 items which address the subjects' beliefs and attitudes of clinical trials by using a Likert scale ranging from (1) strongly disagree to (5) strongly agree. The third section is comprised of two open-ended questions and 24 items which address the subjects' perceived advantages and disadvantages of participating or not participating in a clinical trial by using a Likert scale ranging from (1) very much a disadvantage to (5) very much an advantage. Section four is comprised of six open and closed-ended questions that pertains to the subjects' current and past involvement in clinical trials. Section five is comprised of 17 questions which address influencing factors of participation. The final section includes 11 items related to personal demographic characteristics of the respondents.

Content Validity of the PPCR

Prior to use of the PPCR questionnaire in this study, content validity was assessed through the use of a panel of judges. Ten experts in the field of clinical research and questionnaire development were used as experts to review the questionnaire for relevance,

completeness, conciseness, and clarity. A peer group of ten Master of Nursing graduate students also reviewed the questionnaire for clarity and relevance. Following the feedback of the expert panel and subsequent revision of the questionnaire, a pilot study was conducted with a convenience sample of 20 subjects recruited from Cardiology Clinical Trial/s X. Following return of the questionnaire, it was reviewed and only minor revisions to the questionnaire were required at this time. The revisions included minor changes being made to the format of the questionnaire and changing some open ended questions to categorical questions.

Data Collection Procedure

The investigator obtained the names of potential subjects from the research nurse/s of Cardiology Clinical Trial/s X. Within 24 hours of the subject's decision to participate or not participate in Cardiology Clinical Trial/s X, the investigator approached potential subjects and provided them with a letter of introduction (Appendix B). The study was then explained to them. A package containing a covering letter, the questionnaire, and a return addressed stamped envelope was then given to each subject. The investigator then completed a follow-up telephone call within one week of contacting the subject.

Data Analysis

Descriptive statistics deemed appropriate to the level of measurement for the structured items of the PPCR were calculated. For example, mean, median, range and standard deviation were calculated for interval-ratio level data, while mode and relative frequencies were calculated for ordinal and nominal data. A number of variables were

collapsed into categorical variables for further analysis. The statistical analysis of the data was conducted utilizing the SPSS (Version 7.5) software program.

Although the primary purpose of the study was descriptive in nature, tests of association were also conducted to identify factors influencing subjects' participation or nonparticipation in clinical research. This was done recognizing the limitations imposed by unequal numbers of participant versus nonparticipant subjects. The subjects' knowledge of clinical research and characteristics of participants and nonparticipants was analyzed using chi-square. An independent t-test was used to compare the attitudes and beliefs about clinical research, the perceived advantages and disadvantages of participating, and the influencing factors of participating for participants and nonparticipants. When the assumptions of the t-distribution were unable to be met, the nonparametric Mann-Whitney U test was used.

Ethical Considerations

Support to contact subjects was obtained from the Principal Investigator/s of Cardiology Clinical Trial/s X and the Divisions of Cardiology at the University of Alberta Hospital and the Royal Alexandra Hospital. Ethical approval was obtained from the Faculty of Nursing, Faculty of Medicine, and the Capital Health Region.

Participation in the study was voluntary. The study was in no way connected with Cardiology Clinical Trial/s X. Subjects' consent was implied with the return of a completed questionnaire. All subjects were advised that they could ask questions or raise concerns about the study at any time and that these would be answered by the investigator. The investigator's credentials and a contact phone number were provided to

the subjects. It was made clear that participation was voluntary and that the subject could withdraw at any time without penalty. In no situation was the study protocol allowed to interfere with patient care delivery. If this potential was identified, the investigator would withdraw immediately, and the subject would be withdrawn from the study.

To maintain confidentiality, no names were used, instead code numbers were assigned and any identifying information was deleted. Data were kept in a locked file accessible only to the researcher and destroyed seven years after the study is completed. Participants were advised that no names were used in the data analysis or discussion of the findings. Participants were assured that any reports, publications, or presentations of findings would not reveal their personal identity. Participants would be informed of the results of the study if desired. If the data is used in secondary analysis, ethical clearance will first be sought from the appropriate ethical review committee.

Chapter 4

Findings

The purpose of this descriptive survey was to gain an understanding of the knowledge, attitudes, and beliefs that underlie decisions of individuals to either participate or not participate in clinical research. Information regarding the subjects' perceived advantages and disadvantages, and the factors associated with participation or nonparticipation in clinical research, as well as the relationships between these perceptions to reported interest in future clinical research participation were examined.

Subjects' responses were tabulated and analyzed using the Statistical Package for Social Sciences (Version 7.5) software program. Data were analyzed using descriptive statistics. Frequencies of responses (means, medians, modes, percentages), ranges, and standard deviations were calculated for each item of the Perceptions of Participation in Clinical Research (PPCR) questionnaire. An independent t-test, chi-square, or Mann Whitney U test were done to compare the attitudes and beliefs about clinical research, the perceived advantages and disadvantages of participation, and the factors influencing participation between participant subjects and nonparticipant subjects. The level of significance was set at ≤ 0.05.

Characteristics of the Respondents

There were 152 respondents to the PPCR questionnaire. A total of 200 questionnaires were mailed out. This provided an overall response rate of 76 percent. Of the 152 respondents, 123 were participants and 29 were nonparticipants in Cardiology Clinical Trial/s X (Appendix A) during May through September, 1997. The participant

subjects had a response rate of 80.4% (123/153), while the nonparticipant subjects had a response rate of 62% (29/47). Seven cardiology trials generated the participant and nonparticipant subjects (see Table 1).

Table 1

Distribution of Respondents from Cardiology Clinical Trial/s X

Name of Study	N	Percent (%)
Evaluation of the safety/tolerability of long-term treatment with the DMP inhibitor BMS 186716 or Lisinopril in subjects with heart failure.	6	3.9
A phase III randomized comparative trial of Hirudin versus Heparin and Warfarin versus standard therapy for acute myocardial ischemia without ST elevation (OASIS-2).	7	4.6
A multicenter trial evaluating 30 day and 6 month clinical outcomes with three different treatment strategies in patients undergoing coronary intervention (EPILOG STENT).	22	14.5
Canadian trial of atrial fibrillation (CTAF).	18	11.8
Comparison of blood pressure profile of the 18-24 hour period after intake of Telmisartan, Losartan, and a placebo, by ambulatory blood pressure measurement (ABPM) in mild to moderate hypertensive patients.	41	27.0
A three-way, single-dose, fasted and food-effect bioavailability study of Sotalol Hydrochloride tablets (160 mg) versus Betapace (160 mg) in males.	51	33.6
Antiplatelet aggregation useful dose study (APLAUD).	7	4.6

The majority of the total respondents were male (76.8%), Caucasian (87.2%), and married (53.7%). Twenty percent of the sample were aged 18-24 years, 20.1% percent were aged 55-64 years, and 17.4% were aged 65-74 years. The educational background varied: 23.8% (n = 35) had high school, 23.1% (n = 34) had college, trade or technical school, and 19.0% (n = 28) had some university (see Table 2).

Table 2

Total Respondents' Demographic Characteristics-I

Characteristics	N	Percent (%)
Gender	N = 151	
male	116	76.8
female	35	23.2
Ethnicity	N = 148	
Caucasian	129	87.2
Native Canadian	10	6.8
Latin Canadian	1	0.7
South Asian	3	2.0
Chinese	3	2.0
Jamaican	1	0.7
Korean	1	0.7
Marital Status	N = 149	
widowed	6	4.0
divorced	7	4.7
separated	3	2.0
never married	53	35.6
married (includes common law)	80	53.7
Age	N = 149	
18-24 years	30	20.1
25-34 years	23	15.4
35-44 years	13	8.7
45-54 years	19	12.8
55-64 years	30	20.1
65-74 years	26	17.4
75-84 years	8	5.4
Highest Level of Education	N = 147	
elementary school	7	4.8
junior high school	7	4.4
high school	35	23.8
college/trade/ technical school	34	23.1
university (some)	28	19.0
bachelor degree	23	15.6
master degree	9	6.1
doctorate degree	4	2.7

Thirty-five percent of the total respondents ($\underline{n}$ = 52) were employed full-time and 28.0% ($\underline{n}$ = 42) were retired. Seventeen percent of the respondents (n = 24) were employed in technical/skilled trades, 13.6% ($\underline{n}$ = 20) were in clerical/sales/service areas, and 13.6% ($\underline{n}$ = 20) were students. Of the respondents, 31.7% ($\underline{n}$ = 46) reported a net family income of < $20,000, and 31.7 % ($\underline{n}$ = 46) reported a net family income between $20,000 - $39,000. The majority of the sample (69.3%) were living in a large city (population > 100,000). Forty-one percent ($\underline{n}$ = 61) of the respondents were presently living with their spouse, 18.1% ($\underline{n}$ = 27) were living alone, and 12.1% ($\underline{n}$ = 18) were living with their spouse and children (see Table 3).

Participant and Nonparticipant Subject Characteristics

The majority of participant subjects were male (74%), Caucasian (85.8%), and married (56.7%), whereas the majority of nonparticipant subjects were male (86.2%), Caucasian (92.9%), and never married (51.7%). No statistically significant difference was found between the participant and nonparticipant subjects with regards to gender, ethnicity, and marital status. However, a significant difference was noted with whom the participant and nonparticipant subjects lived. Of the participant subjects, 46.3% lived with their spouse, while 42.9% of the nonparticipant subjects lived with someone other than their spouse or their children, or lived alone (25%) (χ^2 = 7.87, $\underline{p}$ = 0.05). The participant subjects were evenly distributed among the age categories of 18-44 years of age (39.2%), 45-64 years of age (34.2%), and 65 and older (26.7%). The majority of nonparticipant subjects were aged 18-44 years (65.5%) ($\underline{U}$ = 1208.5, $\underline{p}$ = 0.01) (see Table 4).

Table 3

Total Respondents' Demographic Characteristics-II

Characteristics	N	Percent (%)
Present Employment Status	N = 150	
full-time	52	34.7
part-time	27	18.0
retired	42	28.0
not employed (compensation/injury)	4	2.7
not employed (unable to find work)	15	10.0
homemaker	1	0.7
student	9	6.0
Occupation	N = 147	
homemaker	8	5.4
student	20	13.6
laborer/construction	16	10.9
skilled trade/technician	24	16.3
clerical/service/sales	20	13.6
farming/horticultural	7	4.8
arts/sports/recreation	2	1.4
managerial/administrative	22	15.0
health care occupations	5	3.4
teaching & related fields	10	6.8
natural sciences/engineering	7	4.8
occupation in religion	2	1.4
occupation in law	3	2.0
other	1	7.0
Net Family Income	N = 145	
< $20,000	46	31.7
$20,000 - $39,000	46	31.7
$40,000 - $59,000	32	22.1
$60,000 - $99,000	12	8.3
$100,000 and over	9	6.2
Living Where	N = 150	
large city (population > 100,000)	104	69.3
city (population < 100,000)	20	13.3
town (population > 3,000)	10	6.7
village (population < 3,000)	5	3.3
rural/farm	7	4.7
acreage	4	2.7
Living With	N = 149	
spouse	61	40.9
spouse and children	18	12.1
alone	27	18.1
other	43	28.9

Table 4

Participant and Nonparticipant Subjects' Demographic Characteristics

Characteristics	Participant	Percent (%)	Nonparticipant	Percent (%)
Gender	N = 122		N = 29	
male	91	74.6	25	86.2
female	31	25.4	4	13.8
Ethnicity	N = 120		N = 28	
Caucasian	103	85.8	26	92.9
Native Canadian	9	7.5	1	3.6
Latin Canadian	1	0.8	0	0.0
South Asian	3	2.5	0	0.0
Chinese	3	2.5	0	0.0
Jamaican	1	0.8	0	0.0
Korean	0	0.0	1	3.6
Marital Status	N = 120		N = 29	
widowed	5	4.2	1	3.4
divorced	7	5.8	0	0.0
separated	2	1.7	1	3.4
never married	38	31.7	15	51.7
married (includes common law)	68	56.7	12	41.4
Living With*	N = 121		N = 28	
spouse	56	46.3	5	17.9
spouse & children	14	11.6	4	14.3
alone	20	16.5	7	25.0
other	31	25.6	19	42.8
Age*	N = 120		N = 29	
18-44 years	47	39.2	19	65.5
45-64 years	41	34.2	8	27.6
65- older	32	26.7	2	6.9

* $p \leq 0.05$

The participant subjects had a diverse range of educational backgrounds: high school education (24.6%), college, trade, or technical school (23.1%), and some university (19.0%). The nonparticipant subjects' educational background varied as well: some nonparticipant subjects had a bachelor degree (31%), others had college, trade, or technical school (24.1%), and some had high school (20.7%). The participant subjects reported being employed in the technical/skilled trades (16.1%), managerial or administration (14.4%), and clerical/sales/service areas (14.4%). The nonparticipant subjects reported a variety of occupations: student (27.6%), managerial or administration (17.2%), and skilled trade or technician (17.2 %). There were no significant differences noted with regards to education level or occupation between the participant and nonparticipant subjects. There was a statistically significant difference found in regards to present employment status. The participant subjects were retired (33.1%), while the nonparticipant subjects were working predominantly full-time (51.7%) (χ^2= 8.91, $\underline{p}$ = 0.03) (see Table 5).

Thirty-four percent ($\underline{n}$ = 40) of the participant subjects had a net family income of $20,000 - $39,000. Nine nonparticipant subjects (32.1%) reported a net family income of < $20,000 and 9 (32.1%) reported a net family income between $40,000 - $59,000. Most participant subjects (66.1%) and nonparticipant subjects (82.8%) were living in a large city (population > 100,000). There were no significant differences noted between the participant and nonparticipant subjects with regards to net income or where they lived (see Table 6).

Table 5

Participant and Nonparticipant Subjects' Level of Education, Occupation, and Employment Status

Characteristic	Participant	Percent (%)	Nonparticipant	Percent (%)
Highest Level of Education	N = 118		N = 29	
elementary school	7	5.9	0	0.0
junior high school	5	4.2	2	6.9
high school	29	24.6	6	20.7
college/trade/technical	27	22.9	7	24.1
university (some)	24	20.3	4	13.8
bachelor degree	14	11.9	9	31.0
master degree	9	7.6	0	0.0
doctorate degree	3	2.5	1	3.4
Occupation	N = 118		N = 29	
homemaker	7	5.9	1	3.4
student	12	10.2	8	27.6
laborer/construction	14	11.9	2	6.9
skilled trade/technician	19	16.1	5	17.2
clerical/service/sales	17	14.4	3	10.3
farming/horticultural	7	5.9	0	0.0
arts/sports/recreation	2	1.7	0	0.0
managerial/ administrative	17	14.4	5	17.2
health care occupations	2	1.7	3	10.3
teaching & related fields	9	7.6	1	3.4
natural sciences/ engineering	7	5.9	0	0.0
occupation in religion	2	1.7	0	0.0
occupation in law	2	1.7	1	3.4
other	1	0.8	0	0.0
Employment Status*	N = 121		N = 29	
full-time	37	30.6	15	51.7
part-time	21	17.4	6	20.7
retired	40	33.1	2	6.9
not employed/ student/homemaker	23	19.0	6	20.7

*$p \leq 0.05$

Table 6

Participant and Nonparticipant Subjects' Net Family Income and Where They Lived

Characteristics	Participant	Percent (%)	Nonparticipant	Percent (%)
Net Family Income	N = 117		N = 28	
< $20,000	37	31.6	9	32.1
$20,000 - $39,000	40	34.2	6	21.4
$40,000 - $59,000	23	19.7	9	32.1
$60,000 - $99,000	8	6.8	4	14.3
$100,000 and over	9	7.7	0	0.0
Living Where	N = 121		N = 29	
large city (pop. >100,000)	80	66.1	24	82.8
city (pop. <100,000)	17	14.0	3	10.3
town (pop.>3,000)	9	7.4	1	3.4
village (pop. <3,000)	5	4.1	0	0.0
rural/farm	7	5.8	0	0.0
acreage	3	2.5	1	3.4

Knowledge of Clinical Research

Knowledge of clinical research was obtained by asking subjects to respond to 22 items of the PPCR using a false/true/unsure scale (see Table 7). When analyzing the participant and nonparticipant subjects' responses, it was noted that the participant subjects responded to the knowledge items of the PPCR in a similar fashion as did the total respondents. The nonparticipant subjects answered similarly to the total respondents with exception to 3 statements (see Table 8 and Table 9).

Ninety-eight percent (n = 149) of the total respondents' knew that every subject should be told about the possible risks and benefits of taking part in clinical research. Ninety-eight percent (n = 120) of the participant subjects and 100% (n = 29) of the

nonparticipant subjects thought that every subject should be told about the possible risks and benefits of taking part in clinical research. Ninety-seven percent (n = 148) of the total respondents understood that it was the subjects' right to refuse to participate in clinical research. Ninety-seven percent (n = 119) of the participant subjects and 100% (n = 29) of the nonparticipant subjects thought that it was the subjects' right to refuse to participate in clinical research. One hundred and forty-five (96%) respondents knew that it was the subjects' right to be made aware of any possible complications or side effects of taking part in clinical research. One hundred and sixteen (95.1%) of the participant subjects and 29 (100%) of the nonparticipant subjects knew that it was the subjects' right to be made aware of any possible complications or side effects of taking part in clinical research. There were no statistically significant differences noted between the participant and nonparticipant subjects.

Ninety-five percent (n = 145) of the respondents understood that clinical research was needed to study the effects of treatments. Ninety-five percent (n = 117) of the participant subjects and 96% (n = 28) of the nonparticipant subjects thought that clinical research is needed to study the effects of treatments. One hundred and forty-three (94.1%) of the total respondents understood that subjects have the right to receive all information that they need to decide whether they want to take part in clinical research. One hundred and sixteen (94.3%) of the participant subjects and 27 (93.1%) of the nonparticipant subjects understood that subjects have the right to receive all information needed to decide whether they want to take part in clinical research. Ninety-two percent (n = 140) of the

total respondents knew that it was the subjects' right to change their mind at any time and to withdraw from clinical research. Ninety-three percent ($\underline{n}$ = 114) of the participant subjects and 89.7% ($\underline{n}$ = 26) of the nonparticipant subjects knew that it was the subjects' right to change their mind at any time and to withdraw from clinical research.

Ninety-one percent of the total respondents understood that being in clinical research involved risks. Ninety-one percent of the participant subjects and 100% ($\underline{n}$ = 29) of the nonparticipant subjects understood that being in clinical research had many risks. One hundred and thirty-eight (90.8%) of the total respondents understood that subjects' have the right keep their participation in clinical research confidential. One hundred and thirteen (91.9%) of the participant subjects and 25 (86.2%) of the nonparticipant subjects understood that subjects' have the right to have their participation in clinical research kept confidential. No statistically significant differences were found between the participant and nonparticipant subjects on the above noted knowledge items.

More than 75% of the total respondents understood that: (1) there may not be a direct benefit to participating in clinical research (participant $\underline{n}$ = 108, nonparticipant $\underline{n}$ = 25), (2) subjects would be protected from mental, emotional, moral, and physical injury (participant $\underline{n}$ = 96, nonparticipant $\underline{n}$ = 25), (3) subjects' have the right to know the purpose of clinical research (participant $\underline{n}$ =92, nonparticipant $\underline{n}$ = 22), (4) the purpose of the written informed consent form was to help subjects' to decide whether or not they would participate (participant $\underline{n}$ = 92, nonparticipant $\underline{n}$ = 22), (5) some subjects who participated in clinical research would be in a "placebo" treatment group (participant

n = 91, nonparticipant n = 27), and, (6) only certain individuals would be asked to participate in clinical research (participant n = 90, nonparticipant n = 25). There were no statistically significant differences noted between the participant and nonparticipant subjects on these knowledge items.

Less than 70% of the participant and nonparticipant subjects understood that: (1) a researcher could not use or release information that was not described in the consent form (participant n = 87, nonparticipant n = 17), (2) subjects are given an equal chance of being in the research treatment group or 'placebo' treatment group (participant n = 70, nonparticipant n = 21), and, (3) subjects are informed when clinical research requires information to be withheld (participant n = 59, nonparticipant n = 13). No statistically significant differences were found between the participant and nonparticipant subjects on these knowledge items.

The majority of the total respondents (70.9%) did not think that they were told to which treatment group they were assigned, and that a subject in clinical research needed to be able to speak and read English (44.1%). Both the participant and nonparticipant subjects understood that subjects were not told to which treatment group they were assigned (participants n = 83, nonparticipants n = 24), and that a subject in clinical research needed to be able to speak and read English (participant n = 49, nonparticipant n = 18). Of the participant subjects, 48.4% (n = 59) knew that the consent form for clinical research protects the researcher from legal action, while 41.4% (n = 12) of the nonparticipant subjects did not. Fifty-two participant subjects (43%) understood that the consent form for clinical research protects the hospital from legal liability, while 12

(41.4%) of the nonparticipant subjects understood this statement to be false. None of these items were noted to have statistically significant differences between the participant and nonparticipant subjects.

Forty percent ($\underline{n}$ = 61) of the respondents were unsure as to whether subjects would be told about the results of clinical research. Of the participant subjects, 40.2% ($\underline{n}$ = 122) were unsure as to whether subjects would be told about the results of clinical research, while 55.2% ($\underline{n}$ = 16) of the nonparticipant subjects did not believe that subjects would be told about the results of the research (χ^2 = 7.97, $\underline{p}$ = 0.02).

Table 7

Total Respondents' Knowledge of Clinical Research

	Responses			N	Frequencies (%)			Mode
Knowledge Statements	**F**	**T**	**U**		**F**	**T**	**U**	
The consent form for a clinical trial protects the researcher from any legal action.	43	68	40	151	28.5	45.0	26.5	2
Subjects have the right to receive all information that they need to decide whether they want to take part in the clinical trial.	4	143	5	152	2.6	94.1	3.3	2
The purpose of the written informed consent form is to help subjects to decide whether or not they will participate in a clinical trial.	25	114	13	152	16.4	75.0	8.6	2
It is the subjects' right to refuse to participate in a clinical trial.	4	148	0	152	2.6	97.4	0.0	2
The consent form for a clinical trial protects the hospital from any legal liability.	44	58	48	150	29.3	38.7	32.0	2
It is the subjects' right to change their mind at any time and to withdraw from a clinical trial.	5	140	7	152	3.3	92.1	4.6	2
Being in a clinical trial may have risks.	5	139	8	152	3.3	91.4	5.3	2
It is the subjects' right to be made aware of any possible complications or side effects of taking part in a clinical trial.	1	145	5	151	.7	96.0	3.3	2
A subject in a clinical trial must be able to speak and read English.	67	37	48	152	44.1	24.3	31.6	1
It is the subjects' right to have their participation in a clinical trial kept confidential.	4	138	10	152	2.6	90.8	6.6	2
Every subject should be told about the possible risks and benefits of taking part in a clinical trial.	149	3	0	152	2.0	98.0	0.0	2
It is the subjects' right to know the purpose of the clinical trial.	7	131	14	152	4.6	86.2	9.2	2
Subjects are informed when a clinical trial requires information to be withheld.	12	72	68	152	7.9	47.4	44.7	2
A researcher cannot use or release information that is not described in the consent form.	12	104	35	151	7.9	68.9	23.2	2
Subjects in a clinical trial must be protected from mental, emotional, moral, and physical injury.	14	121	17	152	9.2	79.6	11.2	2
Some subjects who participate in a clinical trial will be in a "placebo" treatment group.	7	118	26	151	4.6	78.1	17.2	2
There may not be a direct benefit to the subject from participating in a clinical trial.	8	133	9	150	5.3	88.7	6.0	2
Subjects are given equal chance of being in the research treatment group or "placebo" treatment group.	27	91	34	152	17.8	59.9	22.4	2
Subjects will be told about the results of the clinical trial.	58	32	61	151	38.4	21.2	40.4	3
Clinical trials are needed to study the effects of treatments.	1	145	6	152	.7	95.4	3.9	2
Only certain individuals are asked to participate in a clinical trial.	18	115	19	152	11.8	75.7	12.5	2
Subjects are told which treatment group they are assigned.	107	31	13	151	70.9	20.5	8.6	1

Note. F = False T = True U = Unsure

Table 8

Participant Subjects' Knowledge of Clinical Research

Participants		Responses			Frequencies (%)			Mode
Knowledge Statements	N	F	T	U	F	T	U	
The consent form for a clinical trial protects the researcher from any legal action.	122	31	59	32	25.4	48.4	26.2	2
Subjects have the right to receive all information that they need to decide whether they want to take part in the clinical trial.	123	3	116	4	2.4	94.3	3.3	2
The purpose of the written informed consent form is to help subjects to decide whether or not they will participate in a clinical trial.	123	19	92	12	15.4	74.8	9.8	2
It is the subjects' right to refuse to participate in a clinical trial.	123	4	119	0	3.3	96.7	0.0	2
The consent form for a clinical trial protects the hospital from any legal liability.	121	32	52	37	26.4	43.0	30.6	2
It is the subjects' right to change their mind at any time and to withdraw from a clinical trial.	123	4	114	5	3.3	92.7	4.1	2
Being in a clinical trial may have risks.	123	4	112	7	3.3	91.1	5.7	2
It is the subjects' right to be made aware of any possible complications or side effects of taking part in a clinical trial.	122	1	116	5	0.8	95.1	4.1	2
A subject in a clinical trial must be able to speak and read English.	123	49	31	43	39.8	25.2	35.0	1
It is the subjects' right to have their participation in a clinical trial kept confidential.	123	3	113	7	2.4	91.9	5.7	2
Every subject should be told about the possible risks and benefits of taking part in a clinical trial.	123	0	120	3	0.0	97.6	2.4	2
It is the subjects' right to know the purpose of the clinical trial.	123	4	107	12	3.3	87.0	9.8	2
Subjects are informed when a clinical trial requires information to be withheld.	123	8	59	56	6.5	48.0	45.5	2
A researcher cannot use or release information that is not described in the consent form.	122	9	87	26	7.3	70.7	21.1	2
Subjects in a clinical trial must be protected from mental, emotional, moral, and physical injury.	123	12	96	15	9.8	78.0	12.2	2
Some subjects who participate in a clinical trial will be in a "placebo" treatment group.	122	6	91	25	4.9	74.6	20.5	2
There may not be a direct benefit to the subject from participating in a clinical trial.	121	5	108	8	4.1	89.3	6.6	2
Subjects are given equal chance of being in the research treatment group or "placebo" treatment group.	123	24	70	29	19.5	56.9	23.6	2
Subjects will be told about the results of the clinical trial.*	122	42	31	49	34.4	25.4	40.2	3
Clinical trials are needed to study the effects of treatments.	123	1	117	5	0.8	95.1	4.1	2
Only certain individuals are asked to participate in a clinical trial.	123	16	90	17	13.0	73.2	13.8	2
Subjects are told which treatment group they are assigned.	122	83	29	10	68.0	23.8	8.2	1

Note. F = False T = True U = Unsure

* $p \leq 0.05$

Table 9

Nonparticipant Subjects' Knowledge of Clinical Research

Nonparticipants N = 29	Responses			Frequencies (%)			Mode
Knowledge Statements	**F**	**T**	**U**	**F**	**T**	**U**	
The consent form for a clinical trial protects the researcher from any legal action.	12	9	8	41.4	31.0	27.6	1
Subjects have the right to receive all information that they need to decide whether they want to take part in the clinical trial.	1	27	1	3.4	93.1	3.4	2
The purpose of the written informed consent form is to help subjects to decide whether or not they will participate in a clinical trial.	6	22	1	20.7	75.9	3.4	2
It is the subjects' right to refuse to participate in a clinical trial.	0	29	0	0.0	100	0.0	2
The consent form for a clinical trial protects the hospital from any legal liability.	12	6	11	41.4	20.7	37.9	1
It is the subjects' right to change their mind at any time and to withdraw from a clinical trial.	1	26	2	3.4	89.7	6.9	2
Being in a clinical trial may have risks.	1	27	1	3.4	93.1	3.4	2
It is the subjects' right to be made aware of any possible complications or side effects of taking part in a clinical trial.	0	29	0	0.0	100	0.0	2
A subject in a clinical trial must be able to speak and read English.	18	6	5	62.1	20.7	17.2	1
It is the subjects' right to have their participation in a clinical trial kept confidential.	1	25	3	3.4	86.2	10.3	2
Every subject should be told about the possible risks and benefits of taking part in a clinical trial.	0	29	0	0.0	100	0.0	2
It is the subjects' right to know the purpose of the clinical trial.	3	24	2	10.3	82.8	6.9	2
Subjects are informed when a clinical trial requires information to be withheld.	4	13	12	13.8	44.8	41.4	2
A researcher cannot use or release information that is not described in the consent form.	3	17	9	10.3	58.6	31.0	2
Subjects in a clinical trial must be protected from mental, emotional, moral, and physical injury.	2	25	2	6.9	86.2	6.9	2
Some subjects who participate in a clinical trial will be in a "placebo" treatment group.	1	27	1	3.4	93.1	3.4	2
There may not be a direct benefit to the subject from participating in a clinical trial.	3	25	1	10.3	86.2	3.4	2
Subjects are given equal chance of being in the research treatment group or "placebo" treatment group.	3	21	5	10.3	72.4	17.2	2
Subjects will be told about the results of the clinical trial. *	16	1	12	55.2	3.4	41.4	1
Clinical trials are needed to study the effects of treatments.	0	28	1	0.0	96.6	3.4	2
Only certain individuals are asked to participate in a clinical trial.	2	25	2	6.9	86.2	6.9	2
Subjects are told which treatment group they are assigned.	24	2	3	82.8	6.9	10.3	1

Note. F = False T = True U = Unsure

* $p \leq 0.05$

Attitudes and Beliefs Towards Clinical Research

Respondents' attitudes and beliefs regarding clinical research were obtained through 21 items, using a five-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neither agree/disagree, 4 = agree, and, 5 = strongly agree) (see Table 10). When summarizing the participant and nonparticipant subjects responses, it was noted that the participant subjects' responses were similar to the total respondents, while the nonparticipant subjects responded differently to 2 statements (see Table 11 and Table 12).

Ninety-nine percent of the total respondents (n = 150) agreed that subjects have the right not to take part in clinical research. Ninety-nine percent (n = 121) of the participant subjects and 100% (n = 29) of the nonparticipant subjects agreed that subjects have the right not to take part in clinical research. Ninety-five percent (n = 145) of the respondents believed that clinical research was a necessary way to learn about new treatments. Ninety-seven percent (n = 119) of the participant subjects and 89.6% (n = 26) of the nonparticipant subjects believed that clinical research was a necessary way to learn about new treatments. One hundred forty-five (95.4%) of the total respondents considered participation in clinical research to be voluntary. One hundred and seventeen (95.1%) of the participant subjects and 28 (96.6%) of the nonparticipation subjects considered participation in clinical research to be voluntary. Eighty-eight percent (n = 132) of the total respondents believed that information in the consent form was important in helping subjects to decide about participation in clinical research. Eighty-six percent (n = 106) of the participant subjects and 89.6% (n = 26) of the nonparticipant subjects believed that information in the consent form was important in helping to decide about participation

in clinical research. One hundred and twenty-six (84%) of the respondents agreed that subjects' information should be kept confidential. One hundred and three (85.2%) of the participant subjects and 23 (79.3%) of the nonparticipant subjects agreed that subjects' information should be kept confidential. Eighty-four percent (n = 126) of the total respondents believed that they knew what clinical research was about. Eighty-six percent (n =104) of the participant subjects and 75.8% (n = 22) of the nonparticipant subjects believed that they knew what clinical research was about. No statistically significant differences were noted between the participant and nonparticipant subjects on the above attitude and belief items.

Less than 80% of the total respondents agreed that: (1) a subject may not get any benefit from participating in clinical research (participant n = 98, nonparticipant n = 22), (2) it is important for people to take part in clinical research (participant n = 92, nonparticipant n = 19), (3) consent forms are legal forms that protect the physician (participant n = 82, nonparticipant n = 17), (4) taking part in clinical research may expose subjects to harmful side effects or complications (participants n = 79, nonparticipants n = 18), and, (5) subjects have a 50-50 chance of being in the 'placebo' treatment group (participant n = 71, nonparticipant n = 18). There was no statistically significant differences noted between the participant and nonparticipant subjects on these items.

Eighty-five percent (n = 128) of the total sample disagreed that refusing to participate in clinical research affects one's future medical care. Eighty-four percent of the participant subjects (n = 101) and 93% (n = 27) of the nonparticipant subjects disagreed that refusing to participate in clinical research affects one's future medical care (t = 2.10, p

= 0.04). Seventy-six percent (n = 116) of the total respondents did not believe that once a subject began a clinical study, it would become difficult to withdraw. Seventy-eight percent (n = 96) of the participant and 69% (n = 20) of the nonparticipant subjects did not believe that once subjects begin clinical research, it was difficult to withdraw. Ninety-six (70.7%) of the total respondents disagreed with the statement that subjects do not believe what the researcher tells them. Sixty-nine percent (n = 74) of the participant subjects and 75.8% (n = 22) of the nonparticipant subjects disagreed with the statement that subjects do not believe what the researcher tells them. Fifty-one percent (n = 77) of the total respondents disagreed that the researcher often tries to persuade people to take part in clinical research. Sixty-two (50.8%) of the participant subjects and 15 (51.7%) of the nonparticipant subjects disagreed that the researcher often tries to persuade people to take part in clinical research. Sixty-eight (44.8%) of the subjects did not believe in the researcher always knowing what treatment subjects were receiving. Forty-six percent (n = 56) of the participant subjects and 41.4% (n = 12) nonparticipant subjects did not agree that the researcher always knew what treatment subjects were receiving.

There were 3 statements to which the respondents were neutral. First, fifty-one percent (n = 77) of the total respondents did not agree or disagree as to whether subjects who take part in clinical research hear the results. Fifty-one percent (n = 63) of the participant subjects and 48.3% (n = 14) of the nonparticipant subjects did not agree or disagree as to whether subjects who take part in clinical research hear the results. This

item was not found to be statistically significant between the participant and nonparticipant subjects.

Second, of the total respondents, 43.7% (n = 66) were unsure as to whether to agree or disagree with the statement that subjects who participate in clinical research receive the newest treatment. Fifty-six participant subjects (45.9%) were unsure as to whether subjects who participate in clinical research receive the newest treatment, whereas 14 (41.4%) of the nonparticipant subjects disagreed with this statement (t = 2.18, p = 0.03). Participant subjects were unsure or undecided as to whether subjects who participate in clinical research receive the newest treatment as compared to nonparticipant subjects.

Third, forty-one percent (n = 62) of the total respondents did not agree or disagree as to whether family members supported subjects participating in clinical research. Fifty-two of the participant subjects (43%) agreed with the statement that family members supported subjects in participating in clinical research, whereas, 11(37.9%) of the nonparticipant subjects were unsure as to whether to agree or disagree with the statement (t = 2.10, p = 0.04). Participant subjects were more likely to agree with the statement that family members supported subjects participation in clinical research as compared to the nonparticipant subjects, who disagreed that family members supported subjects participation in clinical research.

There were 2 statements with which the participant and nonparticipant subjects were of differing opinions. Forty-two percent (n = 64) of the total respondents did not agree that participation in clinical research takes alot of time. It was the participant

subjects' (n = 59) belief that participating in clinical research took alot of time, while the nonparticipant subjects (n = 14) disagreed (t = - 3.23, p = 0.002).

Furthermore, 45 % (n = 69) of the total respondents agreed that physicians encourage their patients to take part in clinical research. Forty-nine percent of the participant subjects (n = 60) generally agreed that the physicians may encourage their patients to take part in clinical research, whereas 36% of the nonparticipant subjects (n = 10) were undecided as to whether physicians encourage patients to take part in clinical research (t = 2.39, p = 0.02). Thus, participant subjects were more likely to agree that physicians may encourage their patients to take part in clinical research than nonparticipant subjects.

Table 10

Total Respondents' Attitudes and Beliefs of Clinical Research

Statement	SD (1)	D (2)	N A/D (3)	A (4)	SA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
I know what a clinical trial is about	1	5	18	98	28	150	3.98	4	4	0.71
The researcher always knows what treatment subjects are receiving.	22	46	18	41	25	152	3.01	3	2	1.35
Clinical trials are a necessary way to learn about new treatments.	0	2	5	91	54	152	4.30	4	4	0.60
Subjects who participate in a clinical trial receive the newest treatment.	7	37	66	32	9	151	2.99	3	3	0.94
Subjects have a 50-50 chance of being in the "placebo" treatment group.	6	18	38	70	19	151	3.52	4	4	0.99
It is important for people to take part in clinical trials.	0	5	25	75	46	151	4.07	4	4	0.78
A subject may not get any benefit form participating in clinical trial.	3	13	15	92	28	151	3.85	4	4	0.89
Taking part in a clinical trial may expose subjects to harmful side effects or complications.	6	20	28	81	16	151	3.54	4	4	0.99
Subjects do not believe what the researcher tells them.	28	78	39	4	1	150	2.15	2	2	0.77
Consent forms are legal forms that protect the physician.	2	20	30	87	12	151	3.58	4	4	0.87
Subjects have the right not to take part in a clinical trial.	0	0	1	71	79	151	4.52	5	5	0.51
The information in the consent form is important to help subjects decide about participation in a clinical trial.	0	8	11	94	38	151	4.07	4	4	0.73
Participation in a clinical trial is voluntary.	0	3	4	65	80	152	4.46	5	5	0.65
The researcher often tries to persuade people to take part in a clinical trial.	28	49	43	30	1	151	2.52	2	2	1.03
Subjects who take part in a clinical trial never hear the results.	6	28	77	37	4	152	3.03	3	3	0.83
Once subjects begin a clinical trial, it is difficult to withdraw.	46	70	22	12	2	152	2.04	2	2	0.94
Participation in a clinical trial takes alot of time.	13	51	41	40	6	151	2.83	3	2	1.04
Subjects' information is kept confidential.	2	2	20	95	31	150	4.01	4	4	0.72
Physicians may encourage their patients to take part in a clinical trial.	7	18	56	62	7	150	3.29	3	4	0.91
Family members support subjects participation in clinical trials.	5	23	62	48	12	150	3.26	3	3	0.93
Refusing to participate in a clinical trial affects one's future medical care.	64	64	15	5	2	150	1.78	2	1	0.86

Note. S D = Strongly Disagree, D = Disagree, N A/D = Neither Agree/Disagree, A = Agree, S A = Strongly Agree

Table 11

Participant Subjects' Attitudes and Beliefs About Clinical Research

Statement	SD (1)	D (2)	N A/D (3)	A (4)	SA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
I know what a clinical trial is about	1	3	13	79	25	121	4.02	4	4	0.70
The researcher always knows what treatment subjects are receiving.	18	38	13	34	20	123	3.00	3	2	1.36
Clinical trials are a necessary way to learn about new treatments.	0	1	3	72	47	123	4.34	4	4	0.57
Subjects who participate in a clinical trial receive the newest treatment.*	5	25	56	28	8	122	3.07	3	3	0.93
Subjects have a 50-50 chance of being in the "placebo" treatment group.	5	16	30	55	16	122	3.50	4	4	1.01
It is important for people to take part in clinical trials.	0	3	17	63	39	122	4.13	4	4	0.74
A subject may not get any benefit form participating in clinical trial.	3	9	12	76	22	122	3.86	4	4	0.88
Taking part in a clinical trial may expose subjects to harmful side effects or complications.	4	17	22	68	11	122	3.53	4	4	0.96
Subjects do not believe what the researcher tells them.	19	65	33	3	1	121	2.19	2	2	0.76
Consent forms are legal forms that protect the physician.	1	14	25	72	10	122	3.62	4	4	0.83
Subjects have the right not to take part in a clinical trial.	0	0	1	60	61	122	4.49	4.5	5	0.52
The information in the consent form is important to help subjects decide about participation in a clinical trial.	0	8	8	75	31	122	4.06	4	4	0.76
Participation in a clinical trial is voluntary.	0	2	4	57	60	123	4.42	4	5	0.64
The researcher often tries to persuade people to take part in a clinical trial.	22	40	39	21	0	122	2.48	2	2	0.98
Subjects who take part in a clinical trial never hear the results.	6	24	63	26	4	123	2.98	3	3	0.86
Once subjects begin a clinical trial, it is difficult to withdraw.	36	60	16	9	2	123	2.03	2	2	0.93
Participation in a clinical trial takes alot of time.*	13	46	31	28	4	122	2.70	3	2	1.04
Subjects' information is kept confidential.	2	2	14	78	25	121	4.01	4	4	0.74
Physicians may encourage their patients to take part in a clinical trial.*	3	13	46	55	5	122	3.38	3	4	0.83
Family members support subjects participation in clinical trials.*	3	15	51	41	11	121	3.35	3	3	0.90
Refusing to participate in a clinical trial affects one's future medical care.*	46	55	14	4	2	121	1.85	2	2	0.76

Note. S D = Strongly Disagree, D = Disagree, N A/D = Neither Agree/Disagree, A = Agree, S A = Strongly Agree

* $p \leq 0.05$

Table 12

Nonparticipant Subjects' Attitudes and Beliefs About Clinical Research

Statement	SD (1)	D (2)	N A/D (3)	A (4)	SA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
I know what a clinical trial is about	0	2	5	19	3	29	3.79	4	4	0.73
The researcher always knows what treatment subjects are receiving.	4	8	5	7	5	29	3.03	3	2	1.35
Clinical trials are a necessary way to learn about new treatments.	0	1	2	19	7	29	4.10	4	4	0.67
Subjects who participate in a clinical trial receive the newest treatment.*	2	12	10	4	1	29	2.66	3	2	0.94
Subjects have a 50-50 chance of being in the "placebo" treatment group.	1	2	8	15	3	29	3.59	4	4	0.91
It is important for people to take part in clinical trials.	0	2	8	12	7	29	3.83	4	4	0.89
A subject may not get any benefit form participating in clinical trial.	0	4	3	16	6	29	3.83	4	4	0.93
Taking part in a clinical trial may expose subjects to harmful side effects or complications.	2	3	6	13	5	29	3.55	4	4	1.12
Subjects do not believe what the researcher tells them.	9	0	13	6	1	29	1.97	2	2	0.82
Consent forms are legal forms that protect the physician.	1	6	5	15	2	29	3.38	4	4	1.01
Subjects have the right not to take part in a clinical trial.	0	0	0	11	18	29	4.62	5	5	0.49
The information in the consent form is important to help subjects decide about participation in a clinical trial.	0	0	3	19	7	29	4.14	4	4	0.58
Participation in a clinical trial is voluntary.	0	1	0	8	20	29	4.62	5	5	0.68
The researcher often tries to persuade people to take part in a clinical trial.	6	9	4	9	1	29	2.66	2	2	1.23
Subjects who take part in a clinical trial never hear the results.	0	4	14	11	0	29	3.24	3	3	0.69
Once subjects begin a clinical trial, it is difficult to withdraw.	10	10	6	3	0	29	2.07	2	1	1.00
Participation in a clinical trial takes alot of time.*	0	5	10	12	2	29	3.38	3	4	0.86
Subjects' information is kept confidential.	0	0	6	17	6	29	4.00	4	4	0.65
Physicians may encourage their patients to take part in a clinical trial.*	4	5	10	7	2	28	2.93	3	3	1.15
Family members support subjects participation in clinical trials.*	2	8	11	7	1	29	2.90	3	3	0.98
Refusing to participate in a clinical trial affects one's future medical care.*	18	9	1	1	0	29	1.48	1	1	0.74

Note. S D = Strongly Disagree, D = Disagree, N A/D = Neither Agree/Disagree, A = Agree, S A = Strongly Agree

* $p \leq 0.05$

Perceived Advantages and Disadvantages of Participation in Clinical Research

Respondents perceived advantages and disadvantages of participating or not participating in clinical research were obtained in response to 24 Likert response questions (1 = very much a disadvantage; 2 = some disadvantage; 3 = undecided/unsure; 4 = some advantage; 5 = very much an advantage) (see Table 13). In addition, perceived advantages and disadvantages of participating were captured in two questions asking what was the greatest advantage of participating in clinical research and what was the greatest disadvantage of participating in clinical research for the participating and nonparticipating subjects. When analyzing the participant and nonparticipant subjects responses, it was noted that the participant subjects predominantly responded to the 24 statements of in a similar fashion to the total respondents (92%), whereas the nonparticipant subjects did not have agreement with 25% of the total respondents statements (see Table 14 and Table 15).

Doing something that will help others was considered the greatest advantage (86%) of participating in clinical research. One hundred and twenty-nine of the total respondents reported that doing something that will help others was of some to very much an advantage. Eighty-eight percent (n = 107) of the participant subjects and 75.9% (n = 22) of the nonparticipant subjects considered doing something that will help others as an advantage to participating in clinical research. One hundred and eighteen of the total respondents (78.7%) reported that receiving information and being able to ask questions about the research treatments were viewed as advantages of participating in clinical research. Seventy-nine percent (n = 95) of the participant subjects and 79.3% (n = 23) of

the nonparticipant subjects reported that receiving information and being able to ask questions about the research treatments was an advantage of participating.

One hundred and twelve of the total respondents (75.1%) indicated that getting the best medical care was an advantage of participating. Ninety-one of the 120 participant subjects (75.8%) and 21 of the 29 nonparticipant subjects (72.4%) indicated that getting the best medical care was an advantage of participating. Sixty-nine percent (n = 103) of the total respondents viewed doing something positive for themselves as an advantage; seventy-one percent (n = 86) of the participant subjects and 58.6% (n = 17) of the nonparticipant subjects. Getting better care and follow-up was considered an advantage by 62% (n= 93) of the total respondents, and by 65.3% (n = 79) of the participant subjects and 48.2% (n = 14) of the nonparticipant subjects. There were no statistically significant differences between the participant and nonparticipant subjects.

Fifty-nine percent (n = 89) of the subjects believed that receiving the newest treatment was an advantage of participating; sixty-seven percent (n = 76) of the participant subjects and 44.8% (n = 13) of the nonparticipant subjects (t = 3.06, p = 0.003). Participant subjects were more likely than nonparticipant subjects to perceive some advantage in receiving the newest treatment if one participated in clinical research.

Other advantages of participating in clinical research reported by the respondents were: (1) seeing the nurse more often (59%) (participant = 62.5%, nonparticipant 44.8%), (2) receiving money or gifts (54.6%) (participant = 56%, nonparticipant = 65%), and (3) seeing the physician more often (54%) (participant = 55.4%, nonparticipant = 48.2%). An independent t-test revealed a significant difference between the participant and

nonparticipant subjects as to whether they perceived seeing the nurse more often as an advantage or a disadvantage to participating in clinical research ($t = 2.49$, $p = 0.01$). Participant subjects were more likely than nonparticipant subjects to perceive some advantage in seeing the nurse more often.

One hundred and four of the respondents (69.3%) reported that experiencing side effects of the treatment as the greatest disadvantage of participating in clinical research. Eighty-two of the 121 participant subjects (67.7%) and 22 of the 29 nonparticipant subjects (75.9%) reported that experiencing side effects of the treatment as one of the greater disadvantages to participating in clinical research. Having to miss work was considered a disadvantage to participating by 54 % ($n = 80$) of the total respondents (49.6% of the participant subjects and 72.4% of the nonparticipant subjects). Seventy-nine of the respondents (52.7%) reported that having to travel to and from the clinic or hospital was a disadvantage of participating in clinical research (48% ($n = 58$) of the participant subjects and 72.4% ($n = 21$) of the nonparticipant subjects). Other disadvantages of participating in clinical research for the respondents were disrupting one's normal daily routine (52%), and needing to go to the clinic or hospital more often (51.3%). Sixty of the 121 participant subjects (49.5%) and 18 of 29 nonparticipant subjects (62.1%) reported that disrupting one's daily routine was a disadvantage to participating in clinical research. Forty-nine percent ($n = 59$) of the participant subjects and 62% ($n = 18$) of the nonparticipant subjects indicated that needing to go to the clinic or hospital more often was a disadvantage. There were no significant differences noted between the participant and nonparticipant subjects in perceived disadvantages.

Sixty percent (n = 89) of the total respondents were undecided as to whether having a chance of being in the 'placebo' treatment group was considered to be an advantage or disadvantage of participating in clinical research (63% (n = 75) of the participant subjects and 44.8% (n = 13) of the nonparticipant subjects. Fifty-three percent (n = 78) of the total respondents were unsure or undecided as to whether losing one's privacy was viewed as an advantage or a disadvantage (53% (n = 63) of the participant subjects and 51.7% (n = 15) of the nonparticipant subjects). The respondents were also undecided or unsure about: (1) not knowing if one is receiving the research or 'placebo' treatment (52%), (2) having to arrange child care (50.3%), and (3) getting free medications. Fifty-two percent (n = 63) of the participant subjects and 51.7% (n = 15) of the nonparticipant subjects were unsure or undecided as to whether not knowing if one is receiving the research or "placebo" treatment was seen as an advantage of a disadvantage. Other unsure or undecided statements that were identified were: (1) having to arrange child care (participant = 50.9%, nonparticipant = 48.3%), and, (2) getting free medications (participant = 42.1%, nonparticipant = 62.1%). None of the above stated statements were noted to have any statistically significant differences between the participant and nonparticipant subjects.

There were 4 statements that the participant and nonparticipant subjects had differing opinions as to whether they believed it to be an advantage or a disadvantage of participating in clinical research. Fifty-three percent (n = 79) of the total respondents were unsure or undecided as to whether being treated as a "guinea pig" was seen as an advantage or a disadvantage. Seventy-one of the participant subjects (58.7%) were unsure

or undecided as to whether being treated like a "guinea pig" was an advantage or a disadvantage of participating in clinical research, while 19 of the nonparticipant subjects (65.5%) considered it to be a disadvantage. Of these participating subjects 9.9% considered being treated as a "guinea pig" an advantage, and 31.4 % considered it a disadvantage of participating in clinical research ($t = 2.49$, $p = 0.01$).

Seventy-five of the total respondents (50%) reported that being involved in testing new treatments as an advantage of participating in clinical research. Being involved in testing new treatments was viewed as an advantage by 52.1% of the participant subjects ($n = 63$) whereas, 44.8% of the nonparticipant subjects ($n = 13$) were undecided as to whether it was considered an advantage or disadvantage. Of the nonparticipant subjects, 41.4% viewed being involved in testing new treatments as an advantage, and 13.8% viewed it as a disadvantage of participating in clinical research. Eighty of the total respondents (53.4%) reported that getting to know one's physician as an advantage to participating in clinical research. Fifty-five percent ($n = 67$) of the participant subjects perceived getting to know their physician as an advantage to participating in clinical research, while 55.2% ($n = 16$) of the nonparticipant subjects were unsure or undecided as to whether that was an advantage or a disadvantage to participating. Of the nonparticipant subjects, 44.8% considered it an advantage and no nonparticipant subjects considered it to be a disadvantage of participating in clinical research. There were no statistically significant differences noted between the participant and nonparticipant subjects.

Forty-six percent ($n = 69$) of the total respondents were unsure or undecided as to whether not knowing what to expect was considered an advantage of participating in clinical research. The participant subjects (46.3%) were unsure or undecided as to whether

not knowing what to expect was considered an advantage of participating in clinical research, while the nonparticipant subjects (51.7%) considered it a disadvantage. Of the participant subjects, 15% perceived not knowing what to expect as an advantage to participating in clinical research and 39.7% of the participant subjects considered it to be a disadvantage ($t = 2.03$, $p = 0.04$).

Greatest Perceived Advantages and Disadvantages of Participation in Clinical Research

Respondents were asked to describing what they perceived as the greatest advantage and disadvantage of participating in clinical research. Only one hundred and forty-four of the total respondents provided an answer to this question. Listed as the greatest advantages of participating in clinical research were: (1) development of a new treatment and advancement of medical research (25%), (2) financial compensation (23.6%), and, (3) helping oneself and others (18.8%). Listed as the greatest disadvantages of participating in clinical research were: (1) the effects on health, such as side effects or harmful treatments (35.2%), and, (2) increased time and inconvenience of many appointments and having to miss work (16.2%).

The majority of participant subjects perceived that the greatest advantage of participating in clinical research was development of new treatments and advancement of medical research (26.5%), while nonparticipant subjects stated that the financial compensation (37 %) was the greatest advantage to participating in clinical research. Both the participant (34.8%) and nonparticipant (37 %) subjects were of the opinion that the greatest disadvantage of participating in clinical research was the effect on one's health in regards to side effects experienced, harmful treatments, and the risks involved with new treatments.

Table 13

Total Respondents' Perceived Advantages and Disadvantages of Participation in Clinical Research

Statement	VMD (1)	SD (2)	U/U (3)	SA (4)	VMA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
Receiving the newest treatment.	1	6	55	51	38	151	3.79	4	3	0.89
Doing something that will help others.	1	2	18	68	61	150	4.24	4	4	0.77
Free medications.	17	20	69	28	16	150	3.04	3	3	1.10
Getting better care and follow-up.	1	8	48	53	40	150	3.82	4	4	0.91
Having to travel to and from the clinic or hospital.	24	55	55	15	1	150	2.43	2	2	0.90
Doing something positive for yourself.	3	3	41	71	32	150	3.84	4	4	0.85
Miss work.	36	44	53	7	4	148	2.30	2	3	0.99
Being treated like a "guinea pig".	20	37	79	5	9	150	2.64	3	3	0.96
Not knowing whether you are getting the research treatment.	24	31	78	13	4	150	2.61	3	3	0.95
Receiving information and being able to ask questions about the research treatments.	1	1	30	64	54	150	4.13	4	4	0.80
Arrange child care	20	33	73	5	5	145	2.57	3	3	0.92
Losing ones' privacy.	16	44	78	5	4	148	2.57	3	3	0.84
Experiencing side effects of the treatment.	45	59	33	10	2	150	2.09	2	2	0.95
Being involved in testing new treatments.	4	12	59	54	21	150	3.51	3.5	3	0.93
Disrupting your normal daily routine.	17	61	62	9	1	150	2.42	2	3	0.77
Getting to know your physician.	1	2	67	52	28	150	3.69	4	3	0.81
Seeing the physician	1	8	60	57	24	150	3.63	4	3	0.84
Seeing the nurse	4	4	53	65	23	149	3.66	4	4	0.87
Having a chance of being in the "placebo" treatment group.	11	22	89	19	8	149	2.94	3	3	0.89
Needing to go to the clinic/hospital more often.	17	60	52	15	6	150	2.55	2	2	0.96
Receive money/gifts.	16	10	37	36	41	141	3.54	4	5	1.29
Not knowing if you are receiving the research or "placebo" treatment.	22	29	78	15	6	150	2.69	3	3	0.98
Getting the best medical care.	1	2	34	65	47	149	4.04	4	4	0.81
Not knowing what to expect.	18	45	69	10	8	150	2.63	3	3	0.97

Note. VMD = Very Much a Disadvantage, SD = Some Disadvantage, U/U = Undecided/Unsure, SA = Some Advantage, VMA = Very Much an Advantage

Table 14

Participant Subjects' Perceived Advantages and Disadvantages of Participation in Clinical Research

Statement	VMD (1)	SD (2)	U/U (3)	SA (4)	VMA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
Receiving the newest treatment.*	0	3	43	40	36	122	3.89	4	3	0.86
Doing something that will help others.	1	1	12	56	51	121	4.28	4	4	0.74
Free medications.	14	17	51	24	15	121	3.07	3	3	1.14
Getting better care and follow-up.	1	6	35	44	35	121	3.88	4	4	0.92
Having to travel to and from the clinic or hospital.	20	38	49	13	1	121	2.48	3	3	0.92
Doing something positive for yourself.	3	1	31	57	29	121	3.89	4	4	0.86
Miss work.	25	34	47	6	4	119	2.40	3	3	0.99
Being treated like a "guinea pig".*	12	26	71	4	8	121	2.75	2	3	0.92
Not knowing whether you are getting the research treatment.	20	24	63	12	2	121	2.60	3	3	0.94
Receiving information and being able to ask questions about the research treatments.	1	0	25	53	42	121	4.12	4	4	0.79
Arrange child care	14	26	59	4	5	116	2.63	3	3	0.92
Losing ones' privacy.	12	35	63	4	4	119	2.60	3	3	0.85
Experiencing side effects of the treatment.	35	47	28	8	2	121	2.13	2	2	0.97
Being involved in testing new treatments.	4	8	46	44	19	121	3.55	4	3	0.95
Disrupting your normal daily routine.	13	47	52	8	1	121	2.46	2.5	3	0.78
Getting to know your physician.	1	2	51	41	26	121	3.74	4	3	0.84
Seeing the physician	0	6	48	44	23	121	3.69	4	3	0.84
Seeing the nurse.*	2	2	41	54	21	120	3.75	4	4	0.82
Having a chance of being in the "placebo" treatment group.	10	17	70	15	8	120	2.95	3	3	0.93
Needing to go to the clinic/hospital	14	45	41	15	6	121	2.62	3	2	1.01
Receive money/gifts.	15	10	31	26	30	113	3.41	3.5	3	1.33
Not knowing if you are receiving the research or "placebo" treatment.	19	22	63	12	5	121	2.69	3	3	0.99
Getting the best medical care.	1	2	26	51	40	120	4.06	4	4	0.83
Not knowing what to expect.*	12	36	56	9	8	121	2.71	3	3	0.98

Note. VMD = Very Much a Disadvantage, SD = Some Disadvantage, U/U = Undecided/Unsure, SA = Some Advantage, VMA = Very Much an Advantage

* $p \leq 0.05$

Table 15

Nonparticipant Subjects' Perceived Advantages and Disadvantages of Participation in Clinical Research

Statement	VMD (1)	SD (2)	U/U (3)	SA (4)	VMA (5)	N	Measures of Central Tendency			
							M	Mdn	Mode	SD
Receiving the newest treatment.*	1	3	12	11	2	29	3.34	3	3	0.90
Doing something that will help others.	1	1	12	56	51	29	4.07	4	4	0.84
Free medications.	3	3	18	4	1	29	2.90	3	3	0.90
Getting better care and follow-up.	0	2	13	9	5	29	3.59	3	3	0.87
Having to travel to and from the clinic or hospital.	4	17	6	2	0	29	2.21	2	2	0.77
Doing something positive for yourself.	0	2	10	14	3	29	3.62	4	4	0.78
Miss work.	11	10	6	1	1	29	1.89	2	1	0.88
Being treated like a "guinea pig".*	8	11	8	1	1	29	2.17	2	2	1.00
Not knowing whether you are getting the research treatment.	4	7	15	1	2	29	2.66	3	3	1.01
Receiving information and being able to ask questions about the research treatments.	0	1	5	11	12	29	4.17	4	5	0.85
Arrange child care	6	7	14	1	1	29	2.36	3	3	0.87
Losing ones' privacy.	4	9	15	1	0	29	2.45	3	3	0.78
Experiencing side effects of the treatment.	10	12	5	2	0	29	1.97	2	2	0.91
Being involved in testing new treatments.	0	4	13	10	2	29	3.34	3	3	0.81
Disrpting your normal daily routine.	0	4	14	10	1	29	2.28	2	2	0.75
Getting to know your physician.	0	0	16	11	2	29	3.52	3	3	0.63
Seeing the physician.	1	2	12	13	1	29	3.38	3	4	0.82
Seeing the nurse*	2	2	12	11	2	29	3.31	3	3	0.97
Having a chance of being in the "placebo" treatment group.	1	5	19	4	0	29	2.90	3	3	0.67
Needing to go to the clinic/hospital more often.	3	15	11	0	0	29	2.28	2	2	0.65
Receive money/gifts.	1	0	6	10	11	28	4.07	4	5	0.98
Not knowing if you are receiving the research or "placebo" treatment.	3	7	15	3	1	29	2.72	3	3	0.92
Getting the best medical care.	0	0	8	14	7	29	3.97	4	4	0.73
Not knowing what to expect.*	6	9	13	1	0	29	2.31	2	3	0.85

Note. VMD = Very Much a Disadvantage, SD = Some Disadvantage, U/U = Undecided/Unsure, SA = Some Advantage, VMA = Very Much an Advantage

* $p \leq 0.05$

Factors Influencing Participation in Clinical Research

Subjects were asked about certain factors, such as written material, family and friends, and their doctor, to identify what factors influenced their decision to participate or not participate in clinical research. Responses were solicited through a yes/no/don't know response set. As well, subjects' perceptions of how well they were informed of clinical research topics were obtained in response to 7 Likert response questions (1 = poorly informed; 2 = barely informed; 3 = casually informed; 4 = informed; and 5 = very well informed). One open-ended question was provided to solicit additional information. Furthermore, subjects were asked to indicate what would be helpful to learn more about clinical research on a Likert scale (1 = not at all helpful; 2 = barely helpful; 3 unsure if helpful of not; 4 = moderately helpful; and 5 helpful).

The majority of the total respondents (n = 134) indicated that they had received written materials outlining what the research study was about and what their participation would involve. The majority of the total respondents had received written materials (yes = 88.7%; no = 10.6%; don't know = 0.7) (see Table 16). One hundred and nine of the participant subjects (88.6%) and 25 of the nonparticipant subjects (89.3%) indicated that they received written materials that described what the clinical research was about and what was needed for them to do (see Table 17).

More than 60% of the total respondents reported that they spoke with their family or friends first before making their decision to participate or not participate (yes = 60.7%; no = 38.7; don't know = 0.7). Fifty-seven percent (n = 69) of the participant subjects and

78.6% (n = 22) of the nonparticipant subjects did talk to family or friends before making their decision to participate or not participate.

Subjects were then asked if they had spoken to their physician first before making their decision to participate or not participate in clinical research. More than 65% of the total respondents stated that they had not spoken with their physician prior to making their decision to participate or not participate (yes = 31.1%; no = 68.2%; don't know = 0.7%). Sixty-three percent (n = 77) of the participant subjects and 92.9% (n = 26) of the nonparticipant subjects did not speak with their physician prior to making their decision.

Table 16

Factors Influencing Total Respondents' Decision to Participate in Clinical Research

Components	Responses			N	Percent (%)			Mode
	yes	no	don't know		yes	no	don't know	
written materials	134	16	1	151	88.7	10.6	0.7	1
family and friends	91	58	1	150	60.7	38.7	0.7	1
physician	47	103	1	151	31.1	68.2	0.7	2

Table 17

Factors Influencing Participant and Nonparticipant Subjects' Decision to Participate in Clinical Research

Components	Responses			N	Percent (%)			Mode
	yes	no	don't know		yes	no	don't know	
Participant								
written materials	109	13	1	123	88.6	10.6	0.8	1
family and friends	69	52	1	122	56.6	42.6	0.8	1
physician	45	77	1	123	36.6	62.6	0.8	2
Nonparticipant								
written materials	25	3	0	28	89.3	10.7	0.0	1
family and friends	22	6	0	28	78.6	21.4	0.0	1
physician	2	26	0	28	7.1	92.9	0.0	2

Perceptions of Being Informed

Seven items were reviewed as to how well informed subjects were of certain research topics when they had made their decision to either participate or not in clinical research. One open-ended question was also included to identify other information subjects considered helpful with making their decision to participate or not participate in clinical research.

The majority of the total respondents (84.6%) indicated that they were very well informed of what they would need to do in the clinical research study (see Table 18). One hundred and twenty-two (84.4%) of the total respondents reported they were very well informed about the purpose of the research. One hundred and eighteen of the total respondents (80.8%) reported that they were very well informed of how much time it would take to participate in the clinical research. Furthermore, 76% (n = 113) of the total

respondents stated that they were very well informed of the benefits of participating in the research study, and over 65% of the subjects agreed that they were informed regarding: why they were asked to participate (74%), possible personal risks involved (i.e. side effects) (73.1%), and, how the study findings would be used (65.8%).

Table 18

Total Respondents' Perception of Being Informed

Topics	Responses					N	Measures of Central Tendency			
	PI (1)	BI (2)	CI (3)	I (4)	VWI (5)		M	Mdn	Mode	SD
The purpose of the research.	2	3	24	58	64	151	4.19	4	5	0.87
What you would need to do.	2	7	14	55	71	149	4.25	4	5	0.91
Possible personal risks involved.	6	7	27	58	51	149	3.95	4	4	1.04
Benefits of participation.	6	10	20	53	60	149	4.01	4	5	1.08
Why you were asked to participate.	8	7	23	59	49	146	3.92	4	4	1.09
How the study findings would be used.	8	16	26	62	34	146	3.67	4	4	1.11
How much time it would take.	5	8	15	59	59	146	4.09	4	4	1.02

Note. PI = Poorly Informed, BI = Barely Informed, CI = Casually Informed, I = Informed, VWI = Very Well Informed

Eighty-six percent (n = 105) of the participant subjects and 75% (n = 21) of the nonparticipant subjects considered themselves very well informed of what they would need to do in the clinical research study (see Table 19). This difference was not statistically significant. Participant subjects (n = 102, 83%) were more likely to report being informed about the purpose of the research compared to the nonparticipant subjects (n = 20, 71.4%) (t = 0.998, p = 0.05).

Ninety-eight (83%) of the participant subjects and 20 (71.5%) of the nonparticipant subjects indicated they were very well informed of how much time it would take to participate in the research study. No significant differences were noted. A significant difference was noted between the participant and nonparticipant subjects and why they were asked to participate in the clinical research study. Participant subjects (n = 94, 80%) were more likely to report being informed about why they were asked to participate in clinical research as compared to the nonparticipant subjects (n = 14, 50%) who reported being only casually informed (t = 2.71, p = 0.008).

Ninety-five (78.5%) of the participant subjects and 18 (64.3%) of the nonparticipant subjects stated they were informed as to what were the benefits of participation in the clinical research. No statistically significant difference was noted. There was a significant difference noted between the mean ranking of the participant and nonparticipant subjects with regards to how well they were informed of the possible side effects of participating in clinical research. The participant subjects (n = 95, 78.5%) were more likely to feel casually informed with regards to the possible personal risks involved in participating in clinical research as compared to the nonparticipant subjects (n = 14, 50%) who felt they were poorly informed as to the possible personal risks involved in participating in clinical research (U = 1167, p = 0.007). Seventy percent (n = 82) of the participant subjects and 50% of the nonparticipant subjects (n = 14) reported they were informed of how the study findings would be used. An independent t-test indicated a significant difference between the participant and nonparticipant subjects. Participant

subjects and nonparticipant subjects were likely to report that they were casually informed with regards to how the study findings would be used ($t = 2.45$, $p = 0.02$).

Other Helpful Information for Understanding Clinical Research

In order to find what other information would have helped make their decision to participate or not participate, respondents were asked two questions. First, was there any other information that would have helped them to make their decision and secondly, to specify what information would be helpful.

One hundred and forty-seven respondents provided an answer to this first question. Among them, ninety-eight (66.7%) of the total respondents reported that they did not need any other information in regards to helping them make their decision of participating or not participating in clinical research (yes = 11.6%; no = 66.7%; don' know = 21.1%). Of those who responded favorably to more information, 7% made the suggestion of having more information sheets available to explain what can be expected of participants in the particular clinical research study. Of the participant subjects, 7.4% ($n = 7$) agreed with the suggestion of more information sheets outlining expectation of the participants in clinical research. Eleven percent of the nonparticipant subjects ($n = 2$) suggested having more precise information on time commitments needed by the participant for each research study.

Table 19

Participant and Nonparticipant Subjects' Perception of Being Informed

Topics	Responses					N	Measures of Central Tendency			
	PI (1)	BI (2)	CI (3)	I (4)	VWI (5)		M	Mdn	Mode	SD
Participant										
The purpose of the research.*	2	2	17	44	58	123	4.25	4	5	0.87
What you would need to do.	2	5	9	43	62	121	4.31	5	5	0.90
Possible personal risks involved.*	3	5	18	50	45	121	4.07	4	4	0.96
Benefits of participation.	4	7	15	48	47	121	4.05	4	4	1.02
Why you were asked to participate.*	7	1	16	51	43	118	4.03	4	4	1.04
How the study findings would be used.*	5	10	21	52	30	118	3.78	4	4	1.06
How much time it would take.	3	6	11	51	47	118	4.13	4	4	0.96
Nonparticipant										
The purpose of the research.*	0	1	7	14	6	28	3.89	4	4	0.79
What you would need to do.	0	2	5	12	9	28	4.00	4	4	0.90
Possible personal risks involved.*	3	2	9	8	6	28	3.43	3.5	3	1.23
Benefits of participation.	2	3	5	5	13	28	3.86	4	5	1.33
Why you were asked to participate.*	1	6	7	8	6	28	3.43	3.5	4	1.17
How the study findings would be used.*	3	6	5	10	4	28	3.21	3.5	4	1.26
How much time it would take.	2	2	4	8	12	28	3.93	4	5	1.25

Note. PI = Poorly Informed, BI = Barely Informed, CI = Casually Informed, I = Informed, VWI = Very Well Informed

* $p \leq 0.05$

Helpful Learning Techniques for Clinical Research

Six items were identified as helpful suggestions for ways to help others learn about clinical research (see Table 20). One hundred and twenty-seven (85.2%) of the total respondents suggested that having information about the research study presented by the physician was a very helpful technique. Eighty-eight percent (n = 104) of the participant subjects and 79.3% (n = 23) of the nonparticipant subjects agreed that information about the clinical study presented by the physician was a helpful technique. No statistically significant differences were noted between the participant and nonparticipant subjects.

One hundred and twenty-four (83.3%) of the total respondents considered that information about the clinical study presented by the nurse, was suggested as a very helpful technique to learn about clinical research (see Table 21). Eighty-six percent (n = 103) of the participant subjects and 72.4% of the nonparticipant subjects (n = 21) believed that information about the clinical research study presented by the nurse, was a helpful technique. This difference was found to be statistically significant (t = 2.00, p = 0.05).

Seventy-four percent (n = 109) of the total respondents agreed that hearing about the good things that have been discovered from clinical research was a very helpful technique to learn about clinical research. Eighty-nine participant subjects (74.8%) and 20 nonparticipant subjects (69%) agreed that hearing about the good things that have been discovered from clinical research was a helpful technique. No statistically significant differences were noted between the participant and nonparticipant subjects.

Ninety-eight of the total respondents considered speaking to people who have previously taken part in clinical research as another helpful technique. Sixty-seven percent (n = 77) of participant subjects and 72.4% of nonparticipant subjects (n = 21) viewed this as a helpful strategy. No statistically significant differences were noted between the participant and nonparticipant subjects.

Fifty-two percent (n = 75) of the subjects considered it to be a helpful technique to hear one person's story from the beginning and all the way through a clinical research study. Fifty-five percent (n = 64) of the participant subjects and 37.9% of the nonparticipant subjects (n = 11) considered this to be a helpful technique. No statistically significant differences were shown to exist between the participant and nonparticipant subjects.

Only fifty percent (n = 72) of the total sample of subjects believed that TV shows or video tapes with people in who have previously been in clinical research studies to be a helpful technique. Sixty-four of the participant subjects (55.2%) believed it was a helpful technique to view TV shows or video tapes with people who have previously been in clinical research. Thirteen nonparticipant subjects (n = 44.8) were unsure as to whether it was a helpful technique or not. There were no statistically significant differences found between the participant and nonparticipant subjects.

Table 20

Total Respondents' Suggestions for Learning Techniques for Clinical Research

Techniques	Responses					N	Measures of Central Tendency			
	NAH (1)	BH (2)	UHN (3)	MH (4)	H (5)		M	Mdn	Mode	SD
Information about the clinical trial presented by the physician.	2	5	15	51	76	149	4.30	5	5	0.88
Information about the clinical trial presented by the nurse.	1	4	20	57	67	149	4.24	4	5	0.84
Talking to people who have taken part in clinical trials.	9	13	24	49	49	144	3.81	4	4	1.18
TV shows or video tapes with people in clinical trials.	18	17	38	45	27	145	3.32	3	4	1.26
One person's story from the beginning and all the way through a clinical trial.	16	21	33	45	30	145	3.36	4	4	1.27
Hearing about the good things that have been discovered from clinical trials.	7	5	27	59	50	148	3.95	4	4	1.04

Note. NAH = Not at all Helpful, BH = Barely Helpful, UHN = Unsure if Helpful or not, MH = Moderately Helpful, H = Helpful

Table 21

Participant and Nonparticipant Subjects' Suggestions for Learning Techniques for Clinical Research

Techniques	Responses					N	Measures of Central Tendency			
	NAH (1)	BH (2)	UHN (3)	MH (4)	H (5)		M	Mdn	Mode	SD
Participant										
Information about the clinical trial presented by the physician.	2	3	11	38	66	120	4.36	5	5	0.88
Information about the clinical trial presented by the nurse.*	1	2	14	45	58	120	4.31	4	5	.081
Talking to people who have taken part in clinical trials.	9	9	20	37	40	115	3.78	4	5	1.23
TV shows or video tapes with people in clinical trials.	14	13	25	42	22	116	3.39	4	4	1.26
One person's story from the beginning and all the way through a clinical trial.	11	18	23	38	26	116	3.43	4	4	1.26
Hearing about the good things that have been discovered from clinical trials.	3	3	24	47	42	119	4.03	4	4	0.94
Nonparticipant										
Information about the clinical trial presented by the physician.	0	2	4	13	10	29	4.07	4	4	0.88
Information about the clinical trial presented by the nurse.*	0	2	6	12	9	29	3.97	4	4	0.91
Talking to people who have taken part in clinical trials.	0	4	4	12	9	29	3.90	4	4	1.01
TV shows or video tapes with people in clinical trials.	4	4	13	3	5	29	3.03	3	3	1.24
One person's story from the beginning and all the way through a clinical trial.	5	3	10	7	4	29	3.07	3	3	1.28
Hearing about the good things that have been discovered from clinical trials.	0	4	2	3	12	29	3.62	4	4	1.35

Note. NAH = Not at all Helpful, BH = Barely Helpful, UHN = Unsure if Helpful or not, MH = Moderately Helpful, H = Helpful

* $p \leq 0.05$

Current and Future Participation in Clinical Research

Respondents were asked to respond to 5 questions regarding their current and past participation in clinical research using a yes/no/don't know response scale. In addition current and past participating practices were captured in 3 open ended questions where respondents who answered yes to a question could explain their answer further.

The majority of the total respondents (n = 124) indicated that they would participate in clinical research in the future (yes = 81.6%; no = 4.6%; don't know = 13.8%) (see Table 22). Eighty-six percent of the participant subjects (n = 106) and 18 of the nonparticipant subjects (62.1%) reported that if asked, they would participate in clinical research in the future (see Table 23 and Table 24). There were no statistically significant differences noted between the participant and nonparticipant subjects.

The total sample were asked if they were currently involved in a clinical trial. Results indicated that over 67% of the total respondents (n = 102) were presently involved in a clinical study (yes = 67.1%; no = 31.6%; don't know = 1.3%). Seventy-two percent of the participant subjects (n = 72.4) and 13 of the nonparticipant subjects (44.8%) stated that they were presently involved in a clinical study (Fisher's Exact Test = 8.87, p = 0.004).

The majority of the total respondents who were participating in clinical research (n = 111) stated that they were not involved in more than one clinical trial (yes = 7.2%; no = 73%; don't know = 2%). Of the participant subjects who were currently enrolled in clinical trial/s, 78% (n =96) were presently involved in only one clinical trial, and 7.3%

(n = 9) were involved in more than one clinical trial at the same time.Of the nonparticipant subjects, 55.2% (n = 15) reported that they were presently involved in only one clinical trial, and 6.9% (n = 2) reported they were involved in more than one clinical trial. Differences noted were not statistically significant.

Respondents were asked if they had ever been in a clinical trial in the past. The majority of the total respondents (n = 101) indicated that they had never been in a clinical trial in the past (yes = 33.6%; no = 66.4%). Eighty of the participant subjects (65%) had not been in a clinical trial in the past, and 22.3% (n = 27) of the participant subjects had been in one clinical trial in the past. Twenty-one of the nonparticipant subjects (72.4%) had not been in a clinical trial in the past, and 27.6% (n = 8) of the nonparticipant subjects had been in one clinical trial in the past. Differences noted were not statistically significant.

Respondents were asked if they were "glad" that they took part in clinical research. Results indicated that more than 72% (n = 152) of the total respondents reported that they were "glad" that they had taken part in clinical research (yes = 72.2%; no = 2.6%; don't know = 15.2%; never participated = 9.3%). The majority of participant subjects (n = 95, 77.2%) were "glad" that they had taken part in clinical research for the primary reasons of helping themselves and others (18.4%), extra income (13.8%), and that it provided an interesting, fun experience to meet other people (11.5%). Fifty percent of the nonparticipant subjects (n = 14) were "glad" to have participated in clinical research for the stated reasons of extra income (39.1 %) and to help in the development of a new and better medications (8.7%). Differences noted were not statistically significant.

Respondents were also asked if they had ever been approached to participate in a clinical trial, and then decided not to participate. The majority of the total respondents ($\underline{n}$ = 119, 78.3%) indicated that did go on to participate in the clinical trial. With regards to the participant subjects who had been asked to participate in clinical research ($\underline{n}$ = 12), only 9.8% had decided not to participate for reasons of: other commitments (3.3%) (i.e. a job, they were already in another trial, marriage and family commitments, and conflicts with leisure activities), and time conflicts and disruptions (1.7%). Of the nonparticipant subjects who had been asked to participate in clinical research ($\underline{n}$ = 21), the majority (72.4%) had decided not to participate for reasons of: other commitments (32%), no advantages perceived by them for participating (12%), and they felt that the bad side effects had been down played by the study administrators (12%). Of the participant subjects, 90.2% reported that once asked to participate in a clinical trial, the majority of the participant subjects did go on to participate in the clinical trial, while 72.4% of the nonparticipant subjects reported that once asked to participate in a clinical trial, the majority of the nonparticipant subjects would decline participating in the clinical trial ($\chi^2 = 54.20$, $\underline{p} = < 0.005$).

Table 22

Total Respondents' Current and Future Participation in Clinical Research

Statements	Responses			N	Frequencies (%)			Mode
	Y	N	DK		Y	N	DK	
If you were asked, would you participate in a clinical trial?	124	7	21	152	81.6	4.6	13.8	1
Are you currently involved in a clinical trial?	102	48	2	152	67.1	31.6	1.3	1
Have you ever been in a clinical trial in the past?	51	101	0	152	33.6	66.4	0.0	2
Are you glad that you took part in the clinical trial(s)?	109	4	23	151	72.2	2.6	15.2	1
Have you ever been asked to participate in a clinical trial, and decided not to participate?	33	119	0	152	21.7	78.3	0.0	2

Note. Y = Yes, N = No, DK = Don't Know

Table 23

Participant Subjects' Current and Future Participation in Clinical Research

Statements	Responses			N	Frequencies (%)			Mode
	Y	N	DK		Y	N	DK	
If you were asked, would you participate in a clinical trial?	106	4	13	123	86.2	3.3	10.6	1
Are you currently involved in a clinical trial?*	89	32	2	123	72.4	26.0	1.6	1
Have you ever been in a clinical trial in the past?	43	80	0	123	35.0	65.0	0.0	2
Are you glad that you took part in the clinical trial(s)?	95	3	19	123	77.2	2.4	15.4	1
Have you ever been asked to participate in a clinical trial, and decided not to participate?*	12	111	0	123	9.8	90.2	0.0	2

Note. Y = Yes, N = No, DK = Don't Know

* $p \leq 0.05$

Table 24

Nonparticipant Subjects' Current and Future Participation in Clinical Research

Statements	Responses			N	Frequencies (%)			Mode
	Y	N	DK		Y	N	DK	
If you were asked, would you participate in a clinical trial?	18	3	8	29	62.1	10.3	27.6	1
Are you currently involved in a clinical trial?*	13	16	0	29	44.8	55.2	0.0	2
Have you ever been in a clinical trial in the past?	8	21	0	29	27.6	72.4	0.0	2
Are you glad that you took part in the clinical trial(s)?	14	1	4	28	50.0	3.6	14.3	1
Have you ever been asked to participate in a clinical trial, and decided not to participate?*	21	8	0	29	72.4	27.6	0.0	1

Note. Y = Yes, N = No, DK = Don't Know

* $p \leq 0.05$

Chapter 5

Discussion of Findings

This study was designed to describe patients' perceptions of participation in clinical research. Specific areas that were explored included: (1) knowledge of clinical research; (2) attitudes and beliefs about clinical research; (3) advantages and disadvantages of participating in clinical research; and, (4) factors that influence the decision to either participate or not participate in clinical research. Relationships among the study variables to the potential future participation in clinical research were reviewed. Each of these areas will be discussed, summarized, and compared to current literature. This will be followed by implications for nursing. Finally, limitations of the study and suggestions for future research will be outlined.

Data were obtained from responses to the Patients' Perceptions of Participation in Clinical Research (PPCR) questionnaire consisting of both open-ended and fixed-format questions. Section I had 22 items related to knowledge of clinical research. Section II contained 21 items related to attitudes and beliefs concerning clinical research. Section III contained 26 perceived advantage and disadvantage of participation in clinical research questions. Section IV involved 6 current and future participation in clinical research questions. Section V contained 17 items related to factors influencing participation in clinical research. Section VI, the final section, involved 11 demographic questions.

Of the 200 surveys mailed, 152 respondents returned their questionnaires. Of the 152 respondents, 123 were participants and 29 were nonparticipants in a Cardiology Clinical Trial/s X (Appendix A). One hundred and fifty-two of the total respondents

(92.4%) returned completed questionnaires (participant subjects = 91.6%, nonparticipant subjects = 96%). The overall response rate was 76 percent. The participant subjects had a response rate of 80.4% (123/153), while the nonparticipant subjects had a response rate of 62% (29/47). The response rates are reflective of the nature of the two cohorts sampled. The participant subjects were eligible subjects who chose to take part in a cardiology study. The nonparticipant subjects were eligible subjects who chose not to take part in a cardiology study. The rate of decline or the number of eligible nonresponders was 24 percent. The participant nonresponders had a nonresponse rate of 20% (30/153). The nonparticipant nonresponders had a nonresponse rate of 38% (18/47). The reasons given by the nonparticipant subjects for not consenting to participate in the cardiology study were: (1) other commitments (i.e. employment, vacation); (2) family members did not want the subject to participate in the research study; (3) became ill and could not participate; (4) refused parts of the protocol (i.e. blood draws, refusal to stop previous medications); (5) afraid of future health consequences; (6) felt too stressed to participate; (7) too much traveling to and from the clinic/hospital; and, (8) unknown reasons/did not come for first appointment. The lower response rate to the questionnaire by the nonparticipant subjects could be due to several of these same contributing factors.

Characteristics of the Respondents

Overall, the characteristics of the respondents were typical of the population who would be expected to enroll in a cardiology clinical trial. That is, the respondents were male, aged 18-74 years, Caucasian, living in a large city, and married. One-third of the respondents were employed full-time and approximately one-third of the respondents were

retired. They had varied educational backgrounds and occupations. The respondents' net family income ranged from < $20,000 - $ 39,000.

The participant subjects were predominantly married, whereas, the nonparticipant subjects were never married. Of the participant subjects, most lived with their spouse, while nonparticipant subjects lived with someone other than their spouse or their children, or lived alone. The participant subjects were evenly distributed among the age categories of 18-44 years of age, 45-64 years of age, and 65 and older; whereas, the majority of nonparticipant subjects were aged 18-44 years. Age has been negatively correlated with willingness to participate in research, with an overall participation rate being reported in the literature of less than 60% for the elderly (Zimmer, Calkins, Hadley, Ostfield, Kaye, & Kaye, 1985). Also, the participant subjects were retired, whereas the nonparticipant subjects were working predominantly full-time. In a recent study of Gorkin et al.(1996) of clinical trial participant versus nonparticipant subjects, several demographical variables discriminated participants from nonparticipants, including sex, age, ethnicity, and employment status. Participants were more likely to be male and younger than the nonparticipants. Race was found to be a significant predictor with Caucasians comprising 80% of participants and 90.6% of the nonparticipants. However, no significant group differences were found with regard to education or marital status.

The participant subjects in this study were Caucasian, married, retired, males between the age of 55-74 years old, living with their wife. The participant subject had a high school education, a net income between $20,000-$39,000 and is/was employed in the technical/skilled trades area; in contrast, the nonparticipant subjects in this study were

Caucasian, male bachelors, working full-time, 18-24 years of age, and living alone or with a roommate. The nonparticipant subjects had a bachelors degree, a net income of < $20,000, and mostly classified their occupation as a student. Predominantly, the participant subjects in this study represented a group of older men who had more free time and more money because of no financial burdens or employment commitments; whereas, the nonparticipant subject in this study represented a younger, not married, retired, more educated male who had personal time commitments and financial concerns of being a student or working full-time.

Rosenthal and Rosnow (1975) in their original work on volunteer characteristics, noted that volunteers tend to be better educated, have higher social-class status, and are more intelligent. They also noted that females are more likely to volunteer for research in general, but not for stressful research. In addition, they noted that there was some evidence to suggest that volunteers tend to be younger than nonvolunteers. DeLuca et al. (1995) and Endo (1975) also reported that more educated subjects are more likely to respond to surveys and that education seems to be the pivotal factor in distinguishing between participants and nonparticipants. In this study, however, education level was higher in the nonparticipant group. Hudmon and Chamberlain (1994) found that employed subjects were 2.7 times more likely to participate than were subjects who were not employed, and men were 2.4 times more likely to enroll than were women. These findings were partially supported in this study, in that males overwhelmingly participated.

More than four-fifths of the participant subjects and three-fifths of the nonparticipant subjects stated that if asked, they would participate in clinical research in

the future. Hudmon et al.(1996), study on participants' perceptions of a phase I colon cancer chemoprevention trial also found that three-quarters of the participants expressed an interest in future trials. Similar findings were also reported in several other studies in which investigators have asked study participants about their interest in joining future trials, over two-thirds have indicated an interest (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Leonard, 1994; Henzlova et al., 1994, Schron & Pressel, 1995).

At the time of this study, the majority of participant subjects and more than half of the nonparticipant subjects reported that they were presently involved in a clinical study. Predominately, respondents were only involved in one study. The majority of respondents stated that this was their first experience of being involved in clinical research and that they had not been in a clinical trial in the past. More than half of the respondents expressed that they were "glad" that they had taken part in clinical research. The participant subjects reported that they had taken part in clinical research primarily to help themselves and others, for extra income, and that it had been an interesting and fun experience for them to have met other people. The nonparticipant subjects stated that they had taken part in clinical research primarily for the extra income and to help with the development of new and better medications. Very few participant subjects who had been asked to participate in a clinical study declined the opportunity to participate. If they did, it was primarily for the reasons of other commitments and time conflicts; whereas, the majority of nonparticipant subjects did decided not to participate for reasons of other commitments, no advantages perceived for participating, and felt that the side effects had been down played by the study administrators.

More than three-quarters of the participant subjects and half of the nonparticipant subjects stated they were happy with their decision to participate in clinical research. The participant subjects perceived and stated that by participating they were able to have helped others and themselves without interfering with other commitments in their life. Developmentally, when one considers the demographics of the participant subjects in this study, it serves to strengthen why a group of older, retired men who had more free time, more money, and fewer commitments came to the decision to participate in clinical research. As for the nonparticipant subjects, more than likely they had perceived the extra income as a benefit to their participation but to some nonparticipant subjects they needed to balance the benefit of extra income with other commitments they had. For both the participant and nonparticipant subjects this had been their first experience with clinical research.

Factors Influencing Participation in Clinical Research

Knowledge of Clinical Research

There was a high agreement (> 90%) among respondents on knowledge relating to clinical research. The majority of the respondents understood that it was a subject's right: to be told about the possible risks, benefits, complications and side effects of taking part in clinical research; to refuse to participate in clinical research; to receive all information that they need to decide whether they want to take part in clinical research; to change their mind at any time and withdraw from clinical research; and to have their participation in clinical research kept confidential. It was recognized by respondents that clinical research was needed to study the effects of treatments. There has not, at present, been a

standardized, widely applicable tool with which researchers have determined subjects' knowledge and understanding of clinical research. Although many studies have been conducted to inquire about subjects' knowledge of the consenting process, no study was found which investigated subjects' knowledge of clinical research.

It was understood by respondents that subjects: may not directly benefit from participating in clinical research; have the right to know the purpose of clinical research; are protected from mental, emotional, moral, and physical injury; and, are given a written informed consent form to help decide whether or not they would participate in clinical research. Although the participant subjects were in agreement, there was a slightly higher understanding by the nonparticipant subjects that: some subjects would be in a 'placebo' treatment group and that only certain individuals would be asked to participate in clinical research. Nonparticipant subjects may not have a clear understanding that not all clinical research have 'placebo' treatment groups, or even what is meant by a 'placebo' treatment group. A 'placebo' treatment group can be a term to describe what is considered treatment by normal care (Spilker, 1991). The nonparticipant subjects also did not notice, or did not understand, the definition of 'placebo' provided in the questionnaire.

Fewer respondents knew that a researcher could not use or release information that was not described in the consent form; that subjects are given an equal chance of being in the research treatment group or 'placebo' treatment group or that subjects are informed when a clinical study requires information to be withheld. The respondents did not know that: subjects were told to which treatment group they were assigned and that subjects needed to be able to speak and read English.

Less than half of the participant subjects were of the understanding that the consent form for clinical research protected the researcher and/or the hospital from legal action or liability, whereas the nonparticipant subjects predominantly were of the understanding that this was false. Joseph (1994) emphasized that many subjects perceive the consent form as too long and complex for them to assimilate. The consenting process is perceived as one designed to protect the physician in case of adverse outcome, rather than as an instrument of subject advocacy that allows them to assess the risk/benefit ratio. Less than half of the participant subjects were unsure as to whether subjects would be told about the results of clinical research, whereas the majority of nonparticipant subjects did not believe that subjects would be told about the results of the research. Joseph (1994) supports this finding by acknowledging that the long waiting period before release of even preliminary information on the progress of a study is a deterrent. Joseph suggested the release of interim data analysis to participants to alleviate discomfort. Rosenberg, Gagnon, Murphy-Gismondi, Ooi, Kiel and Lipsitz (1996) reported that in clinical gerontologic research certain factors influenced potential subjects decisions to participate, particularly having written results.

Attitudes and Beliefs Toward Clinical Research

Respondents overwhelmingly believed that: subjects have the right not to take part in clinical research; clinical research was voluntary and a necessary way to learn about new treatments; information in the consent form was important in helping subjects to decide about participation in clinical research; subjects' information should be kept confidential; and they knew what clinical research was about. An interesting finding in this

study was that the participant subjects strongly believed that they knew what clinical research was about more so than did the nonparticipant subjects.

Respondents also believed that: a subject may not get any benefit from participating in clinical research; it is important to take part in clinical research; consent forms are legal forms that protect the physician; taking part in clinical research may expose subjects to harmful side effects or complications; and subjects have a 50-50 chance of being in the 'placebo' treatment group. It is interesting to note that, the participant and nonparticipant subjects believed that it was important to take part in clinical research. However, the participant subjects more strongly believed this than did the nonparticipant subjects. Again when one reflects back to the knowledge the participant and nonparticipant subjects had of clinical research, the respondents stated that they definitely knew that clinical research was needed to study the effects of a treatment. Another interesting point was the respondents were of the belief that the consent form was a legal form that protected the physician. This finding is congruent with the poor understanding of consent forms that was also demonstrated by the participant and nonparticipant subjects previously. Does it influence whether a potential subject participates in clinical research? In this study the understanding of consent forms appears to influence what is understood and what attitudes potential subjects may have of consent forms.

More than half of the respondents believed that: subjects do not believe what the researcher tells them; the researcher often tries to persuade people to take part in clinical research and that the researcher always knew what treatment subjects were receiving. Respondents did not agree that once a subject began a clinical study, it would become

difficult to withdraw. The majority of nonparticipant subjects were more likely to disagree that refusing to participate in clinical research affects one's future medical care than participant subjects.

Some of the respondents were unsure as to whether: subjects who take part in clinical research hear the results; subjects who participate in clinical research receive the newest treatment; and family members supported subjects participating in clinical research. It is an interesting finding that the respondents were unsure if they would ever hear the results of the study that they participated in. This is congruent with the findings where the participant subjects were unsure as to whether subjects would be told about the results and the nonparticipant subjects understood that they would not be told. Joseph, (1994) and Rosenberg et al.(1996) stated the importance of imparting the findings of clinical research to participants as it influences willingness to participate in clinical research.

In this study there was some uncertainty as to whether a subject would receive the newest treatment if they participated in clinical research. Participant subjects were unsure and the nonparticipant subject did not believe that they would receive the newest treatment if they decided to participate. This may reflect the poor understanding of what the participant and nonparticipant subjects knew about the 'placebo' and treatment groups in clinical research.

DeLuca et al.(1995), study found that spousal approval was a significant predictor of research participation. Ninety-seven percent of subjects who had the approval of their spouse consented, whereas 96% of those who spouse opposed the research study declined. The opinion of family members other than the spouse also had a significant

influence on subjects' involvement in a clinical trial. Ninety-three percent of subjects with the approval of a family member participated, whereas those for whom a family member advised against participation unanimously declined (DeLuca et al., 1995). In this study, 43% of the participant subjects agreed that family members supported subjects in participating in clinical research, whereas 37.9% of the nonparticipant subjects were unsure as to whether family members supported them participating in clinical research.

Participant subjects were more likely to agree that physicians may encourage their patients to take part in clinical research than nonparticipant subjects. This finding is interesting, as Joseph (1994) cautions physicians not to be judgmental. The physician should only reassure any potential participant who is having unusual difficulty in reaching a decision regarding participation that whatever decision he or she makes will be the right one for him or her.

Hewlett (1996) reports that there may be influences on the potential subject who is invited to join a research study which are circumstantial and possibly accumulative, and therefore, affect whether one volunteers. The voluntary decision to join a research study should be made independently of controlling influences of others, such as coercion, manipulation, and persuasion (Beauchamp & Childress, 1989). Hewlett suggests influences could include: a desire to please or not displease the researchers; feelings of obligation; practical pressures such as access to a clinic on a particular day that may be for research subjects only; a belief that superior health care will be obtained; misunderstanding of information; gratitude for past care and the need for future care; and access to new or the only potential treatment in some illnesses where there is no current, effective treatment

available. Therefore, there is some evidence that potential subjects may experience difficulty in refusing to participate in research. While decisions on clinical research cannot be completely removed from the influential scenario of illness or the physician-patient relationship, as this study and Hewlett (1996) suggests, there still needs to be an awareness or steps taken to improve the process of obtaining consent and participation. There was only one area that the participant and nonparticipant subjects had direct differing opinions. Nonparticipant subjects' believed that participating in clinical research took alot of time, while the participant subjects did not.

Perceived Advantages and Disadvantages of Participation in Clinical Research

The majority of respondents in this study reported that the greatest advantage of participating in clinical research was doing something that will help others. The majority of participant subjects perceived the greatest advantage of participating in clinical research was development of new treatments and advancement of medical research, while the nonparticipant subjects stated that the financial compensation was the greatest advantage.

The respondents reported that receiving information and being able to ask questions about the research treatment was an advantage to participating in clinical research. Other advantages of participating in clinical research provided were: getting the best medical care; doing something positive for themselves; getting better follow-up and care; seeing the physician more often; and receiving money or gifts.

The majority of the respondents perceived they would be receiving the best medical care if they participated in clinical research. Cassileth et al. (1982), in determining attitudes toward clinical trials, sent questionnaires to patients with acute illnesses on

attitudes towards clinical research among patients and the public. They reported that both patients and the public agreed that clinical research was an opportunity to get increased medical care. It is an interesting to reflect that although the respondents perceived getting the best medical care as an advantage to participating in clinical research, it was the participant subjects who perceived getting better care and follow-up to be more of an advantage to them than did the nonparticipant subjects. In this study, the nonparticipant subject believed clinical research took alot of time, the nonparticipant subject did not have as much flexible personal time, whereas, the participant subjects had more flexible time. Specifically, the nonparticipant subjects are younger and traditionally have fewer health problems than does an older population, therefore, having better care and follow-up for the participant subjects could be viewed as a stronger advantage and a reason to participate in clinical research.

The use of money as a financial reward for participating in clinical research has been studied (Bigorra & Banos, 1990; Rudy et al., 1994; Wineman & Durand, 1992; Belizzi & Hite, 1986). It is well known that money is probably the easiest and most widely used incentive for increasing subject recruitment and retention, and some researchers believe that it increases compliance (Rudy et al., 1994). Financial reward is a major factor for healthy volunteers in agreeing to participate in clinical research (Bigorra & Banos, 1990). The results of this study are consistent with this finding; both the participant and nonparticipant subjects rated receiving money or gifts as an advantage. Monetary payment of subjects, however, is complicated by the issue related to the morality of payment and to the reasonable amount of payment that subjects should receive. It is interesting to note

that a larger percentage of the nonparticipant subjects reported receiving money or gifts as an advantage. The nonparticipant subjects in this study reported a lower net family income compared to the participant subjects and this could be a reason why the nonparticipant subjects perceive receiving money or gifts as an advantage to participating in clinical research.

Interestingly, the participant subjects were more likely than the nonparticipant subjects to perceive some advantage in receiving the newest treatment if one participated in clinical research. It was the nonparticipant subject who did not understand the nature of the research treatment group and the 'placebo' treatment group, and it is perhaps this lack of understanding which may account for not perceiving it as great an advantage as the participant subjects. As well, participant subjects were more likely than nonparticipant subjects to perceive some advantage in seeing the nurse more often. Similarly, in a study completed by Pearce et al. (1992), Stroke Prevention in Atrial Fibrillation (SPAF), participant subjects rated liking the nurse coordinator and liking the physician investigator as important motivators in their decision to participate.

The literature is fairly consistent in describing advantages to participation in clinical research. The most commonly cited advantage of participation in 4 studies was related to close medical follow-up (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Leonard, 1994; Hudmon, Stoltzfus, Chamberlain, Lorimor, Steinbach, & Winn, 1996; Cassileth et al., 1982). Although this was not the most commonly cited advantage in this study, it was seen as an advantage by the respondents.

Altruistic reasons appeared to be the most or second most stated advantage of participation in 6 previous studies (Mattson et al., 1985; Tangrea et al., 1992; Nasco & Leonard, 1994; Sutherland et al., 1993; Henzlova et al., 1994; Schron & Pressel, 1995). The findings of this study also suggest that altruistic concerns are very important to most potential subjects considering participation in clinical research. When approaching a potential subject for a clinical research study, it may be helpful to appeal to the person's desire to contribute to the advancement of medical science and to help others as well as themselves. When approaching a potential subject, it may also be beneficial to mention the frequent medical care provided by the clinical research.

The majority of respondents in this study reported that the greatest disadvantage of participating in clinical research was experiencing side effects of the treatment. The respondents were of the same opinion that the greatest disadvantage of participating in clinical research was the effect on one's health in regards to side effects experienced, harmful treatments, and the risks involved with new treatments. This finding was supported by Tangrea's et al. (1992) and Hudmon et al. (1995), who also found that the main disadvantage of participation in both chemoprevention trials was the amount of time spent in the clinic, followed by side effects of the study medication.

It was well recognized by respondents that having to: miss work; travel to and go more often to the clinic or hospital; and disrupt one's normal daily routine to attend appointments, were disadvantages of participating in clinical research. Review of the literature also showed that reported disadvantages of participation were related primarily to transportation and parking for clinic appointments (Mattson et al., 1985; Nasco &

Leonard, 1994; Henzlova et al., 1994; Kusek et al., 1996; Schron & Pressel, 1995). Sutherland et al. (1993), found that attending appointments to be the most common reported disadvantage of participating in clinical research. In a study that compared participant to nonparticipant subjects in a head and neck cancer prevention trial, Hudmon and Chamberlain (1994) also found transportation problems to be the greatest disadvantage of trial enrollment.

Although there was agreement by the respondents as to what was perceived as a disadvantage to participating in clinical research, it was the nonparticipant subjects who perceived a greater disadvantage of: experiencing side effects of the treatment, missing work, traveling to and from the clinic/hospital, disrupting of normal daily routine, and, needing to go to the clinic/hospital more often than did the participant subjects. The nonparticipant subject in this study reported having less personal time available, and as all the stated disadvantages appear to have some negative effect on time availability, this may affect whether a potential younger subject decides to participate in clinical research. The participant subject also stated that the one reason that they participated in clinical research was because it was an interesting, fun experience to meet people, suggesting that they are more willing to accept the extra time commitments it takes to participate in clinical research.

The majority of respondents were unsure as to whether: losing one's privacy; not knowing if one is receiving the research treatment or 'placebo' treatment; having to arrange child care; and getting free medications were considered more of an advantage or disadvantage to participating in research. More participant subjects were undecided as to

whether having a chance of being in the 'placebo' treatment group was considered an advantage or disadvantage compared to the nonparticipant subjects who were also undecided. Joseph (1994) agrees that many potential subjects will have difficulty dealing with the uncertainty associated with a placebo-controlled trial, and the physician and nurse must be prepared to answer many questions and reiterate the importance of this design.

Furthermore, participant subjects were unsure or undecided as to whether being treated like a 'guinea pig' was an advantage or disadvantage of participating in clinical research, whereas nonparticipant subjects considered it a disadvantage. Joseph (1994) identified with this ambivalence towards clinical research. She stated that there is a lack of trust in physicians that is currently widespread. Negative reporting in the media has reinforced this attitude and subjects frequently voice the fear of being a 'guinea pig'. Being involved in testing new treatments was viewed as an advantage by the participating subjects, while the nonparticipant subjects were unsure as to whether it was considered an advantage or disadvantage. Joseph (1994) believed it is the physician's and nurse's responsibility to explain potential advantages of participation in clinical research, such as closer supervision and access to promising new therapies. The majority of participant subjects viewed getting to know one's physician as an advantage to participating in clinical research, whereas the nonparticipant subjects were unsure or undecided as to whether that was an advantage or disadvantage to participating. It is perhaps the nonparticipant subject who perceive the patient-physician relationship as intimidating. A simple request by the physician regarding participation in a study may make the subject feel potential subject feel uncomfortable, yet obligated to enroll in the study. Potential subjects may fear they will

endanger their association with the physician. It is particularly difficult for those patients with a strong dependence on their physician (Diamond, 1995). The participant subjects were also unsure or undecided as to whether not knowing what to expect was considered an advantage of participating in clinical research, while the nonparticipant subjects considered it a disadvantage.

Thus, the respondents had difficulty deciding whether certain factors were perceived as an advantage or disadvantage of participating in clinical research. Perhaps, the respondents uncertainty is not understanding the question being asked (i.e., losing one's privacy; being treated as a 'guinea pig'), whether the situation applied to the respondents (i.e., arranging child care; getting free medications), or whether the respondents did not know the answer (i.e., not knowing if one is receiving research or 'placebo' treatment).

Other Factors Influencing Participation in Clinical Research

The majority of respondents identified similar factors that influenced their decision to participate or not participate in clinical research. Respondents indicated that they had received written materials describing what the clinical research was about and had talked to family or friends before making their decision to participate or not participate. It is interesting to note that the nonparticipant subjects responded more favorably than did the participant subjects. The nonparticipant subjects did not live with family members; they either lived with a roommate or they lived alone. The majority of nonparticipant subjects were also not married. One can potentially conclude that friends, and not just family members are people that the younger potential subjects may speak with before making

their decision to participate. Respondents also stated that they had not spoken with their physician prior to making their decision to participate or not participate. Nonparticipant subjects overwhelmingly did not talk with their physician before making their decision to participate or not participate in clinical research. The nonparticipant subject perceived any extra visits or time commitments as impingements on their personal time, therefore, speaking with their physician would be considered an extra visit or telephone call to their physician, which they would perceive as not having the time to do. Whereas, the participant subjects viewed seeing the physician more often more of an advantage than did than did the nonparticipant subjects. The participant subjects as well, believed that physicians encouraged patients to participate in clinical research. Newburg, Holland, and Pearce (1992) maintain that knowing the factors that motivate subjects to participate in research trials may help the researcher to develop an approach that will elicit a positive response from potential candidates in future research studies.

Perceptions of Being Informed About Clinical Research

Participant subjects were more likely to report being informed about the purpose of the research compared to the nonparticipant subjects, although all respondents in this study stated that they knew and understood the purpose of clinical research. Participant subjects reported being informed about why they were asked to participate in the clinical research as compared to the nonparticipant subjects. Of interest, the nonparticipant subjects were of the understanding that only certain individuals were asked to participate in clinical research. In response to how informed of the possible side effects of participating in clinical research, the participant subjects described being more informed

with regards to the possible personal risks involved in participating in clinical research than nonparticipant subjects. Initially the respondents understood that subjects had the right to be told of the all risks, benefits, complications and side effects of their participation in clinical research. As well, all respondents believed that participating in clinical research may expose them to harmful side effects or complications. It was the nonparticipant subjects who stated the reason they did not participate in clinical research was because they perceived the side effects as being too great.

Participant subjects were more likely than nonparticipant subjects to describe that they were casually informed with regards to how the study findings would be used. The respondents did not know and believed they would not be told about the results. Predominantly the respondents considered themselves very well informed of what they would need to do in the clinical research study; the purpose of the research; and of how much time it would take to participate in the study.

Suggested Learning Techniques for Clinical Research by Respondents

The most frequently described suggestions for ways to help other potential subjects learn about clinical research was to have the information about the clinical study presented by the physician and the nurse. The participant subjects more than the nonparticipant subjects believed that information about the clinical research study presented by the nurse was a helpful technique. This was in keeping with this study's finding that the participant subjects perceived seeing the nurse as an advantage to participating in clinical research. DeLuca et al. (1995) found comparable results to this study, there was a significant difference in the rate of participation based on the person

who initially approached the subject for the study. DeLuca et al. stated that the subjects who were approached by a physician, 93% agreed to join. Of the subjects who were approached by an experienced cardiovascular research nurse, 66% of them joined.

The majority of the respondents agreed with the suggestions of: hearing about the good things that have been discovered from clinical research; hearing one person's story from the beginning and all the way through a clinical research study; and to speaking to people who have previously taken part in clinical research. Joseph (1994) supported the finding of hearing one person's story from beginning and all the way through the clinical research study and suggested that a 'buddy' system be incorporated for potential participants to meet someone already enrolled in the protocol in question. Already enrolled subjects often are effective advocates for clinical research.

There were differing opinions between the respondents with regard to the suggestions of viewing TV shows or video tapes with people who have previously been in clinical research. The participant subjects believed both to be helpful techniques and the nonparticipant subjects were unsure as to whether either were helpful techniques or not.

Participant subjects suggested more information sheets outlining expectations of the participant subjects in clinical research would help make the decision to participate in clinical research, whereas, the nonparticipant subjects suggested having more precise information on time commitments needed by the participant for each research study would be helpful. This finding is not new but is consistent with the nonparticipant subjects strongly implying that clinical research impinges on his personal time and interferes with other commitments. A qualitative study using focus groups by Butler (1996) identified a

similar finding to the participant subject in this study, when she asked participants in a clinical trial to identify issues that individuals should know to agree to participate in a research study as part of their treatment. Consistently rated was the need for more information about a study when asked to participate to facilitate subjects' questioning. In another study, this finding was not supported. Hejl, DeLuca, and Grano (1987) provided potential subjects with a brief easy-to-read information sheet as an adjunct to the standard informed consent process of a verbal description and an written consent form with the intent of increasing subjects' understanding of the EPILOG study and/or decision to participate. Surprisingly, they scored significantly lower on a quiz than potential subjects who did not have an information sheet, as well it did not increase the likelihood that they would agree to participate in the clinical trial.

Implications for Nursing

Based on the data generated from this study, a number of implications for clinical nursing are identified. Clinical research nurses/coordinators play a key role in the provision of information prior to obtaining a subject's consent for participation. Assessing a potential participant's readiness to consent to a clinical study and ensuring that all questions are answered to the participant's satisfaction should be the nurse's responsibility. Nurses are most often the person directly involved in explaining the study for recruitment purposes. It is frequently the nurse who also maintains ongoing contact with study participants for data collection purposes throughout the study. Providing explanations and information about their involvement in the study could be part of the

ongoing dialogue. Participants may also feel more comfortable asking the nurse with whom they have been able to establish an ongoing relationship questions about a study.

The results of this study suggest some helpful guidelines for preparing potential subjects for future studies:

1) Provide maximum opportunity for the younger male to participate in clinical research by recognizing his lack of free time and financial concerns with recruitment strategies such as flexible and short appointments and financial stipends or incentives. The older male participant subject can be retained with suggestions that participation will offer an opportunity to become involved in a new experience that will help others and themselves. The female subject in this study definitely needs considerably more support, resources and encouragement for them to decide to participate.

2) It is important to maintain complete demographic and personal information registry of participant and nonparticipant subjects, in so far as being able to accurately depict a study's sample, but also for a potential recruiting reference in the future. From the literature and this study's results, participant subjects will often decide to participate again in future studies, unless the study does interfere with other previous or time commitments. As well, the nonparticipant subject can also be approached again even if they have previously decided not to participate in clinical research. Nonparticipant subjects may consider participation if a stipend/incentive is offered and if the study does not interfere with other commitments.

3) In an effort to increase potential subjects understanding and comprehension of clinical research, as well as encouraging a more equal partnership with researchers by informing

subjects about clinical research and empowering them to ask appropriate questions, Hewlett (1996) suggests providing to all potential subjects invited to participate in clinical research a leaflet entitled, " A Patient's Guide to Medical Research". By providing this leaflet, potential subjects can increase their knowledge of clinical research which in turn, improves the quality of an informed, voluntary decision to participate.

As a researcher recruiting potential subjects, discussion with potential subjects highlighting areas of clinical research that may not be well understood could influence the subject's decision not to participate to be a more affirmative one. Suggestions from this study include: 1) explaining to potential subjects which and why certain individuals are asked to participate in clinical research, and others not; 2) discussion of what exactly is considered the 'placebo' treatment group according to the protocol and what is the chance of the potential subject being in this 'placebo' treatment group versus the research treatment group. Potential subjects need to be informed and know that a researcher cannot use or release information that is not described in the consent form.

All potential subjects need more knowledge regarding the consent form, what it does and whom does it protect. If allowed by the particular protocol, all potential subjects need to be made aware if they need to be able to speak and read English, and if any considerations will be made if they do not. Potential subjects, be it the potential participant and nonparticipant subjects, need to know that at the end of a study they can find out what treatment group they were assigned to in the study. As well, all potential subjects need to be made aware that if information in a study needs to be withheld, they would be informed of this. It is also important that all potential subjects know that at the end of a study they

will be informed about the results of the study. Keep participants aware of the study's progress and notify study participants as soon as results are available.

4) Be responsible for the discussion of the research study and encourage questions. Allow potential subjects to articulate their understanding of what the clinical study entails. By being able to articulate what a clinical study is about imparts to the researcher and the potential subject an understanding and comprehension of what the study is about, therefore, allowing the potential subject to make a informed decision regarding their participation in clinical research.

5) Discuss in broad terms to potential subjects the importance of clinical research. Inquire from potential subjects their opinion of the importance and value of clinical research. A positive attitude about clinical research is reflective of participation in clinical research.

6) Be responsible for the discussion of the consent form and encourage questions from potential subjects. The potential subject should be given the opportunity to take the consent home and discuss it with his/her family. Include family members to accompany potential subjects to information sessions and to assist them with study requirements.

Findings from this study illustrate the need for nurses to advocate on behalf of the potential subject and to play a more active role in ensuring family involvement in the consent/participating process. This will help to facilitate questioning and provide the opportunity for more than one person to hear the message. Family members can then help each other to understand what has been said. The timing and delivery of information is crucial to subjects' understanding of clinical research. If family members are unavailable to

potential subjects to discuss the decision of participating, friends of the potential subject should not be ignored, especially if a potential subject is younger and not married.

7) Minimize as much as possible disruptions to potential participants schedules. Be flexible in fitting the participant's schedule to minimize disruption of daily routines. Be conscience of the younger male potential participant who has many personal time commitments. If possible, make creative suggestions on how the study will not impact or be of a great burden to a potential participant.

8) Emphasize to the older potential participant the care and follow-up that will be provided; i.e., laboratory or diagnostic testing. To the younger potential participant emphasize that care and follow-up will be provided but will not be done outside the original specified time boundaries initially stated.

9) Consider providing compensation (money or gifts) for time in completing a study with a complex protocol.

10) Be clear in describing to potential participants what is meant by being in the research treatment group versus the 'placebo' treatment group, and how these ratios will affect who will receive the newest treatment.

11) Provide potential participants times of accessibility and contact numbers to the nurse for participants questions or concerns.

12) Provide accessible and subsidized parking. Incorporate travel expenses to and from clinic/hospital. This will encourage retention of participants.

13) Reassure participants that side effects will be treated and that they will receive prompt attention to problems that may arise from the study.

At the time health professionals offer participation to potential subjects, they must be aware of factors that may influence decisions about enrollment. Assessing knowledge, attitudes, perceived advantages and disadvantages and factors of influence would provide an opportunity for health professionals to address these issues directly. Surveying why subjects participate in clinical research and finding out what they feel they receive in return for their time and effort as volunteers is useful to enhance recruitment and retention rates, and also helps study investigators/coordinators make the clinical trial experience a satisfying and valuable one for the participant.

Limitations

The generalizability of this study is limited due to the use of a convenience sample. The study results cannot be generalized to the larger population of research participant and nonparticipant subjects due to the non-representativeness of this sample. This means that the results are specific to the persons who responded to the PPCR questionnaire and the specific Cardiology Clinical Trials for which they were recruited. Another limitation is the sample size of the nonparticipant subjects. Although a high response rate was obtained, the overall sample size was limited, especially with regards to the nonparticipant subjects. This made comparisons between the participant and nonparticipant subjects problematic. Furthermore, the results of this study are difficult to compare with other studies because of the variation in questionnaire designs, differences in the health condition studied, and demands of the different study protocols.

With consideration to the future use of this questionnaire, rewording one question and eliminating one question from Section IV would be suggested. That is, question # 70,

"If you were asked, would you participate in a clinical trial?", would be better stated as, " If you were asked, would you participate in a clinical trial in the future?". Question # 75 read, " If asked again, would you still decide not to participate?". It is suggested to eliminate this question, as it did not provide any additional information.

The Cardiology Clinical Trials from which the respondents were drawn had varying protocol complexity, such as time commitments and remuneration. These differences would contribute to the findings being unique to this study. A point to consider would be to determine whether the degree of subject involvement or the potential perceived advantages and disadvantages associated with the different cardiology trials influenced subjects' decision to participate or not. That would encompass rating the 7 trials according to level of difficulty (low, medium, or high) and commitment required by the subjects. A complex protocol in a study may account for nonparticipant subject rates.

There is also a potential bias towards rating socially acceptable responses like "helping others" as important. Participation in the study was not anonymous. Subjects with the most negative experiences may have decided not to participate in the study. Furthermore, it is possible that "seeing the nurse" is reported as an important factor because positive relationships have developed between the cardiology research nurses and the researcher through follow-up phone calls regarding the completion of the questionnaire and the study participants by completion of the questionnaire. Lastly, it is important to note that the respondents defined as nonparticipants in this study, may not be reflective of their previous experience in clinical trials.

Directions for Future Research

The participation process in clinical research is not clearly understood in detail, that is, there is limited to no research done looking at the factors influencing participation and nonparticipation in clinical research, specifically the knowledge, the attitudes and beliefs, and the perceived advantages and disadvantages of clinical research participation and nonparticipation. It would be recommended that clinical research include questionnaires to both participant and nonparticipant subjects to further explore why they choose to participate and why they choose not to participate in clinical research.

The rates and reasons for subjects refusing to participate are not reported in nursing research studies, despite that such information would expand the understanding of how potential subjects view certain concepts and research processes. The most revealing information can be obtained by first documenting how many eligible participants refuse, followed by calculating the rate of declining for each study and comparing reasons for declining to reasons for agreeing to participate. By documenting rates and reasons of refusals, it would describe study samples accurately and identify study designs that have excessive demands on participants or in other ways discourage participation. Such information would be helpful to designing nursing studies that facilitate participation and maintain scientific rigor.

At present, more studies are needed to increase our understanding of the multiple factors related to participation and nonparticipation in clinical research as well as different types of clinical trials. Studies of this undertaking can be incorporated as part of future study protocols without excessive burden to staff or participants/nonparticipants and need

to continue in order to improve recruitment techniques. Knowing the factors that potential participants consider when deciding to consent or refuse and the refusal rates likely to occur with certain types of studies will assist researchers in making more accurate projections regarding sample size and recruitment time.

Conclusion

The respondents of this study were able to provide valuable insights into the knowledge, attitudes and beliefs, perceived advantages and disadvantages, and factors influencing participation in clinical research. The findings from this study could be used to field questions to a future studies that would aim to explore these issues with a larger number of subjects. In order that the experience of these individuals be understood, it is important to include not only the views of subjects who decide to participate, so are the views of those who choose not to take part in clinical research. By considering both perspectives, the process of decision-making to participate or not participate in clinical research can be more fully understood.

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APPENDIX A

Cardiology Trials Accessed for Study Participation

1. A three-way, single-dose, fasted and food-effect bioavailability study of Sotalol Hydrochloride tablets (160 mg) versus Betapace (160 mg) in males. **ISOCLINIKA Research, Edmonton, Alberta**

2. Comparison of blood pressure profile of the 18-24 hour period after intake of Telmisartan, Lorsartan, and a placebo, by ambulatory blood pressure measurement (ABPM) in mild to moderate hypertensive patients. **ISOCLINIKA Research, Edmonton, Alberta**

3. Canadian trial of atrial fibrillation (CTAF). **University of Alberta Hospital, Edmonton, Alberta**

4. Evaluation of the safety/tolerability of long-term treatment with the DMP inhibitor BMS 186716 or Lisinopril in subjects with heart failure. **Royal Alexandra Hospital, Edmonton, Alberta**

5. A multicenter trial evaluating 30 day and 6 month clinical outcomes with three different treatment strategies in patients undergoing coronary intervention. (EPILOG STENT). **University of Alberta Hospital, Edmonton, Alberta**

6. A phase III randomized comparative trial of hiudin versus heparin and warfarin versus standard therappy for acute myocardial ischemia without STelevation (OASIS-2). **University of Alberta Hospital, Edmonton, Alberta**

7. Antiplatelet aggregation useful dose study. (APLAUD). **University of Alberta Hospital, Edmonton, Alberta**

APPENDIX B

Letter of Introduction (on U of A Faculty of Nursing letterhead)

Dear Sir/Madam:

My name is Donna McLean. I am a graduate student in the Faculty of Nursing, University of Alberta. I am doing a study about people's views of participating in clinical research. The purpose of this study is to gain a better understanding of the knowledge, beliefs, and attitudes that affect decisions of individuals to either participate or not participate in clinical research. The findings from this study may improve the experience in future clinical research.

Your participation in this study would involve completing the enclosed questionnaire. It will take about **30 minutes** for you to complete. All replies will be treated confidentially. No names will appear on the questionnaire, only a code number.

Do not put your name on the questionnaire or the return envelope. Participation in this study is voluntary and your consent will be implied with the return of the completed questionnaire. The responses will be stored in a locked filing cabinet. The information may be used in another study after permission is received from an appropriate ethical review committee. **This study is in no way connected with any specific research study. The information that you share will not be given to anyone else, or used for any purposes except for this study.**

If you agree to participate, please complete and seal the questionnaire in the addressed, stamped envelope provided. If you have any questions about this survey, please contact me or my supervisor at the telephone numbers given below. A copy of the completed study will be available at the Faculty of Nursing, University of Alberta.

PLEASE RETURN THE QUESTIONNAIRE WITHIN TWO WEEKS

Thank you for your assistance in completing this questionnaire.

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APPENDIX C

Questionnaire **Perceptions of Participation in Clinical Research**

Perceptions of Participation in Clinical Research

Instructions for Completing the Questionnaire

Please read each question carefully. Circle the response which is most appropriate for you. Choose only ONE response unless otherwise specified.
On a few questions, you will be asked to write out your answer.

There are no right or wrong answers. Please answer each question as best as you can.

CONFIDENTIAL

THIS QUESTIONNAIRE CONTAINS SEVENTEEN (17) PAGES

Perceptions of Participation in Clinical Research

The questions in this survey are about "clinical trials research".

A "clinical trial" is a research study conducted to test a treatment. In research, clinical trials test treatments such as surgery, new procedures, new drugs, or a combination of treatments. Researchers ask eligible subjects to be in a clinical trial. Before participating, subjects must give their consent. Some subjects in the clinical trial may receive different treatments. Subjects are assigned by chance to a research treatment group or a "placebo" treatment group (treatment by normal care). Researchers observe and compare the results of each treatment group.

After reading the above definition of a clinical trial, please answer all of the following questions. Your answers are important **whether or not** you have ever participated in a clinical trial.

Section I

These items are about your understanding of clinical research. Please circle whether you think the following statements are (1) FALSE, (2) TRUE, or that you are (3) UNSURE. It is important that you answer each question. Please circle only one response.

		False	True	Unsure
1.	The consent form for a clinical trial protects the researcher from any legal action.	1	2	3
2.	Subjects have the right to receive all information that they need to decide whether they want to take part in the clinical trial.	1	2	3
3.	The purpose of the written informed consent form is to help subjects to decide whether or not they will participate in a clinical trial.	1	2	3
4.	It is the subjects' right to refuse to participate in a clinical trial.	1	2	3
5.	The consent form for a clinical trial protects the hospital from any legal liability.	1	2	3
6.	It is the subjects' right to change their mind at any time and to withdraw from a clinical trial.	1	2	3
7.	Being in a clinical trial may have risks.	1	2	3
8.	It is the subjects' right to be made aware of any possible complications or side effects of taking part in a clinical trial.	1	2	3
9.	A subject in a clinical trial must be able to speak and read English.	1	2	3
10.	It is the subjects' right to have their participation in a clinical trial kept confidential.	1	2	3
11.	Every subject should be told about the possible risks and benefits of taking part in a clinical trial.	1	2	3

		False	True	Unsure
12.	It is the subjects' right to know the purpose of the clinical trial.	1	2	3
13.	Subjects are informed when a clinical trial requires information to be withheld.	1	2	3
14.	A researcher cannot use or release information that is not described in the consent form.	1	2	3
15.	Subjects in a clinical trial must be protected from mental, emotional, moral, and physical injury.	1	2	3
16.	Some subjects who participate in a clinical trial will be in a "placebo" treatment group.	1	2	3
17.	There may not be a direct benefit to the subject from participating in a clinical trial.	1	2	3
18.	Subjects are given an equal chance of being in the research treatment group or "placebo" treatment group.	1	2	3
19.	Subjects will be told about the results of the clinical trial.	1	2	3
20.	Clinical trials are needed to study the effects of treatments.	1	2	3
21.	Only certain individuals are asked to participate in a clinical trial.	1	2	3
22.	Subjects are told which treatment group they are assigned.	1	2	3

Section II

These items are about your and beliefs about clinical research. Please indicate whether you AGREE OR DISAGREE with each of the following statements. Read each statement carefully. Circle only one response.

		strongly disagree	disagree	neither agree/disagree	agree	strongly agree
23.	I know what a clinical trial is about.	1	2	3	4	5
24.	The researcher always knows what treatment subjects are receiving.	1	2	3	4	5
25.	Clinical trials are a necessary way to learn about new treatments.	1	2	3	4	5
26.	Subjects who participate in a clinical trial receive the newest treatment.	1	2	3	4	5
27.	Subjects have a 50-50 chance of being in the "placebo" treatment group.	1	2	3	4	5
28.	It is important for people to take part in clinical trials.	1	2	3	4	5
29.	A subject may not get any benefit from participating in clinical trial.	1	2	3	4	5
30.	Taking part in a clinical trial may expose subjects to harmful side effects or complications.	1	2	3	4	5
31.	Subjects do not believe what the researcher tells them.	1	2	3	4	5

		strongly disagree	disagree	neither agree/disagree	agree	strongly agree
32.	Consent forms are legal forms that protect the physician.	1	2	3	4	5
33.	Subjects have the right not to take part in a clinical trial.	1	2	3	4	5
34.	The information in the consent form is important to help subjects decide about participation in a clinical trial.	1	2	3	4	5
35.	Participation in a clinical trial is voluntary.	1	2	3	4	5
36.	The researcher often tries to persuade people to take part in a clinical trial.	1	2	3	4	5
37.	Subjects who take part in a clinical trial never hear the results.	1	2	3	4	5
38.	Once subjects begin a clinical trial, it is difficult to withdraw.	1	2	3	4	5
39.	Participation in a clinical trial takes alot of time.	1	2	3	4	5
40.	Subjects' information is kept confidential.	1	2	3	4	5
41.	Physicians may encourage their patients to take part in a clinical trial.	1	2	3	4	5
42.	Family members support subjects participation in clinical trials.	1	2	3	4	5
43.	Refusing to participate in a clinical trial affects one's future medical care.	1	2	3	4	5

Section III

Below is a list of possible advantages or disadvantages of participating in a clinical trial. Your answers are important, whether or not you have decided to participate in a clinical trial. Please indicate HOW MUCH OF AN ADVANTAGE OR HOW MUCH OF A DISADVANTAGE YOU BELIEVE EACH STATEMENT IS. Circle only one response.

Participation in a clinical trial means:		**Very much a disadvantage**				**Very much an advantage**
44.	Receiving the newest treatment	1	2	3	4	5
45.	Doing something that will help others	1	2	3	4	5
46.	Getting free medications	1	2	3	4	5
47.	Getting better care and follow-up (for example, with laboratory tests)	1	2	3	4	5
48.	Having to travel to and from the clinic or hospital	1	2	3	4	5
49.	Doing something positive for yourself	1	2	3	4	5
50.	Having to miss work	1	2	3	4	5
51.	Being treated like a "guinea pig"	1	2	3	4	5
52.	Not knowing whether you are getting the research treatment	1	2	3	4	5
53.	Receiving information and being able to ask questions about the research treatments	1	2	3	4	5
54.	Having to arrange child care	1	2	3	4	5
55.	Losing ones' privacy	1	2	3	4	5
56.	Experiencing side effects of the treatment	1	2	3	4	5
57.	Being involved in testing new treatments	1	2	3	4	5

Participation in a clinical trial means:		**Very much a disadvantage**				**Very much an advantage**
58.	Disrupting your normal daily routine	1	2	3	4	5
59.	Getting to know your physician	1	2	3	4	5
60.	Seeing the physician more often	1	2	3	4	5
61.	Seeing the nurse more often	1	2	3	4	5
62.	Having a chance of being in the "placebo" treatment group	1	2	3	4	5
63.	Needing to go to the clinic/hospital more often	1	2	3	4	5
64.	Receiving money or gifts	1	2	3	4	5
65.	Not knowing if you are receiving the research or "placebo" treatment	1	2	3	4	5
66.	Getting the best medical care	1	2	3	4	5
67.	Not knowing what to expect	1	2	3	4	5

68. What do you think is the **greatest advantage** of participating in a clinical trial?

_____

_____

_____

69. What do you think is the **greatest disadvantage** of participating in a clinical trial?

_____

_____

_____

Section IV

It is very important that you answer all six (6) of the following questions. These questions are about your current and past participation in clinical trials. Please circle the appropriate response.

70. If you were asked, would you participate in a clinical trial?

yes.....1
no.....2
don't know.....3

71. Are you **currently** involved in a clinical trial?

yes.....1
no.....2
don't know.....3

If **yes**, are you involved in more than one trial?

yes.....1
no.....2
don't know.....3

72. Have you ever been in a clinical trial **in the past**?

yes.....1
no.....2
don't know.....3

If **yes,** how many?_____

73. Are you glad that you took part in the clinical trial(s)?

yes.....1
no.....2
don't know.....3
never participated.....4

If **yes**, why?

_____

_____

_____

74. Have you ever **been asked** to participate in a clinical trial, and **decided not to participate**?

yes.....1
no.....2
don't know.....3

If **yes,** why did you decide not to take part in the clinical trial?

_____

_____

_____

75. If asked again, would you still decide not to participate?

yes.....1
no.....2
don't know.....3

If **yes,** why?

_____

_____

Section V

These next questions are about your decision to participate or not participate in a clinical trial. Your answers are important whether or not you decided to participate in the trial. If you have been asked to participate in a clinical trial more than once, please refer to the most recent time. Please circle the appropriate response.

76. Did you receive any written materials that described what the clinical trial was about and what you would need to do?

yes.....1
no.....2
don't know.....3

77. Did you talk to family or friends before making your decision to participate or not participate?

yes.....1
no.....2
don't know.....3

78. Did you talk to your doctor before making your decision to participate or not participate?

yes.....1
no.....2
don't know.....3

When you made your decision to participate or not participate, how well informed were you about each of the following topics? Please circle one response.

		Poorly informed				Very well informed
79.	The purpose of the research	1	2	3	4	5
80.	What you would need to do	1	2	3	4	5
81.	Possible personal risks involved (for example, side effects)	1	2	3	4	5
82.	Benefits of participation	1	2	3	4	5

		Poorly informed				Very well informed
83.	Why you were asked to participate	1	2	3	4	5
84.	How the study findings would be used	1	2	3	4	5
85.	How much of your time it would take	1	2	3	4	5

86. Was there any other information that would have helped you make your decision?

yes..... 1
no..... 2
don't know..... 3

If **yes**, please specify what information would have been helpful?

_____

_____

_____

Below is a list of ideas/suggestions for ways to help people learn more about clinical trials. Please indicate how helpful you believe each one is. Circle one response for each question.

		Not at all helpful				Very helpful
87.	Information about the clinical trial, presented by the physician.	1	2	3	4	5
88.	Information about the clinical trial, presented by the nurse.	1	2	3	4	5
89.	Talking to people who have taken part in clinical trials.	1	2	3	4	5
90.	TV shows or video tapes with people in clinical trials.	1	2	3	4	5
91.	One person's story from the beginning and all the way through a clinical trial.	1	2	3	4	5
92.	Hearing about the good things that have been discovered from clinical trials.	1	2	3	4	5

Section VI

This section asks for some general information about yourself. Please circle the appropriate response.

93. What is your gender?

male.....1
female.....2

94. What is your age?

18-24 years.....1
25-34 years.....2
35-44 years.....3
45-54 years.....4
55-64 years.....5
65-74 years.....6
75-84 years.....7
85 years and over.....8

95. What is your current marital status?

widowed..... 1
divorced..... 2
separated..... 3
never married..... 4
married (including common law)..... 5

96. What is your highest level of education?

elementary school..... 1
junior high school..... 2
high school..... 3
college, trade, technical school..... 4
university (some)..... 5
bachelor's degree..... 6
master's degree..... 7
doctorate degree..... 8

97. What is your present employment status?

employed full time..... 1
employed part time..... 2
retired..... 3
not employed (on compensation/due to disability or injury)..... 4
not employed (unable to find work)..... 5
homemaker..... 6
student..... 7

98. What is (was) your main occupation?

homemaker.....1
student.....2
laborer/construction.....3
skilled trade/technician.....4
clerical/service/sales.....5
farming/horticultural.....6
arts/sports/recreation.....7
managerial/administrative.....8
health care occupations.....9
teaching & related fields.....10
social sciences & related fields.....11
natural sciences, engineering, mathematics.....12
occupation in religion.....13
occupation in law.....14
other (specify)_____15

99. What is your net family income?

under $20,000..... 1
$20,000 - $39,000..... 2
$40,000 - $59,000..... 3
$60,000 - $99,000..... 4
$100,000 and over..... 5

100. What is your ethnic/racial identity?

Caucasian..... 1
Native Canadian..... 2
African Canadian..... 3
Latin Canadian..... 4
South Asian..... 5
Chinese..... 6
Japanese..... 7
other (specify)_____ 8

101. With whom do you presently live?

spouse..... 1
spouse and children..... 2
alone..... 3
other (specify)_____ 4

102. Where do you presently live?

large city (population over 100,000)..... 1
city (population less than 100,000)..... 2
town (population more than 3,000)..... 3
village (population less than 3,000)..... 4
other (specify)_____ 5

103. In general, would you say your health is:

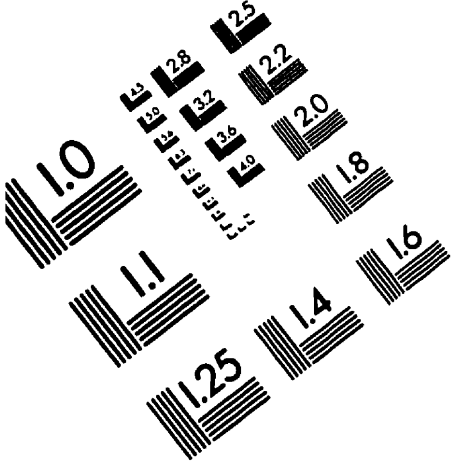
Excellent..... 1
Very Good 2
Good..... 3
Fair..... 4
Poor..... 5

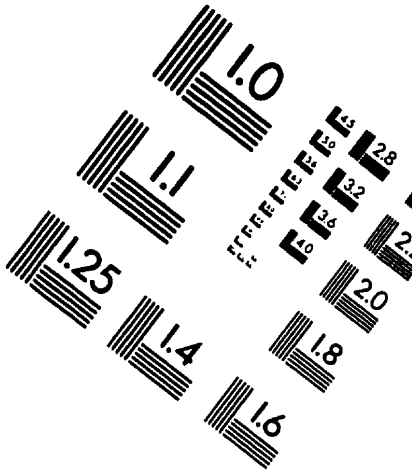
Please use this space to add any additional comments.

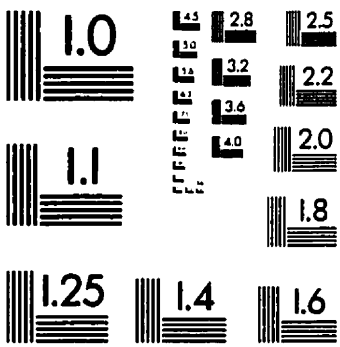
Thank you very much for taking part in this survey. The information you have provided will be very useful to other individuals who are asked to participate in a clinical trial.

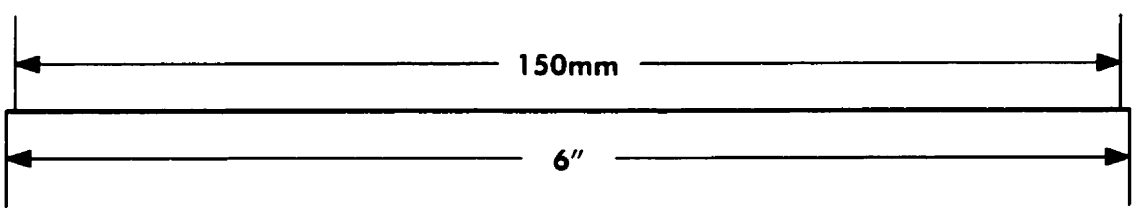
Please seal this questionnaire in the envelope provided.

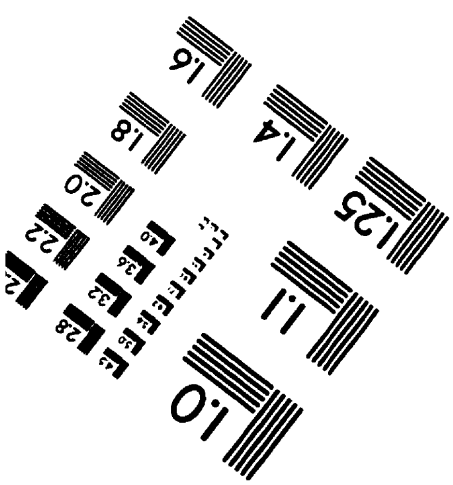
TEST TARGET (QA-3)

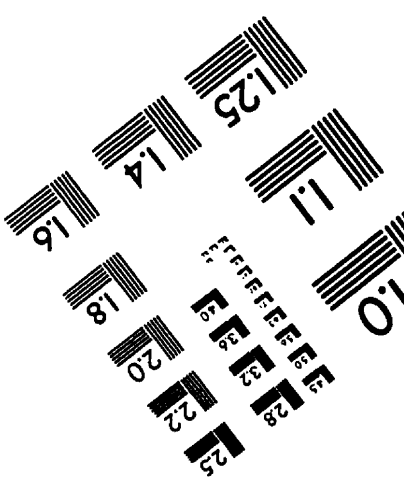












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