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ATTITUDES, BELIEFS, AND NORMS OF ADULT RESEARCH PARTICIPANTS

AS A BASIS FOR OUTREACH EDUCATION PROGRAMMING

A Dissertation in Adult Education

by

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Abstract

Millions of adults volunteer as research participants annually at research institutions across the nation. This research explored the attitudes, beliefs, and norms of rurally situated, adult research participants at a large research university. This systematic exploration of research participant experiences gathered information to inform the development of research protections outreach programming at the institution that reflects the adult education principle of learner participation in planning. Empirical data is lacking regarding the use of adult education principles in the design and development of research protections-oriented outreach programming, particularly in the area of non-clinical trial research that is conducted in non-urban areas.

This exploration consisted of a secondary analysis of focus group data collected from experienced research participants at the same research university. The secondary analysis of five focus group transcripts used a content analysis approach, guided by the Theory of Planned Behavior (TPB). Categories contained within TPB were used *a priori* to examine the data for beliefs, attitudes, and norms related to the known behavior of research participation. Four themes were identified in the analysis: Motivation to Participate, Participants' Personal Investment, Expectations and Rights as Research Participants, and Expectations by Participants of the Institution and Researcher. Results showed positive and negative attitudes towards a number of participation topics. Attitudes, beliefs, and norms varied across the participants. Despite these variations, however, all focus group participants had volunteered for between five to 10 studies within the past five years. Overall, commitment to helping others and making a contribution to research, the university, the community, and others was a strong motivating factor for participation. Personal benefits gained from participation were also strong factors influencing the intention to participate.

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And lastly, a message to all returning adult students: good for you and you can do it!

Chapter 1

Introduction

Millions of adults across the United States, in a variety of geographical, social, medical, educational, and other contexts, volunteer to participate in research every year (McGee, 1999; Tishler & Bartholomae, 2003). Universities and institutions rely on these individuals to volunteer as participants in research in a wide variety of disciplines, including those in the health/medical and social science fields (McDonald & Cox, 2009). Little empirical data is available about whether or how research participant experience informs the content of outreach programming which is specifically designed to address the general rights and protections afforded to individuals as research participants, outside of specific research contexts. A systematic exploration of research participant experiences gathered information to inform the development of outreach programming that reflects the adult education principle of learner participation in planning.

Research institutions rely on volunteers from the communities surrounding the institutions to further their myriad of research programs and agendas. Many institutions also rely on volunteers who may be located in distant geographical areas for online/internet research; however, this type of research is outside the scope of this discussion. Research institutions also rely on research protections programs within the institution, consisting of Institutional Review Board (IRB) members and others, to facilitate this research, while protecting the volunteers who are involved in it. Existing outreach efforts aimed at raising awareness of the public about their rights as research participants—which are most often delivered through research protections programs—are uneven in their availability, approach, and content, as evidenced by an internet search of major research institutions' webpages identified as containing information for research

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volunteers. Information and research is lacking on how outreach programming is developed to raise awareness of citizens, particularly in non-urban areas. Learner participation in program planning is a prominent principle in adult education theory and practice. Given that the programs to orient research participants are arguably a form of adult education, what is the level of participant involvement in the planning of programs for adult research participants? What stakeholders are involved in its development? Who decides what the content will be? How should it be designed and implemented to educate citizens, particularly in non-urban areas? Basic information about citizens' beliefs and attitudes toward research participation, especially citizens residing in non-urban areas, is needed.

Coming to the Problem

My interest in the area of outreach education for research participants grew from one experience that I had as a female, married adult with children. One sunny fall afternoon over 25 years ago, I answered the phone. A young male voice asked if I would answer some questions to help him with his graduate work at a local university. I asked no questions of him and agreed to do so. The questions began innocuously and gradually became more and more sensitive. I grew increasingly uncomfortable with the questions and with answering them, but continued. Finally, not knowing what else to do, I hung up without finishing answering all of the questions. I was embarrassed by the questions themselves, felt guilty that I might have had a major effect on the caller's graduate work, and also felt angry thinking that maybe I had been duped into answering sensitive questions as part of a prank. I vividly recall this experience to this day and I believe it played a role in shaping my subsequent professional life.

After years in the health care and other fields, I was looking for a change and answered an advertisement for a research position at the same local university. I do not think it was a

coincidence that I gravitated toward this research position, nor do I think that it was a coincidence that I moved on to work in the field of research protections at the same local university. That particular experience of so many years ago has never left me and piqued an interest in research participants' rights: how those rights are communicated to individuals, and what I would have wanted to know, and was not told, before I had participated in the study. Since that time, I have participated in over 30 biomedical and social science studies and continue to have an interest in this area. From initially being a participant, to working in a research environment interacting with research participants, to research protections work in which I observe the consenting process and review recruitment scripts and materials, my interest and involvement in the ethical conduct of research and research participant experience remains strong. The specific question of what information is and should be provided to research participants through outreach programs at a rurally situated research university was the personal and professional impetus for this study.

Historical Perspective

Ethical principles guide the protections of research volunteers. The Belmont Report, which was prepared and written by a national commission charged with establishing principles for the conduct of human participant research, identified three ethical principles that subsequently formed the basis of federal regulations related to research protections. Respect for persons, justice, and beneficence are the three principles that are the basis for the federal regulations that guide research protections activities, and they translate into the rights of research participants. The respect for persons principle broadly encompasses the concept of being informed and is most relevant to this discussion.

As a result of the Belmont Report, protections for research volunteers are defined and regulated by the federal government. Federal regulations protect research participants' rights and welfare and are administered through research protections programs associated with the institutions and organizations conducting the research. These regulations are the minimum standards for research protections. Many institutions and organizations additionally seek accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which holds them to more demanding standards.

Rationale for This Study

During 2009, more than 250 research studies were approved to be conducted by a large, rurally situated research institution's research protections program (institutional electronic management system, personal communication, 2009). These studies could have potentially enrolled more than 102,000 participants from one Pennsylvania county and its surrounding areas (institutional electronic management system, personal communication, 2009). The 2010 United Status Census shows that this county's population was nearly 154,000 people, including university students. Considering that potentially 66% of the individuals residing in this rural county alone were eligible to be research participants, attention to the design and development of research protections outreach programming for the general public is warranted. In addition, at this same institution, the long-term staff of the research protections program, who hold the program's institutional memory for the past 15 years, revealed that there was no involvement of community members in planning the outreach programming that currently exists.

Research protections personnel and organizations, especially those who are seeking national accreditation and are charged with developing required outreach programs, can benefit from an examination of rurally situated research participants' attitudes and beliefs about

participating in research. Researchers may benefit from this information by deepening their understanding and appreciation for the viewpoints of the participants upon whom they depend. AAHRPP evaluators may benefit from insight into participants' attitudes and beliefs about research participation, as they review outreach programming to determine if it is appropriate for the institution's or organization's size, location, culture, and population. Lastly, and most importantly, potential and experienced research participants also may benefit from this study in that empirical research will support development of appropriate outreach programs.

Gaining insight into the experiences of these volunteers, particularly their beliefs and attitudes toward participation, may be useful in developing instruments to effectively evaluate the educational needs of potential research participants. Such instruments could inform the development of effective models for designing and implementing outreach programming to potential adult research volunteers, thereby contributing to knowledge and practice in the field of research protections.

Research Questions

For the purpose of this study, several new research questions were developed and applied to an existing data set. The data set used was from a focus group study (Lyons & Hunt, 2011 ["parent study"]) conducted at a large, rurally situated research university. Perceptions of rural life, according to a 2002 Kellogg Foundation report, differ from perceptions of urban life, by rural and urban populations in a number of ways. These differences suggest that there could also be difference between rural and urban populations in terms of perceptions about research participation.

The data, previously collected for a related, but different research purpose, was secondarily analyzed for the purpose of this dissertation (Lyons & Hunt, 2011). The new

research questions were designed to: (a) identify common beliefs and attitudes of research participants drawn from a rural location, (b) lay the groundwork for further exploration of the topic, and (c) provide empirical data to use as the basis for developing appropriate outreach education and programming for this population. The overarching research question was: What are the attitudes and beliefs of rurally situated, adult research participants about their participation in research? Experienced research participants were defined as adults (age 18 and above) who self-reported participation in on-site research studies of any type at the institution within the past five years. The sub-questions that guided the secondary analysis were: (a) What attitudes, beliefs, and norms are reflected in adult research participants' responses during focus groups about their participation in research at a rural research university? (b) What attitudes and beliefs are related to their decisions to participate or not participate in research projects? and (c) What factors contribute to the attitudes and beliefs they express? Since little empirical data is available about how research participant experience informs the content of outreach programming specifically designed for rurally situated research participants outside of a specific research study context, the identification and description of these attitudes and beliefs could provide data to aid the design of such a program.

Definitions

According to the Code of Federal Regulations (45 CFR 46.102), research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Activities that meet this definition, whether wholly or in part, are considered to be research. Within this same section of the federal regulations, a human participant or subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through

intervention or interaction with the individual, or (2) Identifiable private information." The regulations further define an intervention as procedures that include those that physically gather data and/or manipulate the participant or the participant's environment for the purpose of research. Interaction encompasses communication, whether in person or through other contact that occurs between the researcher and the participant (45 CFR 46.102).

Private information, as defined in the regulations, includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). To constitute human participant research, private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or others) (45 CFR 46.102).

The definitions used in these particular regulations that apply to human participant research do not differentiate among types of research, recognizing that interventions and interactions can be combined in many ways. Physical interventions, such as blood sampling, are commonly referred to as biomedical research; survey, interviews, and focus group types of studies are commonly referred to as social-behavioral research. Much research, however, cannot be classified purely as biomedical or social-behavioral, and it encompasses components of both types of research.

Adult Education Perspective

The development of outreach programming and the participation of learners in that process reflects an adult education perspective. Several adult education scholars (Knowles, 1980, 1984; Cervero & Wilson, 1994) were strong advocates of the participation of learners in

program planning. This participation is a practical application of the respect for persons

principle. Participation of potential research volunteers in the program planning, initially

through an exploration of their attitudes and beliefs, will provide information relevant to the

design of outreach efforts. Knowles was also an advocate of participants being involved in

identifying and deciding about what and how they learn, which speaks to relevant content of

outreach programming (1980, 1984).

Theoretical and Analytic Frameworks

Content analysis and the Theory of Planned Behavior (TPB; Ajzen, 2005) guided the

formation of the research questions and the interpretation of the parent study's focus group

transcripts. TPB (Ajzen, 2005) predicts a particular behavior based on attitudes, beliefs, and

norms. These attitudes, beliefs, and norms influence intention to perform that behavior. The

intention to perform the behavior, according to Ajzen, is the best predictor of the actual

performance of the behavior. Perceived control or beliefs about the ability to perform a behavior

and the consequences of performing a particular behavior contribute to the intention to perform

behavior. The three categories—attitudes, beliefs, and norms—described by Ajzen's theory were

used to formulate the research questions for the secondary analysis and applied *a priori* to the

analysis of the transcripts. This allowed for identification of attitudes, beliefs, and norms as they

related to the actual performance of the behavior of participating in research.

Although TPB is used to predict behavior, in the context of this research, its value was in

helping to identify the precursors to intention and subsequent known behavior of participating in

research. The Theory of Planned Behavior guided the content analysis of the focus group texts.

Both TPB and content analysis are often associated with quantitative data and approaches, but

Krippendorff (2004), in discussing qualitative approaches and content analysis, writes that they

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are compatible. Content analysis is designed to be used with texts, such as transcripts. Frequency counts of words in the texts are part of a content analysis and help shape the development of a coding scheme. The development of the coding scheme can also be guided by the use of a theory, which is known as directed content analysis, according to Hsieh and Shannon (2005). In this case, the Theory of Planned Behavior provided the initial categories of norms, beliefs, and attitudes, to guide the coding scheme. Directed contact analysis is a structured approach to the process. Hsieh and Shannon note that when using a theory to direct the analysis, the findings may or may not support the theory, and examples to illustrate both can be described. Frequency counts that are used in a directed content analysis are not intended to be used for statistical tests in qualitative data; rather, they can be used to compare the rank order of codes, which aids in theme development and interpretation.

In content analysis, a coding scheme consists of grouping similar words and ideas together and naming or assigning a code to that group. The codes are then clustered, representing groups of similar ideas, which informs the process of theme development. Themes consist of clusters of codes that do not overlap and are mutually exclusive. The general framework of a directed content analysis, guided by TPB, was used in the qualitative analysis of the transcripts.

Summary

The purpose of this exploration of the beliefs and attitudes towards research participation of rurally situated, adult research participants was to (a) identify common beliefs and attitudes of rurally situated adult research volunteers, (b) lay the groundwork for further exploration of the topic, and (c) provide empirical data to use as the basis for developing outreach education and programming efforts to potential research participants in rural areas. The use of a directed

content analysis with the transcripts guided the theme development, which centered around the

TPB categories of beliefs, attitudes, and norms as expressed by research participants. The TPB

categories focused the analysis on beliefs, attitudes, and norms related to the intent to participate

in research and the actual behavior of participation in research.

Chapter 2

Review of the Literature

This literature review examines the ethical principles and regulatory basis of research protections' activities, the concept and practice of volunteerism, research volunteerism, research protections and research participant experience, general program design and development, and research protections outreach program design and development. The Theory of Planned Behavior also was examined in terms of its use as a theoretical framework. The characteristics of volunteers, in terms of the context in which volunteering for research occurred, characteristics of volunteers in general, as well as the beliefs and attitudes of these populations, including motivations and benefits, were part of this review. The review of the literature as it relates to outreach program planning and development in general, and for research volunteers in particular, focused on how research volunteer outreach programming is designed and developed, who was involved in that process, the communication that took place between institutions and potential research participants, as well as the inclusion of rural populations.

Ethical Principles and Regulatory Basis

Federal regulations that guide research protections' activities were promulgated based on the principles outlined in the Belmont Report [Department of Health, Education, and Welfare (DHEW), 1979], a product of the work of the National Commission for the Protections of Human Subjects of Biomedical and Behavioral Research (National Commission). This Commission was established as a result of the National Research Act (1974), which legislated the federal regulations that guided the development of the research protections system in the United States (Amdur, 2003, p. 16). The three principles contained within the Belmont Report are (1) respect for persons, (2) justice, and (3) beneficence; they form the foundation of the laws

that now regulate human research and human research protections. The Belmont Report itself notes that the principles are meant to be comprehensive and serve as a guide to the ethical conduct of human research for "scientists, subjects, reviewers and interested citizens" (Belmont Report, National Commission, p. 2, 1979).

The origins of the three principles of justice, beneficence, and respect for persons are directly linked to specific occurrences in the history of human research. The Tuskegee Study of Untreated Syphilis in the Negro Male (U.S. Public Health Service, 1932-1972) was the major impetus for the development of the Belmont principles, but many other studies before and after Tuskegee are also often cited as significant factors influencing the development and ongoing application of the principles. Incidents of mistreatment of research participants occurred in the Tuskegee Study and were among the atrocities committed by Nazi physicians in World War II (Bankert & Amdur, 2006). Unethical research conduct occurred in medical and social science human research from about 1930 and into early 1970, including the Thalidomide drug tragedy, the 40-year Tuskegee syphilis study, the injection of live cancer cells into elderly patients in the 1960s, Cold War-era radiation experiments, the Wichita Jury study, the Tearoom Trade study, the Milgram Obedience study, dermatological studies in prisons, and the Stanford Prison experiment (Final Report, 1998; Fisher, 2007; Hornblum, 1998). These examples documented the need for the three principles that were identified in the Belmont Report to serve as the ethical compass for the conduct of research with and the treatment of people.

The principles of justice and beneficence address participant rights in terms of the burdens, benefits, and harms that human research presents to volunteers (National Commission, 1979). The principle of justice addresses the distribution of the benefits and burdens of research—who should receive the benefits of the research and who should bear its burdens.

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Jenkins, Jones, and Blumenthal (cited in Blumenthal & DiClemente, 2004) frame the principle of justice: a breach in the justice principle "occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly" (p. 53). In the decades-long Tuskegee Study, a specific population was burdened with being the research participants in a study about syphilis, when syphilis affected a much wider population. This particular group also, for the most part, did not reap the benefits of the cure that was discovered as a result of their participation in the research. This inequity prompted the inclusion of the justice principle in the Belmont Report. The justice principle also addresses preventing the exploitation of potentially vulnerable individuals and groups of individuals. Vulnerability of a population may be due to its availability, social status, and/or ability to be manipulated (Childress, 2000, p. 357).

Balancing the benefits and harms that occur in human research is recognized widely as representing the principle of beneficence. The benefits of the research should be maximized and the risks or harms minimized (Childress, 2000). The Tuskegee study also strongly influenced the development of this principle. For many years, the participants received no benefits from their participation, and the syphilis that many of them had went untreated or undertreated, even after it was found that the disease could be cured with penicillin (Shavers, Lynch, & Burmeister, 2000). Those untreated or undertreated participants suffered lasting harm from the disease and received no benefits in terms of treatment. The principles of beneficence and justice, along with the third principle, respect for persons, translate into the rights of the participants, which are, in practice, evaluated and ensured through research protections programs and federal regulations.

The respect for persons principle is most pertinent to this discussion. It prescribes what kinds of information should be given to participants who volunteer for research, as well as giving attention to appropriateness in the manner and context that the information is given (DHEW, 1979). The respect for persons principle usually is interpreted to focus mainly on the informed

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consent process (Applebaum, Lidz, & Klitzman, 2009), which provides information to potential participants about specific research contexts. This principle, however, also has application to the information provided to the general population in outreach programs that address the rights of research participants (Fernandez, Kodish, & Weijer, 2000).

Important aspects of the respect for persons principle are the rights represented by the concept of autonomy: (a) the right to decide whether or not to participate in research, (b) the right to withdraw from research without penalty, (c) the right to be informed of the types of procedures to be conducted, (d) the right to know how confidentiality and privacy will be protected, (e) the right to know what the risks and benefits of the research are, and (f) the right to be informed of any new findings that might influence the decision to continue participation (Cassell, 2005). In addition, Lebacqz (2006), one of the authors of the Belmont Report, notes that respect for persons was not intended to focus solely on autonomy, but should include respect for the "social context in which persons gain and express their identity" (p. 102).

Drawing on the example of the Tuskegee Study once again, participants were not fully informed about the risks and benefits of the study and were not informed of new findings that might have affected their decision about whether to continue their participation. Victims of the Nazi doctors' experiments were not afforded a choice in whether to participate nor were they given the option to withdraw. They also were not informed of the study procedures that were being performed on them. The Nuremburg Doctors Trials, in which these Nazi physicians were tried, led to the development of the Nuremburg Code, which preceded the Belmont Principles, but also influenced them (Bankert & Amdur, 2006; National Institutes of Health, n.d.; Office for Human Research Protections, 2009; Shuster, 1997), particularly the respect for persons principle. Essentially, the respect for persons principle, embodied in informed consent, can be

distilled into how, what, when, where, and by whom information is provided, whether in general about participant rights or specifically about a particular study.

The injustices described above led to the development of the three Belmont principles. The Belmont principles form the foundation of research ethics and research protections as practiced in the United States today (Jenkins, Jones, & Blumenthal in Blumenthal & DiClemente, 2004, p. 52) and significantly affect the conduct of human research.

The Concept and Practice of Volunteerism

The Bureau of Labor Statistics at the United States Department of Labor tracks volunteers by the main type of organization for which volunteer activities were performed. The September 2011 report includes data on volunteers defined as "persons who performed unpaid volunteer activities for an organization." The categories of volunteer activities tracked did not include research volunteers. According to Perry and Imperial (2001), in a synthesis of volunteer and service-related research, there is "vigorous debate" over the very definition of what volunteering is and what service is. Where the boundaries lie is not clear, and the spectrum of unpaid "other-oriented" service to "stipend, self-oriented" service and volunteerism allows for many interpretations (Perry & Imperial, p. 469). These authors listed the wide variety of contexts in which volunteering can occur, and volunteering for research was notably absent.

Fisher and Ackerman (1998) defined volunteerism as "a non-market activity that provides services that otherwise would not be available in a community," and volunteers provide "inexpensive or free labor" (p. 262). The aim of these authors was to determine how promotional appeals increase volunteering—a promotional focus to encourage volunteering—in contrast with an educational focus (p. 263). However, their work also sought to show that volunteering is socially desirable, and, therefore, should be viewed as normative behavior. This study examined community volunteers and involved activities such as clerical tasks and

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working in a snack booth, dissimilar to tasks research volunteers are asked to perform. The study targeted factors such as group need and its relationship to recognition and found that sensitivity to the context of these factors was important in the effect they do or do not have on volunteering (p. 273).

Clary et al. (1998) noted that there "remains a need for an inventory that reliably and validly taps a set of motivations of generic relevance to volunteerism" (p. 1519). Social motives identified include curiosity, desire for novelty, power, achievement, social affiliation, and approval. These social motives, in terms of the extent to which they are pursued, are subject to social norms—informal rules reflected in individual behavior to conform to societal expectations (Bicchieri, Muldoon, & Ryan, 2011). Identifying these norms as they relate to the behavior of volunteering to participate in research specifically, especially focusing on a rural context, could be significant factors to take into consideration when planning outreach programming.

A variety of studies have been developed to learn why people volunteer, most often in the areas of human service, arts and culture, education, and health in direct service types of organizations, but not in research, according to Bussell and Forbes (2001). Bussell and Forbes also noted, however, that there "are so many different contexts in which one can donate one's time, the vast and growing literature in this area demonstrates that further investigation is required," and historically, the literature that does exist takes "little account . . . of local variations in volunteering" (p. 253). An example of local variations could include volunteering in research within a rural context.

Benefits of volunteerism is another factor that has been explored by numerous researchers who focused on elderly populations and their health (e.g., Van Willigen, 2000). Herzog and House (1991) found that in general, the "vast majority of adults over 60 believe that

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older people should contribute to society through community service after they have stopped working" (p. 317). Van Willigen (2000) noted that middle-aged adults volunteer "as yet another obligatory task to fulfill in order to be a good parent, worker," which reflects a social norm (p. 317). These findings relate to attitude and beliefs of volunteers in schools, churches, political organizations, senior centers, and "other," unidentified, organizations that were not described and do not specifically address attitudes and beliefs about volunteering in research. Whether these same norms are reflected in research volunteers, especially those who are rurally situated, is not apparent from a review of extant literature.

As Perry and Imperial point out (2001), there are differences among volunteers in regard to the benefits received, whether they are tangible or intangible. Though community-type volunteers are rarely compensated in dollars, many research volunteers do receive money for participation, but generally such benefits are meager in comparison to the benefits society may gain from their participation.

Kemp (2002), who studied volunteers in the Olympic Games, noted that while many volunteer experiences have been studied extensively, most research has focused on volunteers in social services. Her work with volunteers at this huge event found that motive and demographic characteristics tended to be similar to volunteers in social services, but there were some exceptions, such as pride in country, friendship, etc. These findings are relevant to this discussion in that rurally based research volunteers may also have some perceptions, attitudes, beliefs, and characteristics that are different from non-research volunteers.

Exline, Lisan, and Lisan (2012) studied undergraduate students and found that showing kindness (i.e., volunteering or performing an act that benefits others) was considered normative (one that follows social norms related to the context and one's past behavior) and was associated with generating positive emotion. Positive emotion is generated from following social norms, in

terms of behaving in generous ways within a person's comfort level and the positive emotion can serve as a motivating factor for volunteer activities. According to the authors, the performance of the act and resultant positive emotion are reciprocal in nature, i.e., of mutual benefit.

To date, at the large rurally situated research institution that provides the context for this study, very little communication has been established between the institution's research protections program and the research participants it protects, who are drawn heavily from the surrounding rural area. Tyron and Stoecker (2008), in a study conducted to assess service-learning in non-profit community organizations consisting of volunteers, found that in this setting communication was often lacking throughout the service-learning process. Ongoing and effective communication between parties—the institution and the organizations' volunteers—was cited as one of the top three factors contributing to success in this setting. Although the setting in which Stoecker's research was conducted is different than the context of this dissertation's research, it is related in terms of it being an organization that calls upon volunteers to serve. This similarity could suggest that communication between research volunteers and the institutional research protections programs could be an important factor in the development of a university's outreach programming.

Research Volunteerism

In the literature on volunteerism, research volunteerism has been largely overlooked; however, the literature that is available provides some insight into the topic of outreach programming for the general public. Lewis and Graham (2007) framed their work within a research ethics context with adult research participants who volunteered for social science studies. They recognized that "what is striking is that the debate about research ethics [which includes participant rights as protected by research protections programs] is not underpinned by much empirical research with actual or potential participants" and "the voice of research

participants is largely absent" (p. 10). Their work involved 50 in-depth interviews of adult individuals who had participated in social science research in the United Kingdom. They concluded that according to the participants, there was "clear value in . . . information being provided at more than one information event" (p. 75). Their work also provides insight into how the method of information sharing is perceived by research participants, such as the use of letters being perceived by participants as "formal" and "official." These perceptions could have significant implications in outreach program planning in terms of how the program and information is presented. Their work also provides support for offering research-related information to participants at multiple times (before, during, and after study participation). In addition, Graham and Lewis noted that "developing negotiative relationships with participants helps them play an active role in research encounters" (p. 78). Including research participants in program planning for outreach efforts could be a good way to begin a relationship such as Graham and Lewis describe.

Wright (2011) echoes the concerns of Graham and Lewis and describes research participants as "the missing stakeholder" (p. 496). Wright emphasizes the importance of what he calls the "committed-to-participant perspective" in which participants are highly involved in all aspects of research (2011, p. 503). His observations support the involvement of participants in outreach program planning efforts as a valid endeavor.

Graham, Lewis, and Nicolaas (2006) conducted a literature review of empirical studies that dealt with ethical requirements and research participation that provides some insight into the research participants' perspectives, especially participants in social science research. As these authors point out, there is a rich literature base about research participant experience focusing on specific conditions/diseases and about study procedures in a clinical context; these experiences

are largely described by the research team that conducts the clinical study. Clinical research typically involves hospital-based patients who are receiving therapeutic care, along with experimental procedures or products. The articles they reviewed focused on interview-based study procedures only and mostly with regard to participants with particular conditions, such as cervical cancer, psychiatric conditions, trauma, and suicide survivors, who were receiving clinical treatment in addition to or as part of the research process. Only one focus group study was represented. This review did not always indicate whether the populations were located in rural or urban areas. Of those in which location was identified, however, urban areas totaled 20% of the representation. Studies were conducted in the United States, Scandinavia, and other parts of Europe. What appears to be lacking in the literature reviewed by Graham, Lewis, and Nicolaas was a focus on adults residing in rural areas and those who were not patients involved in a combination of therapeutic treatment and research studies.

The Kellogg Foundation Report (2011) explored urban and rural population perceptions and found that there were differences in a number of areas: the economy, values, environment, and atmosphere. It was noted that the 242 respondents to their survey, which included urban and rural participants, cited issues such as access to health care, transportation, isolation/lack of exposure, and lack of opportunities as problematic (p. 10). Increased access to transportation, hospitals, and universities represented an increase in choices that urban populations have and rural populations typically do not. Although Lichter and Brown (2011) write that some of these differences are lessened as the "rural-urban interface" expands, making "sharp rural-urban distinctions . . . problematic," they suggest that more research is needed on rural America since discrepancies remain (p. 565).

Numerous empirical studies of the experiences of research participants in clinical settings are available (e.g., Ladas, 2006; Kirsch, 2000; Turner & Williams, 2002; Sugarman, Lavori,

Boeger, Cain, Edson, Morrison, & Yeh, 2005; Stunkel, Benson, McLellan, Sinaii, Bedarida, Emanuel, & Grady, 2010; Sugarman, 1999; and Sugarman, McCrory, Powell, Krasny, Adams, Ball, & Cassell, 1999), but similar studies conducted outside of the clinical context are much less prominent. Also, these studies tend to study specific disease processes or treatments, unlike research with healthy volunteers. Due to the clinical context, these studies also are most often conducted in urban areas, where medical centers are often located.

Benefits described by clinical trial participants in Mattson et al.'s study (1985) were mostly self-directed in terms of learning that occurred due to medical monitoring, reassurance, and physical improvement. Learning useful information about general health was seen as a benefit by some focus group respondents. Similarly, in a meta-analysis of the literature conducted by Zammar et al. (2010), which focused on participant willingness to participate in clinical trials, the authors found that patients most often cited personal benefits as an advantage of participating in clinical trials, but the desire to help others was found to be the most significant factor as it related to willingness to participate in clinical trials. The authors also noted that fear of side effects was one of the most significant reasons for not participating and concluded that appealing to individuals' desire to be altruistic, coupled with better explanations of side effects would encourage Brazilian patients to participate.

Morris and Balmer (2006) support the exploration of research participant experiences in the research process. They found that these experiences "remained curiously invisible" and that there is "little detailed study of the interaction between researchers and volunteers" (p. 999). The study conducted by the authors explored women volunteers in a biomedical study related to early clinical testing of a new method for diagnosis of breast cancer, similar to other studies focusing on specific disease processes (such as Krasner, 1998—ulcers; Fry & Dwyer, 2001—drug users; Kitchin, 2000—disabled people; Barnett, 2005—chronic obstructive pulmonary disease;

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Nordgren, Asp, & Fagerberg, 2007—heart failure). These empirical studies were conducted in clinical settings, focusing on the disease process rather than the research experience itself. Morris and Balmer also noted that the local context is significant in shaping volunteers' experience. Their work points to the need for additional research in the rural context and the idea that research participants' views "do not conform solely to one or other models of researcher-subject relationship as suggested in the literature, such as patient, donor, collaborator, employee" (2006, p. 1006).

Knapik (2006) focused on qualitative research in social science, specifically on participants who were interviewed by researchers. Knapik's goal was to explore participants' accounts of past research interviews, through individual interviews, in an attempt to determine what is the ideal interactional style in research interviews from the participants' point of view. Four university students were interviewed specifically about their research interview experiences. The overall approach was to ask participants what they remembered "noticing about their research interview at the time that was worth remarking on in the present, explaining an interest in contributing to researchers' debates about best practices" (p. 79). The analysis provided some insight into attitudes and beliefs for participating, including curiosity about the topic and the researcher's specific interest, as well as "a desire to contribute positively to the quality of the research" being conducted (p. 4). The university students participated in the original research interviews in an urban area, prior to Knapik's interviews.

The literature also provides some insight into non-adult populations involved research. Edwards and Alldred (1999) note that research activities do not take place in isolation and state that "it is usually aspects of . . . pre-existing processes and understandings that form the focus of research attention . . . however, they also have implications for how potential participants [including adults] view research. This applies to children as much as to any other social group."

(p. 277). They also note that the topic of the research is a very important factor related to

children's and young people's views of research as part of the wider contexts of their lives. The

authors emphasize the importance of dealing with differences among participants; these

differences can affect participants' "understandings and hence their decisions about

participation" (p. 279).

Specifically, Edwards and Alldred's (1999) research involved 70 British children living

mostly in urban and suburban areas, but also in one rural town. The rural population was mostly

White, but the other populations were ethnically diverse. The authors conducted this study,

gathering anonymous written feedback, because they noted that "there has been little attention

paid to exploring how children can view research and what understandings inform their

decisions about participation" (p. 261). The exploration focused on how boys and girls made

their decisions about whether to participate in a research study at school, before they actually

consented and participated, and it provides some insight into their attitudes and beliefs about

research participation. They found that "personal, local and wider societal contexts of their

lives" were linked to those children's views (p. 277). This insight also may be applicable to

adult volunteers in terms of their decision making process in the contexts of their lives.

Professional research participant experiences were discussed in an article by Weinstein

(2008). Weinstein examined the Belmont Report and a science-oriented professional code and

compared them with articles with contrasting points of view about research participants. He

emphasized the importance of presenting all views about research ethics and participation, within

a professional research participant context. Professional research participants are characterized

in the popular media as those who depend upon the financial incentives received from research

participation for at least a part of their livelihood. Weinstein concluded that "engaging in

polyvocal, situated" communication from "multiple perspectives" (p. 973), not limited to just

researchers, but participants themselves, "empowers . . . understand[ing]" of "both the importance and limitations of current ethical protections," which is the focus of institutional research protections programs. Weinstein's observations, however, were limited to these professional research participants, characterized as predominantly young, White males, participating primarily in pharmaceutical studies.

Institutional research protections programs, in the form of Institutional Review Boards (IRBs), are an abstract concept to research subjects and "rarely is there an understanding or a modest sense of credibility added by the presence of this protection reviewing entity" (Shamoo & Khin-Maung-Gyi, 2002, p. 56). This abstract concept and lack of understanding represents a significant disconnect between research protections programs and the very human participants they protect. The disconnect does not allow for the attitudes and beliefs of the population served to be practically and specifically taken into account when providing the protections and any related outreach programming.

Research Protections and Research Participant Experience

The literature that does exist around research volunteers' beliefs and attitudes about participating in research has largely been applied to informed consent documents and process, but rarely, if ever, applied to outreach programming in research protections. One example of research in which a needs assessment process was used in terms of research protections education was conducted by Sidle et al. (2006); however, the focus of this research had an international context and investigated IRB members, not research participants. Burris and Moss (2006), in their review of American IRBs and researchers' views of them, also noted that there is a "need for better information about how subjects feel about their experiences with research participation" (p.54).

Other selected literature that addresses research participant experience includes the work of Tishler and Bartholomae (2002, 2003), whose essay addressed normal, repeat, veteran volunteers in clinical research and issues related to participation in more than one trial at a time; and Susman et al. (1992) research which assessed children's and adolescents' knowledge of research participation. Susman et al. found that children and adolescents, regardless of chronological age, were more knowledgeable about concrete information (e.g., asking questions, how long the research lasted, and the benefits of research) and less knowledgeable about abstract information (e.g., purpose of the study in terms of science and/or therapy, and other available treatments). Grover's research (2004) focused on giving power and voice to children who participate in social science research; and Harth and Thong (1990) studied sociodemographic and motivational characteristics of parents who involved their children in clinical research in the United Kingdom. Harth and Thong found that the parents were motivated to involve their children by a desire to help others, but also to receive more information about helping their children. These studies provide some insight into attitudes and beliefs of research participants, but most are not focused on rurally situated research institutions or rural populations in non-clinical settings.

Bevan, Chee, McGhee, and McInnes (1993) studied patients' attitudes toward participation in clinical trials in the United Kingdom. They conducted structured interviews with nearly 200 patients and found that the primary motivations for participation were to help others and to help themselves with their own condition. In the United States, Hassar et al. (1977) found that healthy volunteers cited their prime motivations for participation as compensation and professional interest or curiosity.

Weinfurt et al.'s (2006) work addressed the kinds of information potential research participants wanted to know, specifically related to conflict of interest/significant financial

business disclosures prior to enrolling in a study. These researchers determined that participants did want to know whether the principal investigator or treating physician had financial interest in a product that was being used/tested in the study. And, importantly for study recruitment, they found that when information was provided, less than 5% of the participants changed their minds and decided not to enroll. In addition, brief and simple disclosures of this information appeared to be most effective, although the type and level of information desired varied according to the risk posed in the study. The focus group study also showed that prior to involvement in the focus group itself, participants did not know what to ask about financial conflict of interest, but following the focus group, they could identify the information they wanted to know. This study's findings support the value of giving general information to participants prior to encounters with study-specific recruitment, consenting, and participation.

A body of research on the informed consent process and consent forms exists and addresses participant understanding and retention (e.g., Flory & Emmanuel, 2004), consent form complexity, timing of information, method of delivering information, who provides the information (e.g., Sugarman et al., 1999), and other issues surrounding the consent process at the point of contact with potential participants for specific studies (e.g., Kelman, 1972). Less research and information is available on preparing potential participants—the general public— for the initial point of contact with a study-specific document and study personnel. Research focusing on informed consent documents and the informed consent process often examines participant perspectives. The importance of participant perspectives in this context gives credibility to the concept that participant perspectives in outreach program planning should be considered. Much of the informed consent literature represented research that was conducted on patient (clinical) populations, most often in urban areas.

A review of interventions targeted to improve research participants' understanding in informed consent was conducted with 42 clinical trials by Flory and Emanuel (2004). The populations included older individuals; people with mental illness, cancer, and other patients; and healthy volunteers. None of the interventions described included information about how the interventions were developed and what participant factors were taken into consideration during the development.

Other research on informed consent information, again with a population of patients in New Zealand, revealed that "the information patients want differs from what doctors think they want" (Newton-Howes, Bedford, Dobbs, & Frizelle, 2002, para. 4). This observation is pertinent to the discussion of outreach programming: How do we know what potential research participants want and need to know?

Research focusing solely on the informed consent document and consent process is spread across a wide variety of disciplines, according to Sugarman et al. (1999). Meaningful consent, comprehension of consent, quality of consent, length of consent forms, verbal consent, written consent, and readability of consent (Cardinal, 2000) are some of the topics on which research has been conducted. A review of this literature reveals that the informed consent topic, while fairly widely researched over a significant length of time, also tends to focus on urban populations in clinical settings. For example, Sugarman et al.'s work was featured in *Clinical Trials,* and enrolled only patient participants who received care and were involved in clinical trials at Veterans Administration hospitals (2005). The purpose of the research was to develop a general instrument to measure quality of informed consent, specifically designed to allow "the attitudes and beliefs based on experience" in research to be measured (p. 35). However, the instrument development process was in the hands of a small group of "experts in ethics research, informed consent, and the oversight of clinical research" (p. 35). The underlying goal of the

research was to measure responses of participants based on the *experts'* concepts of how quality should be assessed.

Hassar and Weintraub (1976) studied retention of consent information by participants in a clinical trial testing anti-inflammatory drugs and also assessed participants' reasons for volunteering. Two-thirds of the volunteers did not remember information provided in the consent process as it related to risk. Misunderstanding and mistaken information also occurred with many participants. These adult participants cited helping themselves and others with the arthritic condition they suffered from as reasons to participant. The authors recommended group meetings with other participants to discuss consent information and also suggested that the process of consent is very important to retention of information; specifically, presenting consent information multiple times throughout a research study.

The Agency for Healthcare Research and Quality (AHRQ) developed a toolkit for use in research which is focused on strategies for obtaining informed consent and authorization from potential research participants (2010, AHRQ website). According to the AHRQ website, as well as the *IRB Advisor* (November, 2009), this toolkit was developed using interviews and focus groups of research participants located in five metropolitan areas. Testing of the toolkit was conducted at Boston University Medical School, an urban and clinically oriented institution. The toolkit was developed and modified by health literacy, ethics, and clinical research professionals. The perspectives of rural research participants are not reflected in the development of this toolkit. This toolkit was designed to assist investigators at the time of consent by promoting participant understanding of specific clinical study-related information. The data collected in its development and testing targets an urban population involved in clinical research.

The literature on informed consent is pertinent because it is one of the tools used in the education of research participants, although informed consent information is necessarily study specific. The development of outreach programming to prepare citizens to be effective consumers of consent information is not found in the informed consent literature.

The informed consent literature also includes research about the process of obtaining consent. Kelman (1972) discusses the power differential that is inherent at the initial point of contact between study personnel and the potential participant. Study personnel, by the very nature of the work, are looking for information, and the only way they can get it is through interaction with humans. Study personnel are extremely well informed about the study procedures, what will be required of the participant, and the content area of the study topic. In addition, study personnel are familiar with the academic and research environment. Potential participants are at an immediate disadvantage at the first point of contact (recruitment, signing informed consent) because many have never interacted with the research and/or academic communities (Kelman, 1972; Cassell, 1978). Adult and child participants in research can all be affected by this disadvantage, in terms of minimal or no exposure about how research is conducted, as well as most likely having only a lay understanding of the research topic, unlike the investigators who have in-depth knowledge of it.

Other consent form research focused on different aspects of the consent process with a variety of populations. Corrigan (2003) showed that patients in clinical trials with chronic illness and patients with more acute illness varied in their views of participation and consent information given. Patients with chronic illness tended to look at the consent form and research participation as providing them with choices, while the acutely ill patients viewed the consent form and participation as burdensome. Black et al. (2007) in a study of enrolling patients with dementia for research, found that when the consent document was provided at the time of

enrollment and not ahead of time, the affected individuals and their surrogate decision-makers relied more on the information provided verbally and rarely appeared to read the entire consent documents. Turner and Williams (2002) studied surgical patients and found that these patients may have understood information given about consenting for surgery, but quickly forgot the information, whether the information was provided verbally or in written form. These studies and Singer's 1984 study addressed ethical issues related to informed consent. In Singer's study, individuals were randomly sampled from an urban population, contacted by telephone, and informed consent topics related to social research were addressed. Attitudes and beliefs of rurally situated populations were not targeted in this study.

General Program Design and Development

The literature related to the design and development of educational programming is robust, especially in the area of adult education, and representative literature was selected. However, outreach programming design and development as it specifically relates to potential research participants is more difficult to find. Program development principles, including needs assessment strategies and inclusion of learners in the process, may well be transferable to the development of outreach programming for the general public, but evidence of these principles being used in practice is quite limited.

Knowles (1984) was an advocate of participants being involved in identifying and deciding about what and how they learn, which speaks to relevant content of outreach programming. A particular emphasis in his writing is on the autonomy of the individual learner (1980). Vella (2001) echoes the value of "listening to learners' wants and needs" and doing so well before the actual course or program begins (p.5). Vella's listening model encourages dialogue and connection with learners to most reliably find out about attitudes, beliefs, context, and experiences that can have a significant effect on content and approach to programs.

Staff of the Michigan State University's Outreach and Engagement program (2006) identified several dimensions of quality outreach. In their view, planning quality outreach programming depends upon qualitative indicators such as the involvement and testimony of all stakeholders, along with examining the consistency of institutional values with stakeholder interests "according to community held values" (p. 4). Testimony of stakeholders—the input and feedback of major project participants—includes assessment of experience. These knowledge resources available within the community are fundamental quality indicators of outreach programming, and should be considered and documented in the planning phase of outreach programming, and also during the implementation and as follow-up. In the existing programming explored for research participants, these factors were not evident.

Apps (1979, cited in Cervero & Wilson, 1994), indicates that the typical and widely acceptable pattern of improving practice in adult education planning takes the following form: "assessing learners' needs, defining objectives based on those needs, identifying learning experiences to meet those objectives, organizing those learning experiences and evaluating the program in terms of the objectives" (p.3). In the review of materials related to outreach program planning, it is not evident that any of the formal steps described by Apps were used in the current outreach programming reviewed that is used for research participants.

The first step in assessing learners' needs, in this case those of rurally situated adult research participants, is to have a basic understanding of their beliefs and attitudes toward research participation in the context in which they have participated, in this case a non-therapeutic, non-clinical context. According to Cafferella (2002, p. 20), "people and place are acknowledged as important in the planning process." She goes on to emphasize the importance of being "knowledgeable about the people . . . and wider . . . contextual factors" (p. 23) in the program planning process.

Andragogy is a uniquely adult education concept and is based in the writings of Knowles (1980). Andragogy is a way of thinking about working with adult learners, according to Merriam and Brockett (1997, p. 135). One of the basic assumptions of Knowles' concept of andragogy is that adults need to be seen and treated as capable of self-directing their lives and their learning. Self-direction by potential research participants can be met in a practical way by involving them in the planning process for outreach programming.

Knowles (1980) viewed the participation of the constituents, the non-educators to whom outreach and program planning is aimed, as integral to the program planning process and as the basis for educational efforts, rather than using the educators' or staffs' perspectives and feelings about what and how information should be shared. The wealth of life experience that adults have needs to be explored to provide an authentic basis for outreach programming. Learning from experienced adult research volunteers, through an exploration of their beliefs and attitudes towards participating in research, allows for programming to be relevant and useful to them. Relevance and usefulness reflect important principles identified in programming by Vella (2002). Boyd, Apps, and Associates (1980) emphasized the importance of giving consideration to two important questions: for whom is the instructional program intended and by whom is it designed?

Ross-Gordon (1997), in discussing Knowles' approach to program planning, noted that Knowles insisted "that adults have significant involvement in the program planning process" (p. 218). In contrast to this insistence, Pratt (1993) questions Knowles' assumption that every adult learner actually wants to be significantly involved in all aspects of teaching and learning. And Tisdell (1998) criticizes Knowles' assumption from a feminist perspective, in terms of not "foregrounding participants' experience as women" (p. 144). St. Clair (2002) notes Tisdell's viewpoint that Knowles projected a "Western male concept of individuality" (p. 3). However,

Rosenblum (1985) observed that research is still needed to determine the effect of that participation in program outcomes. Until participants are systematically involved in outreach program planning, however, an effect cannot be determined. As Thompson (1992) points out in her review of the literature regarding the inclusion of learners in program planning, there is a wide gap between the theory and actual practice of involving learners in program planning, and that gap continues today.

Cervero and Wilson (2006) focus on whose perspectives and interests are actually being represented during the program planning process. Inclusiveness of perspectives becomes an ethical consideration, related to the Belmont principle of respect for persons—respect for the perspectives brought to the program planning process. Respect for these perspectives is operationalized through their use in the program planning process, especially those perspectives of the participants themselves. As pointed out by Sclove (2010, p.16), lay persons bring different insights to the decision-making process than do experts or typical stakeholders who have extensive knowledge or formal training in related areas of knowledge. The work of Cervero and Wilson and Sclove complement and reinforce Knowles' concept of learner participation in program planning.

Morisky, Fox, Murata, and Stein (1992) explored the steps in designing a community-based mammography education program for urban women and found that in order to develop effective strategies, a needs assessment was needed. This needs assessment used community members' knowledge resources to identify beliefs and attitudes toward mammography. These beliefs and attitudes were then incorporated into outreach programming in the form of strategies to address barriers and prevalent beliefs and were reflected in educational and other materials. The researchers found a relationship between attitudes (positive/negative) and whether or not women actually had mammograms performed. Also, they found that geographical location and

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perceptions about mammography influenced behavior and noted that "this finding is important in that it guides and directs the educational efforts . . . through a broad community education program" (p. 474). Related to this study is the work of Olowokere, Onibokum, and Irinoye (2012) in Nigeria on the same topic. Their focus was on the importance of understanding women's beliefs and behavior in regard to breast screening practices and how this information could be used by community health nurses to address the educational needs of community members on this topic. Both studies addressed incorporating volunteers' beliefs and attitudes into health-based community outreach; however, in this case the focus was on women, on a distinctly health-related topic, and the geographical contexts differed in terms of population density and culture.

Learner participation and an understanding attitudes, beliefs, and norms of individuals involved in the outreach program are important factors in program planning in general. Given the volunteer nature of research participation and risks volunteers may encounter, these factors are especially important to establishing a credible foundation for research protections-related outreach programming.

Hamilton (2008) notes that Bandura's model for the design and development of outreach education emphasizes that it "should be guided by research on how people think and what influences their behavior," and that research-based outreach is better outreach. Bandura also advocates that a variety of research approaches are needed to achieve high quality, research-based outreach (para. 14). An exploration of the attitudes, beliefs, and norms of adult research participants can begin to provide a solid, research-based foundation for research protections outreach program design and development.

Research Protections Outreach Program Design and Development

The literature was reviewed to find evidence of research-based outreach program design and development, specific to research protections.

In the literature review, the focus was on available information pertinent to the topic of outreach programming for the public as it related to participation in research studies. A number of topics were explored to provide evidence of participants' attitudes and beliefs being used in the development of the programming. The literature search for the current study focused on finding references that would provide information about rurally situated institutions, non-hospital/non-clinical populations, evidence of needs assessment and/or systematic data collection used in outreach program planning, and program effectiveness. The search focused on non-study specific topics addressed in outreach, including the general rights of research participants. The basis of the development of research institutions' outreach programs was explored to compare the foundational information used to formulate those programs. Public websites of research institutions were reviewed, specifically targeting sections relating to research participant outreach education. The public website of the federal Office for Human Research Protections (OHRP) also was reviewed for information relating to research participant outreach education. Website searches were conducted using a variety of search terms to locate information about outreach program development for research participants in research institutions. The search revealed a lack of information in many of these areas, but anecdotal information, based on public website explorations, provides some insight into this area.

One example of empirical research that addresses the topic is the work of Dennis and Ebata in 2005, which concentrated on developing research-based outreach to rural families. The rural families studied included only those with adolescent family members. The study focused

on the use of web-based outreach programming. Instead of using self-report, focus groups, interviews, and other means were used to inform the development of outreach and education efforts on parenting, as well as evaluation of the effectiveness of the programs developed. The researchers found that sound principles of instruction are especially important for effectiveness when technology is used. This approach offers support for this study of beliefs and attitudes of research participants, another area in which research-based evidence for the development of outreach programming is lacking.

In 2004, a report by the Human Subject Research Program at the U.S. Department of Energy (DOE) prioritized education and outreach program delivery and stated the following: the "education of potential subjects must . . . be provided with an understanding of their rights and responsibilities as research subjects" (p. 6). The DOE report (2004) encourages open discussion of "fears, risks, and concerns" and recommends that potential participants should "understand the rationale, the process, and their rights" through *"well-designed educational outreach programs"* [my emphasis] (p.7). However, the report does not provide any criteria for the design of the outreach programming. The DOE report (2004, p.7) succinctly states that "the goal of outreach is to educate, not recruit, and should focus on making the community knowledgeable and enlightened about the research enterprise. It must also thoroughly explain what it means to be a research subject." These statements are the only direction given by the DOE in terms of design, development, and implementation of outreach programming for the general public (i.e., potential research participants).

In contrast, Anderson and DuBois (2007), in a review of the literature pertaining to substance abuse research, note that, at least in research about substance-abuse, "well-intentioned protectionist concerns—about recruitment incentives, consent comprehension and drug administration studies—are not supported by empirical data" (p. 95). The literature review

focused on a specific research area and addressed specific study-related activities, but it does give credence to the idea that basing outreach programming on perspectives of those who are working to protect participants may miss the mark. The basis of that outreach programming may be better informed by the perspectives of research participants themselves.

As Mealor and Frost (2012) write, "we believe the most critical component of an effective outreach program is knowing your participants. As educators, we have to ask ourselves: a) what information do my clientele want or need, and b) how does this particular group of participants want to receive the information" (p. 41). Understanding participants by knowing what information they want or need and how they want to receive it supports the need to seek out and consider research participant perspectives for use in the design and development of outreach programming.

As McDonald and Cox (2009, p. 14) assert in reference to outreach education: "the onus is on the research community to collect and use . . . evidence to good effect." As part of the research community, research protections programs, which include Institutional Review Boards, have a responsibility to collect and use information about what happens to volunteers and potential volunteers as they participate in research and apply it in developing outreach programming for these volunteers. McDonald and Cox (p. 15) also assert that these types of explorations are "ethically mandatory."

Mazur (2007, p. 28) supports outreach programming and notes, "The opportunity for education about the spectrum of research should not be missed. Rather, the IRB and research service should consider developing an educational program about various types of research studies being conducted at the institution." The basis for the design, development, and implementation of such outreach programming is not specified; however, the type of educational programming that Mazur supports is in contrast to the specific information about individual

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research studies that is given to potential participants during recruitment and the consent process, which remains the responsibility of the principal investigator and study teams.

Ferman and Hill (2004, p. 241), in their work within community and institutional partnerships, note that there is a "paucity of studies that report the perspective of community partners" in these types of studies. Communities, made up of individuals, have not been comprehensively examined for their perspectives on research. The partnership between institutions and communities as a whole needs more examination. The similar partnership between individuals and research protections programs (including IRBs) also needs in-depth examination (Michigan State University's Outreach and Engagement Program, 2006).

The American Association for the Accreditation of Human Research Protections Programs has developed criteria to evaluate research protections programs in the area of outreach to research participants. Their public website states, "The accreditation process will be responsive to changes in federal regulations and to standards that will evolve based on what AAHRPP learns from accrediting organizations from research settings" (AAHRPP website, Accreditation Principles, subsection 2.6, 2012). An examination of and critical reflection on the basis of institutional outreach programming for research participants thus has national implications for accreditation standards that are applied to all other institutions seeking, undergoing, or having been accredited by AAHRPP. Currently, over 1,075 institutions and organizations are accredited by AAHRPP (AAHRPP website, 2010). This appears to be the only information provided on the public website about the development of standards in general, and outreach-related standards in particular.

Public websites of selected nationwide institutions that are AAHRPP accredited were examined as part of the literature review. This examination revealed that not all of these institutions have research protections outreach programs, some are limited to providing links to

external websites about research participation, and some have video or print-based information available to potential participants. Typically, information contained on these websites reflects the information available on the federal OHRP website, which is aimed at a nationwide, non-context-specific audience. In addition, those individuals responsible for outreach programming within research protections offices typically are not identified on the website, making it impossible to determine whether they had adult education backgrounds and/or formal training in program planning.

Additionally, the federal OHRP website and a website for research participants were examined for evidence of adult education principles used in the development of outreach programing planning. The website for research participants was focused on potential participants in clinical research. It is not apparent on the OHRP website, which is often a link provided on many institutions' research protections websites, whether local or other contexts were taken into consideration in its design. Boone, Safrit, and Jones (2002, p.147) refer to pre-defined, non-specific programs as "canned" and note that they are often used in adult education contexts "without investigating the need for tailoring them to meet local needs."

In considering evidence-based human participant protection, McDonald and Cox (2009) state that such protections would be based on a "careful investigation of the effects of research on human participants" (p. 1). Improved human research protections can result, in part, from "feedback from those involved in research on humans" as part of a process for developing evidence-based human participant protection, which is also applicable to outreach programming (p. 3).

Frequently, as noted by Strauss (2009), any information given, whether in an outreach program or an informed consent, is what research protections offices think participants want and need to know based on the regulations, rather than empirical evidence that reflects attitudes and

beliefs that may influence the development of the programming. Strauss also notes that there is an assumption made by research protections offices that "every subject wants and needs the same amount of information" (p. 107). And as Siminoff (2003) wrote, "although providing information is important, providing information in an indiscriminate fashion is unlikely to be productive" (p. S2).

The Theory of Planned Behavior (TPB)

In program development, the identification of beliefs and attitudes of learners is an important part of the process, as well as considering and incorporating them into the decision-making about content and implementation, and involving the learners in that process. Pinpointing the attitudes, beliefs, and norms that influenced the intention and actual performance of participating in research has value in the process of planning outreach programming for those who have not performed the behavior. Ajzen and Fishbein developed the Theory of Reasoned Behavior (1980), in which they "tried to estimate discrepancy between a person's attitude toward a behavior and the actual performance of that behavior" (p. 87). Ajzen continued to work on the theory with the recognition that human behavior can be both deliberative and planned, adding the component of perceived behavioral control. With this addition, the Theory of Planned Behavior (TPB) was formed. TPB is a familiar theory used in social psychology to explain human behavior. TPB has been used in diverse fields of research representing a wide variety of behaviors (Armitage & Conner, 2001; Godin & Kok, 1996, as cited in Rhodes & Courneya, 2003).

TPB, according to Ajzen (2011), provides a straightforward way to look at a targeted behavior and the factors that influence the performance of that behavior. Ajzen's theory describes three major categories that are instrumental in predicting whether a particular behavior is performed: attitudes, beliefs (which influence perceived behavioral control), and subjective

norms. Attitude toward the behavior is evaluated in terms of being positive (favorable) or negative (unfavorable), and attitudes reflect beliefs about the consequences of performing the behavior. Perceived behavioral control reflects beliefs about the perceived ability to perform the behavior. The subjective norm reflects personal beliefs that are influenced by the perceived societal expectation about the performance of the behaviors. These categories are the main influences on the formation of a behavioral intention.

Ajzen (2011) notes that "As a general rule, the more favorable the attitude and subjective norm, and the greater the perceived behavioral control, the stronger should be the person's intention to perform the behavior in question" (p. 75). The weight the three categories have in determining the intention can differ not only among behaviors for any individual, but also among groups of people. Intention to perform the behavior, if an adequate amount of actual control over the behavior is present, generally is a good predictor of actual performance of the behavior. It is difficult, if not impossible, to identify all of the important factors that may influence actual performance of a behavior, but if people are self-reflective in their evaluations about performing a behavior, the amount of control they perceive as having can be a robust substitute for actual control. In this way, perceived control can then be useful to predict the target behavior (Ajzen, 2006).

The Theory of Planned Behavior (TPB), according to its author Ajzen, is "well supported by empirical evidence" (p.179, 1991). Its value is in the reliable prediction of the performance of behavior. Ajzen found that attitudes towards the behavior, coupled with beliefs about social norms and perceived behavior control, influenced intention to perform a behavior. The intention to perform a behavior, according to Ajzen, is the most powerful precursor and predictor of actual performance of a behavior (1991). TPB's three categories are attitudes, beliefs, and norms.

The categories of attitudes, beliefs, and norms that Ajzen developed focus the application of the theory in the context of this secondary analysis of transcripts. Focusing on these categories as they relate to research participation (the known behavior) and as expressed by the participants themselves, provides a framework for analyzing the discussion that revolved around research participation.

Ajzen (1991) himself notes that exactly how the relationship among the categories of attitudes, beliefs, and norms in predicting behavior works is not known, and that two other factors figure into the predictive equation. These are past behavior and perceived control, which when combined with the other categories has been effective, according to Ajzen, in predicting behavior. Using these categories in this analysis, along with the knowledge of the self-reported past behavior of participating in in research and the perceived control expressed as decisions about participation, provided an opportunity to assess the effectiveness of the theory in this particular context.

Summary

The review of the literature in the broad areas of volunteering and outreach program planning, and the more specific areas of volunteering in research and research protections programming, offers little evidence that adult education principles are used in outreach program planning for the general public. Also clearly lacking is context-specific information that could be used to tailor programs for rural individuals and institutions.

The exploration of the attitudes and beliefs of rurally situated, experienced adult research participants was a first step for at least one institution in developing context-specific research participant outreach programming. Additionally, this programming was intentionally based on sound adult education and program planning principles and concepts.

Chapter 3

Methods

A qualitative approach was taken to explore the attitudes and beliefs of rurally situated volunteers who participated in social science and non-hospital-based biomedical research studies. Using a data set collected from a previously conducted focus group study, a secondary analysis of the data was performed. The secondary analysis of the data was guided by a new set of research questions. A framework for content analysis was developed and followed for the secondary analysis within a theoretical framework based on the Theory of Planned Behavior (TPB). The content analysis framework was chosen because it allows for identification of themes within TPB and also provides for additional, qualitative interpretation of those themes. The quantitative aspects of content analysis, which reflect an objective approach, seemed particularly appropriate since TPB is also, at its roots, an objectively based theory.

Research Questions

For the purpose of this current study, several new research questions were developed and applied to the parent data set. These questions were designed to: (a) identify common beliefs and attitudes of research participants drawn from a rural location, (b) lay the groundwork for further exploration of the topic, and (c) provide empirical data to use as the basis for developing appropriate outreach education and programming for this population. The overarching research question that guided this secondary analysis was: What are the attitudes and beliefs of rurally situated, adult research participants about their participation in research? The sub-questions were: (a) What attitudes, beliefs, and norms are reflected in adult research participants' responses during focus groups about their participation in research at a rural research university?

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(b) What attitudes and beliefs are related to their decisions to participate or not participate in research projects?, and (c) What factors contribute to the attitudes and beliefs they express?

These questions were developed using the three categories of the Theory of Planned Behavior: norms, attitudes, and beliefs. TPB identifies the categories of attitudes, beliefs, and norms as influencing factors for intention to perform a behavior, which is the best predictor of actual performance of a behavior. By using these categories as a guide in the directed content analysis, an understanding of factors important to participating in research can be identified. TPB's traditional value is in predicting behavior; in this case, its value is in guiding the identification of factors that may have influenced a known behavior. Since little empirical data is available about how research participant experience informs the content of outreach programming specifically designed for rurally situated research participants outside of a specific research study context, the identification and description of these attitudes and beliefs could begin to provide data to aid the design of such a program at a large research institution.

Qualitative Research Design

To accomplish the goal of identifying and describing these attitudes and beliefs, a qualitative research approach was deemed appropriate. Qualitative research is a "broad approach to the study of social phenomena and the approach is naturalistic, and interpretive, drawing on multiple methods of inquiry" (Rossman & Rallis, 2003, p. 6). The purpose of qualitative research is to describe, compare and contrast, or forecast in order to build theory, improve practice, and/or change policy (Rossman & Rallis, 2003). Broadly, this descriptive qualitative study begins to provide a basis for improving practice in outreach programming by contributing to a deeper understanding about rurally situated research participants' attitudes and beliefs about

their experiences as research participants. The focus group methodology used in the data collection for the parent study is consistent with a descriptive, qualitative approach.

Parent Study Description

The data for the parent study (Lyons & Hunt, 2011 ["parent study"]) was collected from a population of adult volunteers who had participated in research studies at a rurally situated research institution. All participants lived and worked in the rural counties surrounding the research institution. The data was collected for a related, but distinctly separate, research purpose. The purpose of the parent study was to ascertain the awareness of a rurally situated institution's research protections office and program by experienced adult, ~~experienced~~ research participants. The question guide used also focused on exploring participant experience broadly, which lends itself well to analyzing the same data for a different purpose and using different research questions.

The parent study used a focus group format. Documentation of the recruitment, participation, and data collection was readily available and lends credibility to the data, as was discussed in the secondary analysis issues section previously. The screening tool that was used to enroll experienced research participants provided the information needed to assign participants to homogenous groups (see Appendix A), as advised by Krueger (1994), to encourage comfort and dialogue within the group. Experienced personnel from the institution's Survey Research Center were consulted and offered advice on the development of the interview protocol used (see Appendix B).

Focus Group Methodology

Kamberelis and Demetridis (2008) write that focus groups are practical and efficient, generating "large amounts of material from relatively large numbers of people in a relatively

short period of time" (p. 897). The value of focus groups, according to these authors, is that the data produced is different from and largely unobtainable from individual interviews: "the synergy and dynamism generated in homogenous collectives often reveal unarticulated norms and normative assumptions" (p. 897). The participants in the parent study were grouped primarily by age range, followed by their availability. This information was collected using a screening tool that aided in determining eligibility; that is, participation in research studies at the university within the past five years.

The focus groups were conducted by an experienced moderator employed by the Survey Research Center and were professionally recorded. The moderator also administered the demographic survey to all participants at the end of each focus group session. Unedited recordings of the focus groups were available for comparison with the transcripts, which were professionally transcribed by an experienced transcriptionist, also employed by the Survey Research Center. The transcripts consisted of five separate documents ranging in length from 20 to 33 pages long. Participants were identified as Participant A, Participant B, etc. in the transcripts.

Parent Study Texts

The transcripts serving as the basis for the current study's content analysis were gathered from focus groups designed to explore experienced research participants' awareness of the research protections that structure and safeguard their participation in research conducted at a rural university. The research questions guiding the current study were closely related to, although distinct from, those in the parent study. As a result, the texts from the parent study provide relevant extant content for this secondary analysis. A traditional content analysis "assumes one-to-one relationships between textual units and the phenomena of interest"

(Krippendorff, p. 348). Because the questions asked in the parent study focused broadly on research participant experience, the relationship between the parent study and this content analysis approach is strong; justifying the application of content analysis to the same texts, but using different research questions and the Theory of Planned Behavior as the framework for the analysis.

Focus Group Participants

To the degree possible, participants were homogenously grouped and all sessions were videotaped with audio. Overall, more than half of the focus group participants (63%) had volunteered for from 2 to 10 research studies at the institution, and approximately one-third of the participants had volunteered for more than 10 research studies within the past five years. The remaining 4% of participants had volunteered for one study. The majority (79%) of the focus group participants had participated in both biomedical and social-behavioral research studies at the university. Focus group participants who participated in only biomedical studies or only social-behavioral studies at the institution comprised the remaining 13% and 8%, respectively. The ethnicity of the focus group participants reflected the population of the residents of the rural counties surrounding the institution with 96% identifying as White (non-Hispanic/Latino).

On the advice of Survey Research Center professionals, the age ranges in the demographic survey were established to reflect the population from which participants were drawn. Nearly half (46%) of the focus group participants were in the 40- to 55-year-old age range. Focus group participants in the 65 years and older age range represented over one-fourth (29%) of the total. The 26- to 39-year-old focus group participants accounted for 13% of the total, with the remaining 8% and 4% representing the 18- to 25-year-old group and the 56 to 64 age group, respectively. Females represented more than three-quarters of the total focus group

participants (79%). Half of the participants were employed in professional occupations, and retired individuals comprised another quarter of the total number of focus group participants. Seventeen percent of focus group participants were employed in office or clerical occupations. Those who did not designate an occupation or were completing graduate studies accounted for the remaining participants (4% in each group, respectively). All focus group participants resided and/or worked in rural counties as designated by the U.S. Census Bureau, based on population density.

Current Study: Secondary Analysis Issues

In conducting a secondary analysis of the data collected for the parent study, a number of issues were considered, such as suitability of the data for secondary analysis and pitfalls that can occur. Hinds, Vogel, and Clark-Steffan (1997) discuss the suitability of conducting secondary analysis with qualitative data, but point to the wide acceptance of using the approach with quantitative data. Hinds et al. also point out that qualitative data is "descriptively rich, but underused" as a source of information (p. 409). According to Sandelowski (2000), data from qualitative studies, such as the parent focus group study, "might easily lend themselves to more penetrating re-presentations" such as this secondary analysis (p 339).

Hinds et al. (1997) write that in conducting a secondary analysis of data, "study questions about the same phenomenon or closely related phenomena are more likely to yield data of appropriate depth and pertinent detail" (p. 412). The research questions that were posed for the secondary analysis in this case were very closely related to the focus of the parent study: the phenomenon of research participation.

Hinds et al. (1997) also outline some challenges that can occur when using qualitative data sets for secondary analysis, such as direct access to the data, accuracy in the transcription, sensitivity to context, and currency of the data set. Direct access to the data is optimal, and such

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access was possible with the focus group discussion transcripts. Recordings of the focus groups were transcribed by a professional transcriptionist. These recordings were reviewed multiple times, comparing them directly with the transcripts and verifying them for accuracy. Hinds et al. (1997) also emphasize the need for accuracy in the transcript, as well as completeness. Sections in the transcript identified as "inaudible" were repeatedly compared to the recordings. In most cases, the word or words that the transcriptionist found inaudible I was able to identify and I added them to the transcripts, but not all of these sections were understandable. Typically the comments identified as inaudible and which, after repeated attempts, could not be identified, were made during cross- talk that was not directly related to responding to the questions posed to the groups. The data, as suggested is needed by Hinds et al., is also clear in terms of the relationship between the focus group facilitator's questions and individual responses to those questions.

Hinds et al. (1997) suggest that another challenge to secondary analysis lies in the "sensitivity of researchers to the context of the primary study" (p. 414). As the researcher in both the parent study and the secondary analysis of that data, I am sensitive to the context. This sensitivity is heightened by my work in the human research protections area for over five years, coordinating human participant research for eight years, and engaging as a participant in over 30 biomedical and social science research studies. Although the focus groups were conducted by a professional, academically oriented Survey Research Center, by virtue of my experience, I was and am acutely sensitive to the context of research participation in a rurally situated, research-oriented, institution of higher learning. In approaching and performing the analysis, I applied a heightened awareness of this sensitivity and attempted to identify instances in which this sensitivity could affect the analysis.

Lastly, "currency of the data set" is another challenge that Hinds et al. (1997, p. 415) describe when a secondary data analysis is performed. The data set used was collected over a nine-month period in 2010 and 2011. Although Hinds, Chaves, and Cypess (1992) indicate that contexts change over time, research participation in the studies described was consistent with the types and numbers of research studies that were approved in 2010 and 2011, as well as in 2012 (institutional electronic management system, personal communication, 2012). The stable human participant research climate at the research institution, as well as the context in which the data was collected, and the data itself, are sufficiently current so as to argue for continued relevance. The data transcriptions were accurate, sensitive to context present, and current, thus providing a solid foundation for the secondary analysis of textual content.

Theoretical Framework

The Theory of Planned Behavior (Ajzen, 2004) guided the content analysis strategies that were used in a secondary analysis of the focus group data. Ajzen and Fishbein developed the Theory of Reasoned Behavior (1980), in which they "tried to estimate discrepancy between a person's attitude toward a behavior and the actual performance of that behavior" (p. 87).

The lens of the *a priori* categories (attitudes, beliefs, and norms) that was provided by the TPB was an appropriate approach to the analysis of the data because of the structure it provided to view the data. This structure and lens allowed for the identification of the most useful information in terms of developing appropriate outreach programming (i.e., research volunteers' attitudes, beliefs, and norms about participation in research).

TPB typically is used in a quantitative manner or in a quantitative and qualitative combination to develop questionnaires for predicting behavior. TPB was used in this study in a qualitative manner, departing from the usual approach of using TPB in a quantitative way to predict behavior. Its use with a secondary analysis of a qualitative data set was somewhat

unusual; however, a qualitative approach was taken to deepen understanding, gain insight into the already known and completed behavior of participating in research, and provide direction for the development of outreach programming. As noted, a qualitative approach is a relatively unusual but not unprecedented approach to using TPB (Renzi & Klobas, 2008).

Working with the known behavior (and intention) of participating in research, the transcripts were analyzed for examples of attitudes, beliefs, and norms. Background factors play a role in the beliefs that are held, and, to the extent that the data allowed, these factors were also examined in the analysis (Ajzen, 2005). These beliefs, attitudes, and norms reflect participants' perceived control regarding research participation.

Background factors available in the self-reported demographic data, and described previously, included: age, gender, race/ethnicity, education level, and income. Information-oriented factors were ascertained from the transcripts and the demographics: experience as a research participant, knowledge about research participation, and media exposure.

Ajzen (2002) suggests that qualitative methods are useful and may be indicated, especially for the elicitation of beliefs. In addition, when qualitative data is available, the TPB model can be appropriately applied in data analysis. Renzi and Klobas (2008) point out that "few published studies have used qualitative research methods with TPB," and cited Mynarska's unpublished work (2008) in the area of qualitative study and TPB as supporting this observation (p. 2). Renzi and Klobas (2008) used TPB as a "basis for examination of qualitative research" and provided detailed information about data coding and analysis (p. 2).

The TPB categories of beliefs, attitudes, and norms expressed by individuals who participated in research may help form the basis for planning and developing outreach education. Hartmann (2011) notes that Ajzen's TPB is a versatile, effective, and practical model to use to assess intentions and behaviors. The examination of the underlying beliefs, attitudes, and norms,

as they relate to perceived behavioral control and intention associated with participation in research, can inform outreach education planning to provide information that is useful to experienced and potential research participants.

Since all of the focus group research participants in the parent study had already operationalized an intent to participate in research, "behavioral intention" was assumed through their self-report and was verified by their descriptions throughout the focus group discussions of their participation in specific studies.

The specific steps taken in the secondary analysis of the parent study data, using a content analysis approach with the *a priori* categories as defined by TPB, were guided by the overarching research question and sub-questions.

Content Analysis Approach

A content analysis framework was applied to the previously collected data, guided by the research questions and TPB. Rossman and Rallis (2003) consider content analysis to be "an overall approach, a method and an analytic strategy," to systematically examine forms of communication for patterns or themes (p. 189). Rossman and Rallis also note that any form of communication [such as transcripts of focus group interaction] can serve as the "raw material" for this methodological and analytic approach (p.198).

Content analysis, according to Krippendorff (2004, p. 340), consists of "a procedure for moving from texts [in this case focus group transcripts] to research questions." A problem-driven analysis, as described by Krippendorff (2004), was an appropriate analytic approach since it tends to lend itself to real-world problems: in this case, ascertaining beliefs and attitudes of experienced adult research participants as the basis for developing effective outreach education.

The content analysis of the focus group texts was guided by the Theory of Planned Behavior (TPB) and the *a priori* use of the theory's established categories to ascertain these beliefs and attitudes. Ajzen's TPB is based on behavioral, attitudinal, and other contributors to predict whether or not a person engages in a particular behavior. In this case, the particular behavior was already known —participating in research. The TPB *a priori* categories of beliefs, attitudes, and norms provided the criteria and guidance for the selection and grouping of quotes/comments, although, as Rabiee notes, to an extent the selection and assignment is still subjective (2004, p. 657).

Krippendorff (2004), in discussing qualitative approaches and content analysis, writes that they are not incompatible, and that "the researchers' reflexive involvement manifests itself in the awareness that it is content analysts who construct contexts for their analysis, acknowledging the worlds of others, in the pursuit of their own research questions " (p. 85). Further, Krippendorff asserted that, "whether a close but uncertain reading of small volumes of text is superior to a systematic content analysis of large bodies of text is undecidable in the abstract." The unit of analysis was the group of research participants as reflected in themes developed from the written transcript.

Trustworthiness and Quality of the Analysis

Morrow (2005, p. 254) writes that "one tradition that has become a standard in qualitative research is that of *making one's implicit assumptions and biases overt to self and others"* [author's emphasis], which is one criterion used for trustworthiness in qualitative research. Trustworthiness, as described by Lincoln and Guba (2000) is one foundational aspect to rigor in qualitative studies. In qualitative research, the "researcher-as-instrument" concept embraces the inherent bias and subjectivity of the investigator with the goal of that unavoidable

bias and subjectivity being made as "transparent as possible," according to Hunt (2011, p. 297). Trustworthiness is also established by "reflexivity, or self-reflection, on the part of the researcher" (Hunt, 2011, p. 298). The quality and trustworthiness of the research is also made transparent through the use of "thick, rich description" (Geertz, 1973)—liberal use of direct quotes to illustrate themes extracted from participants' comments. In this way, the voices of the participants become the focal point and contribute to the readers' knowledge in terms of deciding credibility and transferability of the information presented.

I read and parsed the transcripts through the lenses of a researcher for this and other studies, a research participant in numerous other studies, and a current practitioner in the field of research protections. In fact, based on my very first experience as a research participant in the telephone call I received as a young adult, which led to personal feelings of guilt and responsibility, the very first reading of the transcripts was especially attuned to similar reactions by the participants. My experiences as a researcher also attuned me, initially, especially to what researchers "did right"; but in repeated readings, this bias was tempered with the desire to also find what researchers could do better. And from a research protections standpoint, my reading and parsing of the transcript texts was especially focused on perceptions and awareness of research protections activities and how that could begin to provide a foundation for appropriate outreach education. Researcher bias, according to Cresswell (2007), needs to be clarified as one measure of validation since the biases shape the "interpretation and approach to the study" (p. 208). Describing the researcher positionality consists of commenting on "past experiences, biases, prejudices, and orientations" (p. 208). Angen (2000) describes ethical validation as the researcher questions herself all along the way: her agenda, perspective, experiences, goals, etc.

But while the questioning is constant, some practical answers to questions occur, and there is equitable treatment of diverse voices (such as disagreements in the focus group interactions).

The participants' word usage (type and frequency) was analyzed electronically, resulting in an informed selection based on repeated readings of the transcripts. Content analysis is based on texts. As the content analysis process unfolded, the steps were chronicled in a spreadsheet. The quotes of the recipients also were transferred to spreadsheets for organization and categorization. The appropriateness of the sample of the population that was targeted for this research, in terms of recent and substantive experience as a research participant in studies at the institution, is reflected in the self-reported descriptive information collected both at the time of screening and when surveyed at the focus group. The recruitment approach led to self-selection of participants as they determined themselves to be qualified to participate. Their eligibility was queried twice– at screening time and when participating in the focus group through the use of the demographic survey (see Appendix C), which requested each participant to quantify their experiences in research at the institution. Overall, more than half of the focus group participants (63%) had volunteered for from two to ten research studies at the institution, and approximately one-third of the participants had volunteered for more than ten research studies within the past five years.

Cresswell and Kidder note that face validation by participants and researchers also contributes to trustworthiness in qualitative research. The "click of recognition" and "yes, of course" kinds of reactions and comments that were evident in the thorough reading of the transcripts (Kidder, 1982, p. 56) were part of the "informed selection" of data for analysis (Krippendorff, 2004, p. 345). This face validation of the participants was identified within statements of agreement voiced by one or more members of the group and reinforced by

intergroup presence. Wolcott (in Cresswell, 2007) says "validation neither guides nor informs" and that what is important is the identification of critical elements and plausible interpretation of data (p. 24).

A criterion of qualitative inquiry is "openness [and] engagement" with the text, according to Lincoln (1995, p. 282). Breaks of hours or days were taken from engaging with the text, which afforded me the opportunity to look at the text with "fresh eyes" and allowed for some distance to make space for being open to the data.

Lastly, although the original focus group study was not specifically designed with content analysis in mind, as Krippendorff suggests is optimal, the decision to use *a priori* categories to inform the reading of the texts/transcripts, with the techniques of content analysis also in mind, partially mitigates this limitation.

Answers to the research questions based in content analysis should, according to Krippendorff (2004), come from an "informed selection" of the available data (p. 345). The categories of attitudes, beliefs, and norms as part of the theoretical lens were used to guide the selection of data used in the analysis. As noted by Stemler (2001, para. 7): "When dealing with *a priori* coding, the categories are established prior to the analysis based upon some theory." Professional colleagues [dissertation committee members] reviewed and agreed on the *a priori* categories to be used, and the coding that was derived from these categories was applied to the data. Revisions were made as necessary, and the categories were refined to the point that "maximize(d) mutual exclusivity and exhaustiveness" (Krippendorff, 2004, p. 86).

The application of content analysis to texts, such as the focus group transcripts, works to provide answers to research questions, according to Krippendorff (2004). A content analysis approach, focusing on expressions of attitudes and beliefs, was appropriate for this investigation. The focus or lens of finding and viewing attitudes and beliefs as they may relate to or inform the

development of outreach programming also provides an educator's perspective. The categories

of attitudes, beliefs, and norms, as defined by TPB, that informed the behavior of participating in

research at a large research university further focused the analysis of the focus group texts.

Analytic Process

The process of the content analysis of focus group transcripts occurred within the

framework of the Theory of Planned Behavior (TPB). The analysis was guided by the research

questions and detailed notes on the analytic process were kept. Using the *a priori* categories in

the Theory of Planned Behavior, (i.e., attitudes, beliefs, and norms), common beliefs and

attitudes of research participants living and working in a rural location were identified.

Attitude toward a behavior is evaluated as positive (favorable) or negative (unfavorable);

attitudes reflect beliefs about the consequences of performing the behavior. Perceived

behavioral control reflects personal beliefs about the ability to perform the behavior. The

subjective norm reflects personal perceptions of societal expectations about the performance of

the behavior. These three factors are the main influences on the formation of a behavioral

intention, which is the most significant precursor to the actual performance of the behavior.

The written transcripts were read repeatedly and also cross-checked with the audio

recordings for accuracy. These activities aided in establishing the reliability of the data.

Following verification and familiarization with the transcripts, multiple passes were made on the

transcripts. The first pass involved highlighting responses that appeared relevant to the research

questions and the *a priori* TPB categories: attitudes, beliefs, and norms. Responses that

generated exchanges between and among participants, including agreement and disagreement

across all groups, also were targeted for analysis. This subjective, but informed, selection of data

for analysis was supplemented with searching the transcripts in subsequent passes for the

occurrence of words that were observed to be used frequently, such as "help," "results," "benefits," "interesting," "time." The Microsoft Word "find" feature was also used initially to identify words related to attitudes, beliefs, and norms such as: "think," "believe," "like," "dislike," "guilt." These words provided direction for the search of related words, all of which could then be quantified. Although the analysis did not rely solely on how many times a word occurred, it did provide an initial "way in" to "see" the data.

Following is an example of how the coding scheme was developed. The word "help" was used to represent responses that were related to helping. "Help" and related words were quantified and found to have occurred over 70 times across all of the focus group transcripts. "Help" was identified as the code word that represented words that were related to it. In this case, the definition of "help" as a code word was designed to include the idea of providing help or assistance or benefits to others—the institution as a whole, the research mission, themselves as participants, or specific groups to whom research and research participation could benefit. Broadly, making a contribution to the research institution, the researchers themselves, and the community were also identified during the process and led into the process of clustering.

As Krueger (1998) and others observe, reviewing the transcripts is an iterative process and is returned to frequently throughout the analytic process as multiple coding passes through the data are made. Krueger also notes that one option, in addition to searching through the transcripts, is to quantify the occurrences or frequencies of certain words to provide direction for the search of related words, which further enhances coding.

The development of codes was aided by measuring frequencies, which according to Krippendorff (1980) is the "most common form of representation of data" (p. 109). "Absolute frequencies" are described by Krippendorff as the "number of incidents within texts sampled and

relative frequencies: percentage of times used in texts" (p. 109). The words selected for analysis in this study were limited to those that were observed across all transcripts and focus groups. Krippendorff describes "uniform frequency" as the "strength" of distribution—when some terms appear more or less often than others in the texts examined. As advised by Krueger (1994) the frequency (how often something was said), extensiveness (how many people said it), and intensity (how strong was the opinion or point of view) is one way to establish internal consistency within the analysis (p. 35).

A coding scheme for this analysis was developed to aid in the iterative process of identifying, selecting, and categorizing appropriate responses. Structural coding was guided by the research questions and theoretical framework (MacQueen, McLellan, Kay, & Milstein, 2009, p. 214). The coding scheme was shaped by the observation of "co-occurrences" and "clustering" of ideas and words, as described by Krippendorff (1980, p. 115). According to Krippendorff, "clustering seeks to group or lump together objects or variables that share some observed variables that share some observable qualities" (p. 115), and can aid in conceptualization, especially with large amounts of text. Krippendorff (1980) describes the clustering procedures, which are iterative: Identify clusters that have similarities and when they are combined they maintain their meaning to the greatest extent; combine the clusters and adapt the data to show the latest cluster pattern; and finally record and describe the process, repeating the process until all clusters have been merged. In this analysis codes and definitions were constantly refined as the process unfolded through the use of clustering and with knowledge of the frequencies observed. Some codes in the coding scheme were collapsed into each other as clusters or relationships were recognized within each focus group's responses and among all focus group responses.

The responses themselves informed the formation of the codes and subsequent theme development, which informed the selection of representative responses. MacQueen, McLellan, Kay, and Milstein (2009) describe the coding scheme or structure as consisting of "six basic components: the code; a brief definition; a full definition; guidelines for when to use the code; guidelines for when not use the code; and examples" (p. 212).

For organizational and tracking purposes, responses on the electronic transcripts were copied and pasted into spreadsheets. This method was used as an adaptation of the "classic" long table method of transcript analysis described by Krueger and Casey (2009, p. 399). Stockdale (2002) describes the spreadsheet approach as a practical method of sorting, attributing, and working with transcript data, which was appropriate for use with content analysis and the assignation of codes and development of themes.

The application of the coding scheme was continually refined, and the next part of the analytic process was to sort the specific responses and determine whether attitudes were positive or negative in character and to verify that similar responses were present across all focus groups. Responses that were identified using the coding scheme that appeared in all transcripts were focused upon, and representative responses of each code that co-occurred or were common to all groups were selected. In this way, the informed selection and use of representative quotes illuminated participant voice. The coding scheme was applied across all five transcripts and the findings of this analysis are discussed in the next chapter.

Chapter 4

Findings

This chapter describes the results of the content analysis. Four themes were identified from the coding scheme used in the analysis, as illustrated below. The four themes were Motivation, Personal Investment, Expectations and Rights as Research Participants, and Expectations of the Researchers and the University. Each of these themes reflects beliefs, attitudes, and norms (the TPB categories) expressed by the focus group volunteers about their participation in research.

Theme: Motivation

The theme of Motivation reflects the attitudes, beliefs, and norms about the reasons that focus group participants expressed for participating in research. Reasons included helping, making a contribution, personal benefits received, learning, convenience, personal/individual results, and the ability to participate. Attitudes towards, beliefs about (reflecting perceived control over the performance of the behavior), and norms related to why individuals volunteered to participate in research and their influence over participants' decisions to volunteer in research combined to form the theme of Motivation. Attitudes, beliefs, and norms that motivated or were taken into consideration by participants about actually finding out about studies and enrolling in them are part of the theme of motivation. Positive attitudes towards and beliefs about making contributions outside of themselves—to other people, to the university and its research mission, which in turn contributed to the community—were expressed: *"I think for me it's a combination of something interesting; you're contributing to something. It's also eventually fun and educational, and you feel like you're helping the research."* The above response illustrates the participant's positive attitude toward research participation (fun and educational), the norm

(helping), and belief (making a contribution). This participant elucidated some of the reasons for his research participation in terms of attitude, belief, and norm.

The topic of helping appeared throughout all of the transcripts. The word "help," variations of the word "help" and related words, such as "contributing," occurred 70 times across the focus groups. Positive attitudes toward helping others and making a contribution were expressed by all participants. Helping, in terms of the social norm of feeling a responsibility or duty to help others, was important to the participants. "Others" were defined by the participants as individuals with certain conditions who might benefit from their participation in the research, the researchers themselves, graduate students, the university's research mission as a whole, and the community-at-large. As one participant noted, *"I guess I feel like it's a really important part of the university's mission to do research and so I'm not working in the research end of it, so I kinda figured I could be more of a guinea pig."* Helping and contributing were often named as reasons that participants volunteered for research studies. The belief that participating in research benefits the community was mentioned as an impetus for participating in research.

Helping was also applied by participants to themselves as motivation to participate. Studies that enhanced their health or knowledge about their health or lifestyle were seen as beneficial. The information participants received from studies about their personal well-being was seen as a reason to participate in studies. Positive attitudes about helping themselves and others were coupled with the belief in the importance of contributing. Making a contribution to the university, the community, others, a cause, and higher purpose was frequently mentioned, also in the context of believing that contributing, being of service to others, and making a difference are worthy pursuits.

Participants expressed positive attitudes about benefits they personally received from their participation in research including social and psychological benefits. Some participants believed there were psychological benefits of research participation in terms of feeling useful when they had limitations that prevented them from contributing in other ways. Positive attitudes toward the social aspects of research participation, particularly during group meals or meetings, were believed to be beneficial, and these opportunities were sought out by some participants. The personal benefit of compensation, whether trinkets, food, or money was mentioned over 20 times across the transcripts. Overall, compensation of any sort was not seen as the only or prime motivation for participating in studies for many of the participants and in most cases compensation was viewed positively as a welcome side benefit. In only one case was compensation cited as the sole reason for participation. Participants also expressed the belief that compensation usually did not begin to reimburse participants for their time or what was required of them to do in studies, regardless of the amount or type given.

In addition to social, psychological, and concrete benefits received, a robust topic of discussion among study participants was the personal results they received from their study participation. Many cited the results of blood and other tests as a strong motivation to participate in a study. Receiving these results was believed to be an important part of their participation since they aided them, and in some cases, their doctors, in assessing their health status. Receiving individual study results at no cost was seen as a persuasive reason to participate in research.

Positive attitudes about receiving personal laboratory results were expressed and for at least one participant, receiving personal laboratory results was the sole motivational factor for participation. Other physically related results that were mentioned were effects of the study

program itself, such as losing weight and being introduced to new foods. Positive attitudes about these kinds of activities were expressed in terms of enhancement of their personal well-being.

Learning, as an aspect of participant motivation for volunteering for research studies, was evident throughout the responses in all of the focus groups. Participants across all focus groups mentioned words such as "curiosity," "interest," and "learn," more than 100 times. As one participant noted, *"Learning all these different things and how they do things I think enriches your life. So I think it's a definite benefit of participating."*

The majority of participants had positive attitudes about this aspect of participating, citing favorable views of learning something new, such as finding out they liked a food they had never tried before, learning a new exercise, or learning about the research process as motivation to volunteer to be a research participant: *"I'm always interested in learning. Doing something that I thought would be interesting and I wasn't disappointed in that respect."* Aspects of the research itself piqued or captured the interest of participants, which was motivation for participating initially or in additional studies. Many participants had positive attitudes when their curiosity was satisfied, although some participants expressed negative attitudes when their curiosity was not satisfied.

The ability to participate, in terms of qualifying for research studies, was discussed across all focus groups. Negative attitudes toward narrow inclusion criteria were expressed. In particular, many participants noted that the age range for participation in many studies seemed narrow, especially in regard to recruiting older individuals to participate. The qualifications needed to participate in research studies were often seen as limiting the ability to volunteer.

How long a study lasted, how many visits the study required, and when and where the study was being conducted were factors that influenced some participants' decisions to

participate in studies. These factors were related to perceived control over participation. Perceived control can be one influential factor related to intention to participate. Words including and related to convenience, such as "schedule," appeared multiple times across the transcripts. Some participants' decisions to participate were not based on convenience, transportation, location, or similar factors, if they could see benefits to themselves or others by their participation in the research. However, some participants based their decisions on participation heavily on how convenient the study was for them personally to participate in, where some rejected participation in studies that were located in areas on campus or other location that were inconvenient for them to travel to, or they chose not to participate in overly complicated studies. Some participants indicated that if a study was too inconvenient they would either not sign up or would stop participation: *I looked into a study but it was like such a time commitment, so I didn't participate."*

The theme of motivation reflected attitudes, beliefs, and norms about the decision to participate and continue participating in research. Motivation consisted of many factors: service to others, benefits to selves and others, support of a research mission or cause, and being able to ascertain their eligibility.

Theme: Personal Investment

The theme of Personal Investment encompasses the costs and commitment participants considered and made in order to participate in research studies. The code words of time, commitment, and access to information were clustered together to form the theme of Personal Investment. The major cost that participants identified was that of their time, and participants' time was a strong topic of discussion across the focus groups. In the frequency count, time came up over 200 times. Although the frequency counts did not reveal the context for each count of

the word, review of individual responses indicated that how researchers used participants' time and participants' use of time was important to the focus group participants.

Personal investment as it related to the use of participants' time by researchers during the actual study was also a topic discussed. Some participants believed that some investigators were disorganized and participants had negative attitudes about their time being wasted. For example, one participant said, *"I do think researchers are disorganized. I'm like, well they don't have everything—all their ducks in a row there."*

Negative attitudes towards researchers wasting the participants time was also a topic related to traveling across campus or town and upon arrival, finding out that they did not qualify for the study. Participants also expressed negative attitudes toward finding out what a study was really about only after spending time to get there. Time needed to adequately review consent forms was also a topic that occurred throughout the focus groups. Feeling rushed or hurried by the investigator to read and sign a consent form that was not available prior to arriving onsite for the study was viewed negatively by many participants and resulted in skimming the consent document and likely not being fully informed of study procedures: *"I think that getting the consent form as you are sitting down to start something is not enough advance in time because many people do not read things that they sign."*

The belief by many participants that they made a commitment to the researchers was cited as the reason for continuing to volunteer in a particular research study. The word "commitment" appeared 24 times across all the transcripts and was used as the code to represent words and ideas related to personal investment. The norm of carrying out their part of an agreement was expressed as the belief that if a participant enrolls in a study, then the participant should stay committed and remain in the study until the end. As one participant noted, *"When I*

sign up for something and I don't want to back out because I feel committed, and why would I sign up for something if I'm not going to follow through." Related to this is the belief in being good stewards of the resources that researchers expend on research participants and negative attitudes towards wasting those resources.

Negative attitudes about difficulty in finding studies to participate in, not having phone calls returned by investigators, and expired recruitment announcements were prevalent and identified collectively by the code " access to information." All of these situations increased frustration of participants, especially when the topic of the research they were trying to enroll in was personally compelling to them. Despite these negative attitudes, many, but not all, of the participants, persevered by contacting investigators multiple times and/or looking for other studies to participate in. In their view, they had invested their time to find out about a study and volunteer for it and they believed that receiving a timely response from the researchers was reasonable, which speaks to their personal investment.

Many participants reported diligently searching for information about studies that they might qualify for, but expressed frustration at not having a source that acted as a clearinghouse for all studies that are recruiting participants. Older participants expressed negative attitudes about advertisements appearing only online. Others recognized that newspaper advertisements were often effective in grabbing their attention, but that not everyone receives the newspaper.

A subset of participants expressed the belief that some members of the general public think that university employees have better access to recruitment announcements than they do. Participants noted that this perception, real or imagined, of an "inside track" could prevent successful recruitment efforts. This real or imagined perception of easier access by employees was coupled with the belief that overall if there were easier access to print, online, and other

information, more people would participate. There were differences in attitudes toward print advertisements and online advertisements: many, but not all, older people in the focus groups identified themselves as "not connected" online, but some also indicated that not everyone receives a newspaper to see print advertisements.

In summary, the theme of Personal Investment reflects attitudes, behaviors, and norms that are related to the cost of participation in terms of how much time participation in a particular study will take, balanced with the belief that if they begin a study they should see it through, and how easy it is to actually find out about and make contact with study personnel to participate.

Theme: Expectations and Rights as Research Participants

The theme of Expectations and Rights as Research Participants addresses attitudes, beliefs, and norms that are centered around what volunteers anticipate they will receive when they are recruited, given information about the consent process, and when they participate in research, and what they believe they are entitled to receive from their research participation.

The code words "global results" and "type of information" were clustered together and represented by the theme of Expectations and Rights as Research Participants. Global results reflect the overall results of a study: what the study found as a whole, the full results of the research. Type of information refers to documents that are used in recruitment and informed consent and their content. Also reflected in this theme was the right to voluntarily participate in research studies.

Of particular interest to participants across all groups were global or overall study results. "Results," as a code word, was found over 24 times across the transcripts, in addition to related words such as "summary," "report," "feedback," and "record." Receiving global study results was viewed favorably (positive attitude), but many participants expressed disappointment

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(negative attitude) due to rarely, if ever, receiving those results from researchers. As one participant said, *"I've participated in numerous studies. I guess I was a little disappointed because I never learned the results of the study. I never learn much of the studies even on a collective, non-identifiable basis."* Participants expressed frustration in not learning about study results, which they believe was their right as a participant.

A few participants noted that they had received global study results, but at least one participant who had not received them expressed skepticism regarding whether there ever were results or whether they were ever published: *"They told me they publish. They don't let you know. In other words they don't really know the results."* There was a prevalent expectation across the focus groups that they had a right, as study participants, to receive global study results. This belief also reflected a social norm of reciprocity: receiving global results in return for volunteering for a study was a reasonable expectation.

Some participants' beliefs, attitudes, and norms influenced their decisions about whether or not to participate in research and were based on information available to them. Words related to information occurred over one hundred times across all five transcripts. The types of information provided to participants, such as consent forms and recruitment information, and their content were discussed. For some, the information provided in the recruitment and consent materials was adequate, for others, too much, and for others not enough. Positive and negative attitudes toward the information provided were expressed, but participants did express that they had a right to receive information and to have adequate time to review the information. Some participants expressed negative attitudes towards receiving consent information right before participating, with the researcher standing over them and waiting for them to sign. Participants who thought that too much information was given shared that often they did not read the entire

consent form thoroughly and speculated that many others did the same. Many participants said they relied on the researcher to verbally give them information, before and during the research study. These participants had positive attitudes towards this verbal communication.

Related to the type of information participants receive, there were negative attitudes expressed by participants regarding researcher contact during recruitment.

A lot of times it takes a significant amount of time to get in touch with these people. You have to call, then you leave your name, and then they call you back, and then you miss the call, and then you've got to call them again. It's just a huge hassle.

These attitudes centered around researchers taking long amounts of time to contact them or not contacting them at all. Many participants expressed the view that they had invested their time to find out about a study and volunteer for it and they believed that it was the researchers' responsibility to contact them. Negative attitudes were expressed about researchers taking long amounts of time to contact them or not contacting them at all.

The theme of Expectations and Rights as Research Participants was also reflected in positive attitudes toward voluntary participation in studies across focus group participants: *"They* [the researchers] *always tell you – you can stop at any time."* Many participants in the focus groups voiced awareness that they could withdraw or stop participation in a study at any time. Participants also believed that if they wanted to discontinue participation in a study, that they have a right to communicate that with the researcher.

In summary, participants' beliefs, attitudes, and norms about information they receive before participating in research—when, where, what, and how it is received—are factors that can influence their decisions to participate. This and the expectation that they receive global study results, and often don't, and the prevalent belief that participation is voluntary were voiced by

participants in all focus groups and were factors that comprised the theme of Expectations and Rights as Research Participants.

Theme: Expectations of Researchers and the University

Participants anticipate that researchers and the University will behave in certain ways and perform certain actions in relation to their research participation and these attitudes, beliefs, and norms are included in the theme of Expectations of the Researchers and the University.

The codes responsibility and protections formed the theme of Expectations of Researchers and the University. Responsibility includes the obligations that the researchers and university have for the oversight of research. Protections refers to the expectation that participation in research will be safe and will be monitored.

Participants expressed attitudes and beliefs about expectations that they, as participants, had about oversight for their safety and reduction of risk for studies they participated in. Many, but not all, were aware that researchers had rules to follow to protect them and that researcher and university responsibility existed for their safety. Attitudes and beliefs about their own participation as a research volunteer also surfaced. Expectations of Researchers and the University were represented by the code word protection and included related words such as "confidential," "safety," "protect," and "risk," which were found about 41 times across all of the transcripts.

Responsibility that researchers and the university have for protecting participants was expressed through the use of words such as "oversight," "value," and "purpose," as well as "confidential," "safety," and "risk." These and related words appeared over 50 times throughout the transcripts, were grouped together, and identified with the code word of responsibility: *"It's more than following rules, but actually having a super ethical super moral perspective on*

treating everybody the best way possible as opposed to just following the guidelines."

Participants expressed the belief that it was the responsibility of the researchers and university to assure their personal safety—physically and psychologically. The belief that oversight of study procedures, data security, and confidentiality was a shared responsibility was also expressed. Some participants discussed an awareness and belief that the university has a system to assure those protections, and assumed that this responsibility was taken seriously. As one participant stated,

> *I do feel like it's the job of the research protections office to look out for the participants. So even if a research subject is not well educated, isn't proactive, maybe is a shy person who would be embarrassed to walk away, so that person is protected, too.*

Others recognized the same obligation, but placed the responsibility more squarely on the researchers. Many, but not all participants, had positive attitudes toward researchers protecting them since they interacted more directly with them, but others saw researchers as less accessible and relying on other study personnel to safeguard participants. The belief that researchers had an ethical responsibility in terms of handling data with integrity was expressed as follows, *"I think the researchers have a responsibility to verify their data and there's a huge responsibility for integrity."*

Though participants widely held the belief that researchers acted in moral and ethical ways, at least one participant shared his experience in finding out that data was not accurate and the inaccurate data had been published, reflecting badly on the university. According to this participant:

The researcher never really verified the data, and it was wrong. The person who got the data together made a mistake. Actually, the researcher never checked. I mean that's a huge embarrassment to the university.

This was seen as an obvious failure in meeting the obligation of data integrity. In addition, at least one participant expressed strong emotion with regard to protecting confidentiality and assuring data security. At least one other participant expressed skepticism that confidentiality and data security were not up to the standards that he expected would be required.

Participants also believed that the research protections office should assure that the research itself has a valid purpose before allowing participants to be involved: "*I think a study needs to have some value . . . you don't do research just for something to do. Should have some end result value for somebody.*" A number of participants agreed with this belief and the belief that "someone upstairs," referring to the research protections office, should take that into consideration when reviewing and approving studies.

The theme of Expectations of Researchers and the University corresponds to participants' attitudes, beliefs, and norms related to the responsibilities of the researchers and university to individuals as participants in research, assuring that their rights and welfare are respected before, during, and after their participation in research.

Summary

The four themes of Motivation, Personal Investment, Expectations and Rights of Participants, and Expectations of the Researchers and University emerged from the content analysis when the texts were examined for the TPB categories of norms, attitudes, and beliefs about research participation. Using the TPB categories was helpful in focusing the analysis, but the use of the theoretical framework constrained the analysis in some ways. For instance, given

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the transcripts were secondary data, more specific comments about the function of the research protections office at the university were expressed because of the focus of the original study. Participants expressed mixed awareness of both the office of research protections itself and its functions. Also, as the analysis proceeded, I noticed that as the focus groups proceeded, there was an exchange of practical information about different researchers and research studies at the university and suggestions made to each other about where to look for studies, how to enroll, what kinds of benefits they received, how to interact with researchers, etc. These types of information provide important insights into research participation but were difficult to categorize according to TPB's framework.

The themes that emerged from all the focus groups encompassed many aspects of research participation. Information that fell outside of the constraints of the theoretical framework also provided insight into research participation and, particularly, about information that participants currently have about the university's research protections activities. Conclusions about and implications of these findings are discussed in the following chapter.

Chapter 5

Discussion

Information and research are lacking on how research protections outreach programming is developed for citizens, particularly in rural areas and with participants in social science and non-hospital biomedical research (non-clinical trials). Learner participation in program planning and development is a prominent principle in adult education theory and practice, and basic information about citizens' beliefs, attitudes, and norms related to their research participation can help inform the development of appropriate outreach programming. Outreach that raises awareness of the research protections that are in place for participants and educates citizens about their rights as research participants includes the involvement of citizens as partners in the research process and in research protections activities.

The purpose of this study was to identify the attitudes, beliefs, and norms of rurally situated, experienced adult research participants as they described their participation in research at a rurally situated campus of a large research institution. The vast majority of research conducted at the university where the study was conducted is non-hospital based, non-clinical trial, social science and biomedical in nature. The Theory of Planned Behavior (TPB), specifically the categories of attitudes, norms, and beliefs, was applied to the analysis.

The overarching research question that guided this study was: What are the attitudes and beliefs of rurally situated, adult research participants about their participation in research? Norms, beliefs, and attitudes in combination affect intent to perform a behavior, according to TPB. However, the weight of each of them as it affects the performance of the behavior varies with the population as well as with the behavior itself. Although there were negative research experiences for some people, the focus group participants still engaged in research studies—with

most engaged in 5-10 studies in the past five years. So according to TPB, in this case, positive attitudes, beliefs, and especially the norms expressed about research participation often appeared to override negative attitudes in influencing intention to and actual performance of the behavior.

The four themes identified in the content analysis were: Motivation, Personal Investment, Expectations and Rights as Participants, and Expectations of Researchers and the University. Based on these four themes, the following conclusions were drawn as they related to the research questions and compared to the available literature. Also, the limitations of the study are identified, recommendations for practice are outlined, and suggestions for future research are described.

Theme: Motivation

Many attitudes, beliefs, and norms influenced focus group participants to volunteer for research studies. Together, these represent the reasons why participants did or did not participate in research. According to TPB, varying attitudes, beliefs, and norms, combined with past behavior influence intention and actual performance. This aspect of TPB was evident as it related to the theme of motivation. For instance, in some cases the norm to contribute or help appeared to override negative attitudes about convenience, in other cases, negative attitudes about location or complexity of a study appeared to override the norm to contribute or help. This supports TPB's premise that for different populations and at different times, different beliefs, attitudes, and norms can override one another to influence intention and thus performance of the behavior of participating in research positively or negatively.

Receiving personal benefits, especially positive attitudes towards receiving personal laboratory results, from participation in research was an important factor in motivating some focus group participants to volunteer for research. Another personal benefit, but not one that was

emphasized by participants, was receiving compensation for research participation. In contrast, Hassar et al. (1977) found that Americans participating in clinical trials cited compensation as a top motivational factor. Since receiving compensation among these focus group participants was not as strong a motivational factor as was described in the work by Hassar et al., this may suggest a difference between clinical trial participants and non-hospital, non-clinical trial participants.

Positive attitudes about learning and the belief in the importance of learning were cited frequently by focus group participants as motivational factors for them to participate in research. Learning by participants themselves, but as importantly, learning that occurred by researchers and graduate students to achieve the research goals was emphasized by focus group participants. In contrast, the benefits described by clinical trial participants in Mattson et al.'s study (1985) were mostly self-directed in terms of learning that occurred due to medical monitoring and physical improvement.

Focus group participants frequently named and had positive attitudes toward curiosity and interest as motivation for volunteering for research studies. Hassar et al. (1977) found that interest and curiosity were also top motivational factors to participate among patients involved in clinical trials; but Mattson et al. (1985) found that curiosity represented a very small percentage of the clinical trial participants' motivation for participating. Knapik (2006) found in her social science interview study that satisfying curiosity was cited by her participants as a reason to participate. Interest and curiosity were both motivating factors related to research participation for many of this study's focus group participants, which compares to other research findings. Specific levels of interest and curiosity may be dependent on the type of study enrolled in (patient/clinical trial or non-patient/non-clinical trial), the study purpose or topic, or individual

characteristics of the volunteers themselves. Although the importance of interest and curiosity factors varies, this study and other research findings support the significance of both factors as motivation to participate in research.

Altruism, the norm of helping others and making a contribution, was a prevalent topic that was discussed across all focus groups whose members had participated in non-hospital and/or social science research settings. There was widespread agreement among focus group participants about the importance of and responsibility to contribute to society, to the institution, and to the researcher. Similarly, altruistic motives to help others with the clinical condition, society, and research was the second most important motivation to participate in clinical trials, according to the work of Mattson et al. (1985). Having an obligation or responsibility to volunteer was a social norm that was brought up within all focus groups and also reinforces the work of Fisher and Ackerman (1998), who found that volunteerism was socially desirable. Making a contribution, as a social norm recognized by participants, was also found to be important to participants who were interviewed about social science research participation by Knapik (2006). The importance of altruism as it relates to participating in any type of research is reinforced by the focus group findings and suggests that it is a significant motivating factor in research participation for many individuals.

Some participants based their decisions on whether or not to participate on how convenient the study was for them personally to participate in. Focus group participants talked about inconvenience in terms of actual traveling but access to transportation was not discussed. This finding is in contrast to the Kellogg Report (2011), which showed that access to transportation was one of the top differences between rural and urban communities. In the

clinical trial studies reviewed, however, factors related to convenience and study complexity were not cited by participants as part of their motivation to participate.

The ability of individuals to participate in research was focused on the inclusion and exclusion criteria of studies and how participants viewed them. The negative attitudes toward narrow inclusion criteria, especially those with age restrictions, reduced the ability of some individuals to volunteer. While it is understood that sometimes criteria such as age restrictions are necessary for the validity of a study, and in clinical trials a person's condition may be an important factor, none of the research reviewed cited qualifying for studies as a barrier to participation. Inclusion and exclusion criteria as perceived by focus group participants was cited as a barrier to volunteering and suggests that although there appear to be differences between clinical trial participants and non-clinical trial participants, more information is needed to draw any conclusions.

This study's findings, as they relate to motivational topics about participation by non-patients in non-clinical research studies, are comparable to the findings of Zammar et al.'s meta analysis (2010) in which over half of the studies reviewed ranked altruism first as a factor that favored participation in clinical trials, with personal benefits ranked a strong second, and convenience and reimbursement a distant third and fourth. Since Zammar et al.'s meta analysis addressed Brazilian and Indian patients' willingness to participate in clinical trials, this may suggest that the findings have transnational and transcultural significance.

Theme: Personal Investment

Time, commitment, and access to information were combined to form the theme of Personal Investment, which represents the effort participants expend to find out about

research studies and whether or not they qualify, enroll in them, and actually participate in them.

Participants expressed views about considering which studies they could commit to and follow-through with before enrolling. Once enrolled, participants voiced beliefs about being good stewards of researchers' time and resources and feeling a commitment to them to be part of a successful research process. This idea of commitment to and follow-through after enrollment was taken seriously by many participants and was not an aspect that was evident in the literature reviewed.

The rural participants of this study expressed some negative attitudes toward how researchers used their time. They also expressed the belief that not all researchers were organized. In addition, negative attitudes toward finding out what a study was really about only after spending time to get there, speaks to the investment of participants' time. Time needed to adequately review consent forms was also a topic that occurred throughout the focus groups. Negative attitudes about feeling rushed to read and sign a consent form that resulted in skimming the information were expressed by focus group participants. Some participants described relying more on verbal explanations by the researcher than the written consent document. This reinforces the work of Black et al. (2007) who found that participants who received consent forms prior to the consent discussion relied more on verbal explanations about the study for their information. This also reinforces that consenting as a process, often including a written document, but always including verbal exchanges throughout the study are important, and that information events should occur at multiple times throughout a study, as described by Hassar and Weintraub (1976) and Lewis and Graham (2007).

Investment of time and effort were not specific topics often mentioned in the studies reviewed of patients who were volunteers in clinical trials, but were discussion points for participants across the focus groups. Negative attitudes about time commitment were expressed across all of the rural focus group participants and to a lesser degree for patients volunteering for clinical trials (urban), but they were not high priority issues for either group (Bevan, Chee, McGhee, & McInnes, 1993).

Another aspect to consider also relates to the Kellogg Report (2011), in which lack of opportunity was a strong differentiating factor between rural and urban populations, and this was supported within focus group discussions as it related to information about accessing what studies are available to participate in. Across all focus groups, frustration and negative attitudes were expressed in regard to the lack of accessibility to information about studies and having to diligently search for studies to participate in. Discussion across all focus groups identified the belief that increased accessibility or the perception of increased accessibility to this information by employees at the institution, in contrast to non-employees in the geographical region occurred. Access to information about study availability, however, was not an area of concern addressed in studies of clinical trial participants reviewed (i.e., Hassar et al., 1977; Hassar & Weintraub, 1976). This difference may be explained by the clinical care that patients are already receiving and the close relationship between the clinical care for a certain condition and participation in a clinical trial as part of their treatment. As part of the treatment and interaction with a physician or nurse researcher, in person invitations to participate in clinical trials often occur (Bevan et al., 1993), whereas many researchers outside of the clinical setting must use advertisements or other means to reach potential participants and wait for them to respond.

Theme: Expectations and Rights as Research Participants

This theme encompassed the expectation and belief that research study participants have the right to receive global study results and the expectation that the type of information they receive about studies is appropriate. Another aspect of expectations and rights that was expressed across the focus groups was voluntary participation in studies.

Receiving or being made aware of the overall, global results of a study was a strong topic of discussion across all focus groups. Participants reported negative attitudes toward the lack of provision of overall study results and publications to them. In the studies reviewed of clinical trial participation, the desire to be informed of the study results was either not emphasized or not mentioned. In clinical trials, the patient's improvement of condition, access to specialists in their condition, and treatment appeared to be sufficient information, combined with the belief and norm of helping others with the condition who may follow them. The emphasis on this topic by clinical trial participants was different than at least some of the focus group participants to whom it was very important to receive the results of the overall study after it was concluded and to learn how the research they participated in affected the field of study or society as a whole. Having meaningful access by participants to overall study results is a view that is supported by Kelman (1972).

I was especially interested in the information aspect of the discussions, due to my early experience of receiving very little information about participating in a phone-based survey. I found that my experience was not always represented, according to many participants. Information that was provided to participants about studies at recruitment and consent time raised a number of discussion topics across all focus groups. There were differences of opinion across the groups regarding the type and level of consent form and recruitment information

provided, but a common element was that typically enough information was given, although there were some exceptions. These differences of opinion are consistent with Weinfurt's study (2006), which showed that it is common for different types and levels of information to be desired, at least with financial disclosure information, and that the type and level of information desired varied according to the risk posed in the study. Participants in each of the focus groups in this study discussed the quantity and type of information that was provided to them for the studies they participated in and had varied opinions about how much information was given, when it was given, and how it was provided to them.

Positive attitudes toward and the belief that participating in research studies is a voluntary activity were prevalent across the focus groups. Wide awareness across the focus groups of the right to stop participation at any time, as described by 45 CFR 46 and the Belmont Principles, suggests that this message has been disseminated effectively, at least to this group of research participants.

Theme: Expectations of Researchers and the University

Participants expressed beliefs and attitudes about expectations they had related to conduct of research, and to researcher and university responsibilities for oversight of safety and reduction of risk for participants, as well as for the researchers and the university. The belief that the university and the researchers have a responsibility to protect participants from risk was expressed by many focus group participants. Understanding of how those responsibilities were carried out was detailed in some cases. For others, there was less interest in how those responsibilities were carried out, just as long as they were. Common across all groups was the belief that responsibility for safety and for informing participants about the study was institutionally based—whether by the university itself or by the researcher. Participant

discussion indicated that the norm of protection was an important topic: that participants believed that there was an obligation to have protections in place and oversight provided for their safety, including physical welfare, confidentiality and data security, and for institutional liability reasons. Negative attitudes about oversight, for instance, about how well confidentiality is kept, did occur, but again, despite negative attitudes, participation in research continued, which may indicate that enough oversight was in place and was expected to continue.

Absent from the clinical trial studies reviewed were references to oversight and safety. This difference could be attributed to the researcher-participant relationship in terms of the physician-patient relationship that is often inherent in a clinical trial and is not usually present in a non-clinical trial study. Familiarity and trust may play a larger role in the clinical trial researcher-participant relationship than in non-clinical trials. That familiarity and trust may include a stronger assumption of "do no harm" in a clinical trial than in a non-clinical study and could be an important difference between these focus group participants and other groups of study participants. An aspect of the power differential between researcher and participant may also be important; a clinical trial patient-participant's continued health and welfare is dependent on the physician primarily, and secondarily, the physician as researcher. As such, the trust a patient-participant has of his/her physician may be enough to assume proper oversight; whereas the trust among non-patient participants and researchers they encounter may be less. These observations may be supported by the work of Kelman (1972) who described the suspicion and threat of deception as undermining trust established between researchers and participants in his analysis of the rights of social science participants.

The focus group transcripts also provided insight into topics that were not directly related to attitudes, beliefs, and norms, and fell outside of the framework of TPB. Some awareness of

research protections federal regulations was reflected in the discussions, but awareness and accurate information about them varied widely. Based on this wide variation, it would seem that individuals interested in volunteering for research and experienced research participants could benefit from a rudimentary understanding of the protections provided by these regulations would be indicated.

Also, the interactions that occurred within the focus groups in regard to where to look for studies, types of studies, specific experiences with researchers are important to consider. Given the strong belief across the focus groups that helping and making a contribution to the university, research, and others would indicate that interactions such as these should be fostered.

Limitations

The content analysis approach was useful in providing a structure that led to insights based on the transcripts. The codes that were chosen and themes that emerged to represent participants' responses were based on my own perspectives. Despite the steps taken to ensure trustworthiness, other researchers may find different combinations that would be useful and reflective of their perspectives and purposes. The Theory of Planned Behavior does not specify how to identify which particular attitude, belief, or norm, or combination of the three, is the most influential factor in the performance of a behavior. The combination and weighting of each factor, whether in TPB or content analysis, is necessarily "messy" when exploring participants' experiences, opinions, and perceptions.

As this study was a secondary analysis of data already collected, I was removed from direct interaction with the participants in the parent study. The focus groups were conducted by a moderator at the institution's survey center. Responses were prompted by the original questions in the question guide, and little change in the questions occurred as new groups were

brought in, as the moderator closely followed the question guide and this influenced what topics were discussed. However, enough free conversation seemed to have occurred that topics were not strictly confined to those questions. In addition, the original grouping of individuals who volunteered for the focus groups was loosely homogenous. Homogeneous grouping is advised by Krueger (1994) for stimulating interaction among participants. Due to the limited number of focus group participants, group assignment was loosely homogeneous, primarily based on age and availability.

The framework of the Theory of Planned Behavior confined the analysis to identifying themes related to attitudes, beliefs, and norms. This necessarily limited the scope of the analysis. Other theoretical frameworks might have identified other aspects of experienced research participants' perspectives, which could inform outreach programming in other ways. Despite the constraints of the theoretical framework, however, this research provided an opportunity to assess its use with a qualitative approach and data. In terms of focusing the analysis, it was useful. It was also useful in illustrating that varying combinations of attitudes (positive and negative), beliefs, and norms carried varying weight for this group of participants as it related to intention to and actual participation in research.

Recommendations

This study has provided useful information that can be used in the program planning process. Some of the information was expected and served as confirmation for previous experience, observations, and research; other information was unexpected, which provided a new or expanded perspective on research participation, research protections, and outreach program planning for citizens.

The findings in this study support giving general information to participants prior to encounters with study specific recruitment, consenting, and participation. Also, the findings support participation in the focus group as benefitting participants by expanding their knowledge and understanding, in this case about research protections and research participation.

One unexpected finding was the strength of the discussion about the sharing of overall study results. Participants saw the action of receiving overall study results as an important part of their participation that was often, although not always, lacking. Sharing of overall study results is an important consideration for investigators, research protections personnel, and participants. Outreach programming for research participants should address this subject in terms of the participants' expectations. Researchers should be encouraged, in ethical terms, to give consideration to the respect for persons principle and to develop a mechanism to routinely provide summary results of their studies to participants. Other implications for investigators include emphasizing that many participants are interested in and feel that researchers have an obligation to provide them with the overall results of the study within a reasonable period of time. For the participants, outreach programming content could include information about when and how overall study results may be obtained, that it is reasonable for the results to be made available to them, and that it is also reasonable for them to ask for the overall study results.

A component of relaying this information is also informing participants that overall study results may not be available for a very long period of time after the study concludes. In addition to addressing this topic in outreach programming, one mechanism to reinforce to researchers the importance of providing overall study results to participants would be for research protections personnel, as part of a study's annual review process, to remind the researchers of this expectation. If any publications have come out (as must be reported in the

annual review), sharing them directly with the participants, notifying them of public access

sources, and/or providing participants with a lay summary would be appropriate. For

investigators who do this on a regular basis, this study's findings reinforce the importance of the

practice; however, it should be noted that dissemination of overall study results may not be

possible within a reasonable amount of time or may not be warranted. Studies that are

conducted over many years may not have overall study results available and some ongoing

studies and their participants may be negatively affected by releasing overall study results

prematurely. In these cases, consideration of disseminating results of selected parts of the study

may be appropriate.

In practical terms, relating to the dissemination of overall study results, those participants

for whom contact information is still accurate will be provided by mail or email with a summary

of the findings of this study. In addition, this paper is available via "eTD," which will be

recommended to be a link on the research protections program website at the institution. Making

this information as accessible as possible is appropriate, especially in view of the findings of this

research study. One possible implication of making this particular information available is that

the information may not reflect the experience of some participants and some participants may

feel as though their viewpoints were overlooked, particularly considering that only topics that

appeared across all focus groups were addressed. Qualitative studies allow for interpretation by

the readers, and questions may be posed by participants to me, as the researcher, about the

results, which could lead to additional engagement and further discussion.

Evidence of general outreach programming to prepare citizens to be effective consumers

of the consent document information they receive for specific studies is not found in the

informed consent literature, and many participant responses indicated that the information that is

received is usually adequate. However, a number of areas could be focused upon in the development of outreach program planning for participants, as well as in providing information for investigators. Information related to participants having sufficient time to review consent documents could be part of researchers' education and could include an emphasis on researchers encouraging participants to take adequate time to review consent documents without pressure, providing consent documents to participants in advance whenever possible, and actively encouraging participants to ask questions before, during, and after the study, as well as providing information verbally multiple times during a study. Informing participants that it is reasonable to request consent documents in advance if they are not offered and to take the time needed to review the documents thoroughly could be an important component of outreach programming.

Participants were asked about their understanding and awareness of research protections activities. The varied awareness indicates that there is not universal awareness of the research protections that are in place for at least these participants, and outreach programming can raise awareness of the existence of programs and procedures to provide protections, while also educating citizens about their rights as research participants.

In keeping with the concept of participation of learners in the program planning process, research participants should continue to be involved in future phases of planning research protections-related outreach programming. The expression and description of their beliefs and attitudes is foundational, but is not enough to fully represent their interests in the outreach program planning. Further discussion with experienced and potential participants, as well as involving laypersons in the field of research and research protections to develop content and format, would reflect Knowles' (1980) concept of learner participation and is warranted.

The findings also point to the importance of raising awareness through outreach programming about institutional and investigator responsibilities, since, as noted, there was mixed awareness of research protections across all of the focus groups. Responsibilities and oversight in terms of the information provided to participants about the research and how to evaluate that information would be important content to include in outreach programming. Also related to this aspect of this study's findings is that these participants had differing opinions about the type, amount, and format of information available through recruitment/advertisements, informed consent, and throughout the study. Investigators and research protections personnel can benefit from this information in terms of maximizing flexibility in the applicable regulations that address the consent process. The consent process starts with recruitment and continues throughout the study. For both potential and experienced participants, encouraging them to ask questions and to make sure they receive satisfactory answers would be an important outreach programming content-related factor.

Many participants expressed positive perspectives about the contributions that they can make through volunteering for research. Contributions include those made to the institution, the research mission, and to helping others or themselves. Related to these contributions are the tangible and intangible benefits received by the participants. Outreach programming content should be influenced by these perspectives, emphasizing the many contributions that participants can make through volunteering for research and could include providing concrete examples from past research conducted at the institution.

Across the focus groups, the topic of learning was prevalent. Providing specific examples of the learning that can take place during research participation would likely benefit potential participants and reinforce experienced participants' perspectives on learning, satisfying

curiosity, and broadening their knowledge. It is also worth noting that Weinfurt's (2006)

observation that focus group participants knew better what to ask about financial disclosure

information after the focus group may indicate that a focus group approach to outreach is an

effective approach to raising awareness of experienced and potential research participants. The

information about the priority that many focus group participants put on learning could be

beneficial to investigators by raising their awareness of the importance of this aspect of research

participation.

Using participants' time wisely is important information for investigators and their

study teams, and raising awareness of this finding with researchers could be valuable.

Participants across the focus groups placed a high priority on how their time was spent, such as

having their calls returned when they are interested in participating in a study and not wasting

their time by being disorganized. Outreach programming and investigator education content

should include showing respect for use of the participants' time. Consideration also should be

given to providing outreach programming in various geographical areas surrounding the

institution, by offering off-campus opportunities for outreach and bringing the information to

the citizens at convenient locations. Access to information about study opportunities should

also be addressed and a network of experienced participants could be informally established to

aid in this effort; or the existing registry of study opportunities could be expanded and efforts

made to increase its visibility, as well as encouragement of researchers to use both traditional

and novel methods, especially in outlying areas, for recruitment materials.

In the development and implementation of research protections' outreach programming,

using this research as a basis and engaging potential and experienced participants in the planning

process may have positive implications for research participation at the university. These

activities may result in increased participation in research by individuals. Increasing exposure to general information about human participant research and procedures through outreach programs may be helpful in the researchers' and university's recruiting efforts. Researchers may also use the information about beliefs, attitudes, and norms, in recruiting, enrolling, consenting, and follow-up to research studies which may increase satisfaction with the research experience and lead to future participation.

Suggestions for Future Research

This analysis focused on topics that occurred across all focus groups, as expressed by individuals living in a rural area who all had experienced participating in research at a rural research institution. As the analysis unfolded, it became apparent that another focus could have been the type of study participated in (i.e., clinical trial vs. non-clinical trial). Geographical location appeared to play less of a role than expected in terms of the perspectives of experienced research participants; however, there may be other approaches that could be considered that would more fully explore the aspect of rural research participation. Future analyses also could examine specific characteristics within age group, gender, educational level, and/or occupation to identify differences and similarities in research participation perspectives. Further exploration of the learning that is related to research participation by adults would be important: how this learning takes place, what learning takes place, when it takes place, what aspects of this learning are most significant to participants, etc. The transcripts of the focus group discussions and demographic information have been retained and could provide the basis for future analyses in these areas.

This study was focused on experienced research participants at one institution, and further study involving potential volunteers or non-experienced citizens could provide wider,

meaningful, and different perspectives. The focus group method may continue to be useful for this purpose. Further study into differences in attitudes and beliefs between clinical/hospital-based research participants and research participants involved in non-clinical/non-hospital-based research would also be valuable.

Summary

This research contributes to the knowledge base about research participation at a rural institution with experienced volunteers who gave their time to participate in social science and non-hospital based biomedical research. The literature is abundant with studies that focus on patients who were research participants involved in clinical trials, but less information is known about those who are healthy volunteers in social science and non-hospital based biomedical research. Also, there is little evidence of how outreach programming by research protections offices is developed, including what kinds of information are used to develop it. The beliefs, attitudes, and norms of those who have been involved in research studies at a rural institution that conducts non-hospital based biomedical and social science research are important factors to consider in the design of tailored outreach programming for citizens who may be or have been involved in those types of research studies.

Gaining insight into the experiences of volunteers, particularly their beliefs and attitudes toward research participation, should be useful at the rural institution where these focus groups were conducted. These insights can be used to develop instruments to effectively evaluate the educational needs of potential research participants, which can then inform the design, development, and implementation of outreach programming for potential and experienced adult research volunteers. This may contribute to knowledge and practice in the field of research

protections. Many of the topics that were discussed across the focus groups were identified by other studies.

The application of the Theory of Planned Behavior provided a useful framework within which to analyze the participants' responses across focus groups, who had all performed the behavior of participating in research numerous times. TPB served as a framework to identify attitudes, norms, and beliefs, and these *a priori* categories helped to focus the analysis and interpretation. TPB's premise that attitudes, behaviors, and norms can hold different weights for different people in different situations, in terms of different attitudes, beliefs, and responses to norms as they related to intention to and actual participation in research was demonstrated in this analysis. Without the framework of TPB, it is possible that some of these variations may not have been identified. Despite the many perspectives provided by participants, they still participated in research and did so relatively often.

This study addresses Lewis and Graham's (2007) observation that the participant's voice is largely absent in the area of research ethics, which includes research protections activities and related outreach program development and implementation. This study begins to bring participants' voices and perspectives to the field of research protections. Knowles (1980) viewed the participation of the constituents, the non-educators to whom outreach and program planning is aimed, as integral to the program planning process and as the basis for educational efforts, which this study begins to do.

Many of the attitudes, beliefs, and norms that were discussed by the participants can be linked to the Belmont principle of respect for persons. Motivation, Personal Investment, Expectations as Participants, and Expectations of Researchers and the University are themes that are rooted in the respecting persons principle, one of the foundations of the practice and regulatory guidance of research protections activities. The voice of the participants is an

important component in the development of outreach programming, and the focus group format was a mechanism that allowed the voices of the participants to be heard. What was learned from the participants can be used to develop effective and appropriate outreach programming, thereby more fully realizing the respect for persons principle, which is a worthy goal, in the end.

Appendix A

Phone Script, Group Assignment

Part A.

When answering call of interested person or calling back (Survey Research Center).

Hello!

Thank you for your interest in the research study about volunteering for research at the University here at the Survey Research Center.

May I explain a little bit about the study now, please?

- The purpose of this research study is to find out your views of and ideas about volunteering for research studies at the University.
- You will be asked to talk with other volunteers in a group, called a focus group, about your thoughts and ideas about the University's research.
- You will also be asked to fill out a survey form asking some basic information.
- The groups will be audio and videotaped and observed.
- The group will meet one time for about 2 hours at our location.
- You'll receive refreshments and $5 in cash for participating.
- The groups will be scheduled at the convenience of the volunteers and I'll call you back to tell you the times and days.

Are you still interested in participating?   NO - Ok, thank you for your time.

YES. Ok, do you have any questions so far?

      YES. Answer.

      NO. Then may I get some information from you now? This will help us schedule the groups.

What days of the week are best for you to come to a 2 hour session?

MON   TUE   WED   THU   FRI   SAT

What time of day is best for you?

Morning   Afternoon   Evening

Are you available over the next month or so?

YES   NO   If no, when will you be available? _____

Your first name _____

Your phone number and/or email to contact you about dates and times when they are confirmed: _____

Phone (include area code) _____ Best time to call _____

May we leave a message for you about the time/date of the group if you aren't in?   YES   NO

Your email address if you have one (in case we can't reach you by phone) _____

Just a few more questions so that we have some basic information about you:

Just to confirm – have you participated in research studies at the University, at this campus location?

> NO – exclude, thank for interest, and ask if name and contact information can be retained in case volunteers are needed for future research studies.

> YES, continue

Your age range: 18-25   26-39   40-55   56 -64   65 and over

Your highest education level:

High school/GED   Some post-high school education

2-year school graduate (associate's degree/certificate)   4-year college graduate (BA, BS)

Master's degree   Doctoral degree   Professional degree (R.N., M.D., J.D.)

Could you please tell me where you heard about this study?

Email/letter   Flyer   Where did you see it/get it? _____

Word of Mouth

Public service announcement (what publication?) _____

Thank you very much! If you know of any others who might be interested in participating, please feel free to have them call at XXX-XXX-XXXX. We look forward to seeing you and will be in touch within a few days/weeks to let you know when the groups will be held.

Part B.

Phone script: Call back to set appointment.

Hi, this is _____ from the Survey Research Center at the University. You had called about participating in a focus group, and I'm calling back to schedule the exact time. We have a group scheduled for _____. Will you be able to come to that group at that time and date?

NO – see if another time/date will work. If none will work, thank for their willingness to participate and ask if they would be willing to be contacted for future studies on the topic.

       If yes, retain information on Part A.

       If no, destroy information on Part B.

 YES – Ok, thank you. [explain location] Here are the directions: Direct them to the
       SRC from their general location.
       Give phone number and name to contact if have to cancel or get lost
       (_____ at XXX-XXX-XXXX)

We look forward to seeing you on _____ at _____. Thanks again!

Email script:

Dear _____,

Thank you for your interest in the focus group being conducted at the Survey Research Center at the University.

We will be having a focus group on _____ at _____.

Please email or call me at XXX-XXX-XXXX to let us know if this will work for you. There are a few other times and dates that might be more suitable if this will not work for you. The directions to our location, where the focus group will be held, are attached.

I look forward to hearing from you and thank you again for your interest in participating.

Sincerely,

Name
Survey Research Center

Appendix B

Question Guide

Ground Rules—Standard Survey Research Center Protocol
First names only
Audiotaped and videotaped, written notes by moderator and study personnel
Information shared in the group not identified with any individual. We hope that everyone feels
    comfortable sharing their opinions
Ask that people not talk over each other
Respect each other's opinions

Introductions
Would each of you please
- introduce yourself by your first name,
- tell the group a little about yourself, such as how you came to volunteer to
  participate in this focus group,
- any connection with the University or the research protections office,
- what kind of research studies you've volunteered for here at the University

Question #1: You all have participated in research here at the University. What did each of you
know about the research you participated in, and how did you come to know it?

Question #2: What prompted you to decide to volunteer in the research you did participate in?

Question #3: You have said you heard through word of mouth, newspaper ads, etc. about
research studies here at the University. I'd like to hear more about what you thought of the
recruitment materials.

   Probes: What about the method of recruitment? How did you feel about the text/content
   of the recruitment material? How good a job did the materials do of explaining what you
   would have to do for the study and what it would be like?

Question #4: Have any of you heard of the research protections office? Institutions who do
human research are federally mandated to have such offices and programs and they work to
assure participant safety in research.

Question #5: What kinds of things do you think that an office such as the research protections
office does/is responsible for? What kinds of things do you think that an office such as the
research protections office should be responsible for?

   Probes: What do you see as the
            - Role of the research protections office in research at the University?
            - Role of the investigators/researchers?
            - Role for others? Who are the others?

Some folks have indicated in other groups that the information given in the consent forms or other information for specific studies is enough, while others think that it might be helpful to prepare people in general for participation in any kind of research.

Question #6: What are the best ways to get this information out to people in the areas around this campus?

> Probes: Should this be in the recruitment material as well? Should this be general knowledge for all people in this area who may be considering participating in university research?

We have been talking about your ideas about being a research volunteer for the University, about recruitment and consent materials and the role of the research protections office in research at the University. Are there any other thoughts on these topics? Did we miss anything?

What kinds of things do you think that an office such as the research protections office does/is responsible for?

- Before you leave, we ask that you complete a short survey to give us an idea of everyone's background.
- Attached to the survey is a form with information about being contacted for participation in future research about this topic. If you are willing to be contacted about any future projects, please fill out this form and keep it attached to your survey. If you do not wish to be contacted in the future, please fill out the survey and tear off the contact information form.
- When you are finished, please put your papers in the box on the table.
- Each of you will then receive $5 in cash for your participation today.
- That will conclude the study for you.
- Thank you very much for your time and participation today!

Demographic Survey

Code Number _____

1. **Your age now in years. Please check one range:**

    18-25

    26-39

    40-55

    56 – 64

    65 and over

2. **Gender – please check one.**

    Male

    Female

3. **Check the one that best describes you:**

    White (not Hispanic or Latino)

    Hispanic or Latino

    Black, African American or Negro

    American Indian or Alaska native

    Asian Indian

    Asian

    Hawaiian or other Pacific Islander

4. **Approximately how many studies have you participated in at the University, at this campus location, over the last 5 years as an adult (age 18 and older)? Please check one.**

    1

    2-10

More than 10

Do not recall

5. What kind(s) of research studies did you participate in at the University in the last 5 years? (Check one)

Exercise/diet/medical (drew blood, etc.) types of studies

Survey/questionnaire/interview types of studies

Some of both

6. What is your highest level of education? (Check one)

High school/GED

Some post-high school education

2-year school graduate (associate's degree/certificate)

4- year college graduate (BA, BS)

Master's degree

Doctoral degree

Professional degree (R.N., M.D., J.D.)

7. What borough or township do you live in? _____

8. What range does your annual household income fall into? Check one.

Less than $20,000 per year

$20,000 to $49,000 per year

$50,000 - $100,000 per year

More than $100,000 per year

9. What kind/type of work do you do? _____

- If you wish to be contacted for participation if future studies on topics related to research protections and research participation are conducted, please fill out the attached contact information form. When you are finished, please detach the forms from one another and place in the separate boxes provided.

- If you do not wish to be contacted in the future, please detach the contact information form and put just this completed form in the box.

- Thank you for your participation in today's focus group and for completing this survey.

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School Nurse, Bellefonte Area School District, Bellefonte, PA (1979-1992)
Childbirth Educator, Bellefonte, PA YMCA (1984-1989)
Staff nurse positions, Centre County, PA (1975-1979)

Professional License and Certification

Certified School Nurse, Pennsylvania Department of Education (current)
Professional Registered Nurse Licensure, Commonwealth of PA (current)

Publications and Presentations

IACUC Administrators' Best Practices Meeting: Post-approval Monitoring Program, The
Pennsylvania State University. State College, PA (2010).
Thompson, M. M., Campolongo, D., Harp, N., Lyons, J., & Rutter, P. When Staff Become Students:
Trials, Tribulations and Triumphs. Presentation at the Hendrick Best Practices for Adult Learners
Conference. University Park, PA (2008).
Peters, K. F., Lyons, J., Milstein, M., Gabbay, R., & Ulbrecht, J. S. TrialNet abstract presented at
Diabetes Research Retreat, The Pennsylvania State University (2007).
Miller, C. K., Ulbrecht, J. S., Lyons, J., et al. (2007, January-March). A reduced carbohydrate diet
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Young, E., Koch, P. B., & Mauger, J. Lyons. (1988). Smokeless tobacco: Substituting the spittoon for
the ashtray. *Journal of Community Health Nursing, 5*(3), 167-176.
Mauger, J. Lyons. (1984). Cardiovascular programs [in secondary schools]. *Nursing*
Mauger, J. Lyons. (1981). Smokeless tobacco and smoking programs. *Nursing*

Professional Affiliations

Public Responsibility in Medicine & Research, member (current)
Association for the Accreditation of Human Research Protection Programs, member (current)