

THE ROLE OF CULTURE-CENTERED COMMUNITY ENGAGEMENT IN
HIV VACCINE RESEARCH:
THEORY-DRIVEN FACTORS PREDICTING SUSTAINED INVOLVEMENT,
COMMUNITY MOBILIZATION, AND STUDY VOLUNTEER INTENTIONS

by

PAULA MARIE FREW

(Under the Direction of Su-I Hou)

ABSTRACT

For decades, the toll of HIV/AIDS has devastated communities worldwide. HIV counseling and testing, as well as other evidence-based behavioral interventions, are available in many communities, but these measures alone have been unsuccessful in preventing the spread of HIV. A safe, effective, and acceptable method of HIV prevention is therefore necessary to decrease transmission. HIV vaccine research necessitates the involvement of diverse populations to ensure social justice aims of the effort are fulfilled, to maintain scientific integrity, and to claim generalizability of study findings. Therefore, cultivating relationships with local communities are critical to the success of HIV vaccine research. These issues are of particular concern for minority populations who have been underrepresented in HIV vaccine studies and where research suspicion has been a significant barrier.

This study examines the role of a HIV vaccine community engagement model in the attainment of three primary goals: future attendance, community mobilization, and study volunteerism. The Theory of Reasoned Action (TRA), inclusive of consumer-oriented variables, was identified to understand the pathways of influence on participatory decision-making. To this

end, a pilot sample of 212 participants, mostly female and non-White, was conducted for purpose of achieving strong internal subscale consistencies for structural equation modeling. A subsequent study (N =542) was also conducted in the field setting with a similar population to retest the instrument's psychometric measures, and for the purpose of confirmatory factor analyses and model testing.

The findings indicate that the TRA "background variables" of behavioral and normative beliefs, along with motivation to comply, exhibited significant effects on endogenous variables, subjective norms and attitudes. Attitudes towards the three behavioral intentions was the most significant and consistent determinant among models. External variables of personal relevance and organizational involvement also had significant mediating, and direct, influences on the outcomes. However, the effects of these differed with respect to each of the participation considerations. These factors suggest the community participatory model of HIV vaccine promotion has encouraged collective engagement in the cause via messages focused on the value of health research, the personal relevance of volunteerism, and the salience of the clinical organization in the endeavor.

INDEX WORDS: HIV/AIDS, HIV vaccine, community engagement, women, minorities

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PAULA MARIE FREW

B.A., The University of California, San Diego, 1990

M.A., San Diego State University, 1997

M.P.H., Emory University, 2001

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PAULA MARIE FREW

Major Professor: Su-I Hou

Committee: David DeJoy
Dean Krugman
Wendy Macias

Electronic Version Approved:

Maureen Grasso
Dean of the Graduate School
The University of Georgia
December 2007

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INTRODUCTION

This dissertation examines the role of a culture-centered collaborative community engagement model of HIV vaccine research in the realization of specific outcomes of interest (sustained attendance, community mobilization, and study volunteerism). It details the research that integrates an accepted predictive model of behavioral theory, the Theory of Reasoned Action, with consumer marketing measures to assess the potential of a networked partnership collaborative effort in the attainment of HIV vaccine community engagement specifically among women and minorities.

This paper is divided into five chapters. The first chapter gives a research overview, along with a statement of the problem, background issues including the development of a framework of community engagement in health research, the significance and purpose of the study, the research questions, and the study implications. This section presents a conceptual model of the variables hypothesized to influence participant engagement in HIV vaccine research efforts. A review of the literature is provided in the second chapter. This section examines the need for an HIV vaccine, vaccine development in historical perspective, the need for community engagement in this context, socio-behavioral research that guided theoretical development of this study, and it details the reasons for incorporation of "personal relevance" and "organizational involvement" measurement in the theoretical framework. The research methodology for this study is presented in the third chapter. It includes an overview of the study design, study sample, survey instrument and the pilot phase of the measurement development process, data collection procedures, data management, and steps taken in the data analysis phase. All of the analytical results are presented in the fourth chapter. The concluding summary is contained in the fifth

chapter which details the key findings of the study questions, the study limitations, and implications for future HIV vaccine community engagement efforts and related future research.

CHAPTER 1

RESEARCH OVERVIEW

This chapter provides an overview of the research project. It contains background germane to the research problem and introduces the research questions that are addressed in the investigation. Additionally, it covers the significance of the overall study, the purposes of the study, and potential implications associated with the work.

Statement of the Problem

Few public health issues in modern times can match the scope and impact of the human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) pandemic. As of December 2007, HIV/AIDS has infected more than 33.2 million people worldwide with an estimated 6,800 new infections occurring daily (UNAIDS/WHO, 2007). In 2007 alone, an estimated 2.5 million adults and children were newly infected with HIV, and 2.1 million died from AIDS (UNAIDS/WHO, 2007). HIV/AIDS rates continue to rise, particularly among men-who-have-sex-with-men (MSM) in the United States who account for approximately 45% of newly reported HIV/AIDS diagnoses and 54% of AIDS cases, and Blacks who from 2001 to 2004, accounted for 51% of new HIV diagnoses (CDC, 2006a, 2006c).

For two decades, the toll of HIV/AIDS has devastated communities worldwide. Thus, the advent of an effective HIV/AIDS vaccine may provide one of the greatest public health advances of the 21st century (UNAIDS/WHO, 2006). Most agree that a vaccine may not be available for some years (Solomon, 2005; Tramont & Johnston, 2003), despite President Clinton's call for

an HIV vaccine by 2007 (Lawler & Cohen, 1997). This consensus opinion holds in view of the recent failure of the leading candidate vaccine. The vaccine did not protect individuals against HIV acquisition (Altman & Pollack, 2007; Merck/HVTN, 2007). Despite many disappointments, the pipeline of vaccines in clinical trials remains robust with approximately 39 products in the testing process worldwide (IAVI, 2007). These ongoing clinical trials necessitate the support and involvement of the global community to achieve the goal of a safe and effective vaccine.

With the 1994 NIH mandate specifying inclusion of women and minorities in research, greater emphasis has been placed on recruiting and retaining these populations. Yet, there are too few women and minorities participating in HIV vaccine research efforts. Enrollment trends of racial/ethnic minorities in HIV vaccine studies from 1988 to 2002 indicate $\leq 26\%$ enrollment of these groups in all Phase I and II studies (Djomand, Katzman, di Tommaso et al., 2005). This is considerably less than the proportions currently affected by HIV/AIDS in minority communities.

A national survey on HIV vaccine research also found less support for study volunteerism among Blacks and Hispanics (Allen, Liang, Salvia et al., 2005). A lack of representative minority populations may affect not only generalizability of the research (Priddy, Cheng, Salazar et al., 2006), but also public confidence in the results. Barriers also exist among these populations for future product dissemination despite the potential benefit of this new prevention strategy (Frew, Crosby, Salazar et al., 2008; Newman, Duan, Rudy et al., 2004a; Newman, Duan, Rudy et al., 2004b).

Although minorities are not participating in health research at a level equal to Whites (Caucasians) (Corbie-Smith, Thomas, & Marie, 2002; Corbie-Smith, Thomas, Williams et al., 1999; Moutsiakakis & Chin, 2007; Smith, Johnson, Newman et al., 2007), it is important to recognize that knowledge of and access to health research activities may have a favorable impact

on willingness to participate in health research (Wendler, Kington, Madans et al., 2006). In large scale review study of 70,000 persons, minorities were found to be more willing to participate in clinical and surgical studies than Whites (Wendler, Kington, Madans et al., 2006). These findings indicate that little difference is seen in enrollment patterns when minorities are invited to participate in health research studies (Wendler, Kington, Madans et al., 2006). The authors conclude that underrepresentation in health research is likely due to other factors.

Recent evidence on minority participation in health research indicate a desire for information of the research activity in the community, greater demand to understand the relevance of the research efforts in addressing medical problems, and occasions to learn about clinical research entities and study volunteer participants (Smith, Johnson, Newman et al., 2007; Wendler, Kington, Madans et al., 2006). Thus, the creation of opportunities to serve these needs is a necessary precursor for effective community engagement with these groups.

Background Issues

HIV/AIDS in the Southern United States

The Southern region of the United States comprises 16 states and the District of Columbia, extending from Delaware to Florida and from the East Coast to Texas (Mace, 2003). Regional HIV/AIDS data shows that the South has the highest proportion of new AIDS cases in the country, constituting 48% of all cases in 2004, up from 40% in 1996. Between 2000 and 2004, AIDS cases increased 25% in the South, while continuing to decrease in the traditional epicenters of the disease, the Northeast and West Coast ("AIDS at 25," 2006). Furthermore, Black females accounted for 72% of HIV/AIDS diagnoses among women in the South (CDC, 2006b).

Black/African Americans comprise 19% of the population in the South (19 million persons), making this racial/ethnic group much larger in this geographic setting compared to other regions such as the Midwest (6.5 million) (Mace, 2003). Black/African Americans who engage in high risk behaviors in the South may experience greater stigmatization with HIV prevention or care service utilization (Mace, 2003; Whetten & Reif, 2006).

It has been suggested that factors such as poverty, unemployment, inadequate access to healthcare, and sociocultural environment of the Deep South may contribute to this phenomenon (Mace, 2003; Reif, Geonnotti, & Whetten, 2006; Whetten & Reif, 2006). The "Deep South" is historically defined as those southern states that "actively promoted slavery" and whose agricultural and economic base was "cotton and tobacco" (Alabama, Georgia, Louisiana, Mississippi, North Carolina, and South Carolina) (Whetten & Reif, 2006). In these states, sociocultural factors that may impact risk behaviors include racial disparities, a lack of access to prevention and education, high levels of poverty and homelessness, suboptimal healthcare, and the inability to obtain adequate health insurance due to low income levels (Mace, 2003). Issues such as mistrust in the medical system also prevail (Gamble, 1997; Whetten & Reif, 2006) resulting in greater health disparities among minorities living in the region.

Setting an Agenda: The National Institutes of Health Population Survey & HIV Vaccine Research Local Partnership Program

Among the few studies designed to examine broad population attitudes and beliefs related to HIV vaccine trials, a recent NIH telephone survey of 3,509 US adults found a high level of support among Blacks (86.4%) and Hispanics (88.8%) for HIV vaccine research compared to the general US population (73.4%), yet consistently lower levels of support for trial volunteers (34.9%, 45.9%, 28.8% respectively) (Allen, Liang, Salvia et al., 2005). The findings underscore significant variations in knowledge, awareness of, and support for HIV vaccine research among

US subpopulations, suggesting a need for intensified community engagement efforts particularly to address HIV vaccine volunteerism among referent groups and to counter misinformation and distrust of the medical-research community.

As it pertains to HIV vaccine research, community education focuses on understanding the key components of the endeavor (Swartz & Kagee, 2006). Community engagement fosters a sense of empowerment and voice in the effort (Dickert & Sugarman, 2005; MacQueen, McLellan, Metzger et al., 2001). These foundational efforts may potentially contribute to the realization of any number of objectives including building sustained dialogue on issues affecting involvement and support for the cause, cultivating community mobilization, building social support, and generating interest in study volunteerism, although the existing evidence is ambiguous as to which of these will be achieved (Koblin, Holte, Lenderking et al., 2000; Swartz & Kagee, 2006).

The Role of Community Partners

The national survey findings provided impetus for the formation of the NIH-sponsored Community Education & Outreach Partnership Project (CEOPP) and Local Partnership Program (LPP) initiatives for the development of local community engagement programs in cities where HIV vaccine research studies are taking place. In Atlanta, the NIH-funded entities, The Hope Clinic of the Emory Vaccine Center and SisterLove, Inc., developed and implemented the local project – Atlanta HIV Vaccine Community Collaborative (AHVCC). With a focus on increasing the direct relevance of the research effort in the African American community, and consistent with good participatory action practices (Schulz, Krieger, & Galea, 2002), the Hope Clinic and SisterLove sought the experience of community leadership and social networks in the design and implementation of the AHVCC in community settings. The partnership network includes

governmental agencies, academic institutions, faith-based organizations, advocacy groups, professional and social clubs, volunteer entities, service-providers and businesses, and AIDS service organizations. Through integrated programs the AHVCC promotes HIV vaccine awareness, information dissemination processes, educational program development, and the assurance of equitable engagement of all individual and organizational participants.

Specifically, the LPP suggests the following objectives for HIV vaccine community engagement programs:

1. Increase awareness of the urgent need for an HIV vaccine in communities most affected by HIV/AIDS and share of information with these communities about ongoing HIV vaccine research.
2. Establish leadership and foster expansion of support for HIV vaccine research and clinical trials and among community opinion leaders and those eligible to participate in trials.
3. Empower persons to become credible HIV vaccine educators and to promote accurate messages about HIV vaccines and related clinical research.
4. Increase individual and organizational capacity to provide and to become primary sources of accurate and relevant information on HIV vaccine issues.
5. Increase public knowledge and understanding of scientific and social issues related to HIV vaccine research.

The formation of "community advisory boards" (CAB) at research sites is also highly beneficial to community engagement (Morin, 2003). The Hope Clinic community advisory board is an entity within the AHVCC structure which offers ethical review, informs community practices, generates social support for research efforts, and facilitates the diffusion process

among members of social groups. Inclusion and promotion of participatory behavior in research are guiding tenets of the CAB mission statement. Ideally, research site CABs help to develop interventions that reduce health disparities among disenfranchised populations, racial and ethnic minorities disproportionately impacted by disease, and help to identify other "socioenvironmental" and "sociopsychological" determinants that impact health behaviors (Schulz, Krieger, & Galea, 2002).

With input from CAB members, novel integrated approaches can be implemented to achieve individual and community-level changes (Bracht, 2001). However, the lack of empirical assessment of the multilevel determinants (e.g., intrapersonal, social organization) of community engagement formation related to HIV vaccine research has posed difficulties in practical understanding of how to generate broad scale momentum for the concept.

Community Participatory Models of Behavior Change: The "Community Engagement" Concept

The concept of "community engagement" arose from participatory action research traditions (Crotty, 2003; MacQueen, McLellan, Metzger et al., 2001; Miller & Shinn, 2005) with a focus on building public trust in research through consultation, dialogue, and collaboration with communities. It is accepted that successful community engagement in health research, particularly among minority populations, result from building trust and relationships with community (Smith, Johnson, Newman et al., 2007). The long-term success of the HIV vaccine effort depends on meaningful involvement of community members in continuum of the process to sustain efforts beyond those realized from a single research study (Aggleton, 1998; Snow, 2005). At a minimum, community engagement is cultivated through persuasion and empowerment, and is most successful in environments supportive of behavioral change (Aggleton, 1997, 1998).

The development of community networks, use of popular opinion leaders, role models and peers in community campaigns, and attention to cultural constraints in communities has been well-documented in the communication literature related to HIV/AIDS interventions (Dutta-Bergman, 2005; Hadi, 2001; Mittlemark, 2001). However, it has been suggested that these approaches incorporate individualistic, cognitively-focused strategies that ignore essential contextual forces that impact successful community mobilization (Dutta-Bergman, 2005). Therefore, targeted "culture-centered communication approaches" (CCA) have been advocated for its emphasis on collective articulation and on social change participation. It has been argued that these have a greater likelihood of successfully addressing problems and concerns embedded within communities (Airhihenbuwa, 1995; Dutta-Bergman, 2005). Culture-centered efforts use "best practices" drawn from participatory action models to enable community members to equitably collaborate with researchers to identify sociocultural and structural impediments and work to remove those barriers (Petty, Strathman, Cacioppo et al., 1994)

Community-based participatory action research has been in existence for some years (Fleischman, 2007; Green, George, Daniel et al., 1995; Schulz, Krieger, & Galea, 2002), as collaboration with target groups has been shown to be effective in overcoming issues of mistrust and suspicion of research (Hatch, Moss, Saran et al., 1993). Moreover, involvement of the community in health promotion has greater potential for research application and achievement of dissemination among those who would likely benefit from the work (Bracht, 2001; Leung, Yen, & Minkler, 2004).

Although no single definition of "community engagement" exists, its emphasis is on "addressing health from positive and ecological perspectives" (Shultz, Krieger, Galea, 2002, p. 290) for the promotion of "learning and empowerment, equalizing power among participants,

integrating knowledge and change for the mutual benefit of all partners, and ultimately disseminating findings and knowledge gained to all partners" (Israel, Schulz, Parker et al., 1998; Schulz, Krieger, & Galea, 2002). With greater emphasis placed on community engagement in health promotion, social marketing, and health research in general, the Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR), and Academy for Educational Development (AED) developed a special task force to craft a definition of the concept and to identify key principles (CDC/ATSDR, 1997).

The CDC/ATSDR Committee on Community Engagement

The "Committee on Community Engagement" suggested that it "is the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people" (CDC/ATSDR, 1997, p. 9). In public health this process typically "involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices" (CDC/ATSDR, 1997, p. 9; Fawcett, Sterling, Paine-Andrews et al., 1995). The group also recognized important components of community engagement. They include:

1. *Clarity of purpose and goals of the engagement effort* (i.e., target populations and/or communities of interest);
2. *Thorough understanding of target community* (i.e., economic conditions, political structures, norms and values, demographics, history and previous experience with engagement efforts);
3. *Organizational involvement* (i.e., establish relationships, build trust, work with formal and informal leadership, seek commitment from community

organizations and leaders to create processes for community mobilization);

4. *Community self-determination* (recognize the responsibility and the right of those who constitute the community);
5. *Partnerships* to create change and improve health;
6. *Respect for diversity*;
7. *Sustainability* through identification and mobilization of community assets, and by developing capacities and resources for community health decisions and action;
8. Provision to *release actions or interventions* to community and *retain flexibility* to meet the changing needs of the community; and
9. *The long-term commitment* by the engaging organization and its partners (CDC/ATSDR, 1997).

Having identified these principles, the task force recognized other public health projects that exemplified effective community engagement in action. They include: "Identifying Community Leaders" (Thurston County Public Health and Social Services Department and APEX/PH: Olympia Washington), "The Church as a 'Natural' Partner in Health Promotion" (The Jackson County Health Advisory Council: Jackson County, Florida), "Community Self-Determination in Breast Cancer Research" (National Breast Cancer Coalition: Philadelphia, Pennsylvania), "A 'Good Research Agreement': Preserving Community Culture and Self Determination (The Mohawk Community of Akwesasne; Hogansburg, New York), National Cancer Institute: ASSISTing Change in Community Health (American Cancer Society Affiliates, State Health Departments, and Community-Based Coalitions, Detroit, Michigan), and others

(CDC/ATSDR, 1997). With these examples in mind, the Atlanta HIV Vaccine Community Collaborative (AHVCC) adopted the guiding tenets of effective community engagement programming into its model.

A review of these precedent models also assisted in the development of a working definition of the HIV vaccine community engagement for the AHVCC. It is:

A culture-centered collaborative enterprise of interconnected partner organizations, representatives, and local communities, who work in a concerted manner to empower the voice of the community. Through consensus opinion, the AHVCC offers multidirectional informational exchange and educational dialogue on HIV vaccine research. Its overarching purpose is to increase awareness of the cause, promote the personal relevance of the effort, and, through active involvement in the community context, enhance public trust in the Hope Clinic and its research endeavors.

Significance of the Study

This study investigates the potential of a community collectivist interventional model (the "AHVCC") in generating greater community interest in and personal involvement in HIV vaccine research. This project examines three specific participation outcomes of interest to the AHVCC agenda. It examines the likelihood of achieving greater community participation in its organized events and activities, the likelihood of increasing participants' desire to mobilize their communities to HIV vaccine research action, and the likelihood of fostering greater interest in study volunteerism. Therefore, determining participants' attitudes and behavioral intentions are essential not only for a greater understanding of what the AHVCC is achieving, but is necessary to further develop effective strategies to engage communities in what is often viewed as a highly controversial and sensitive topic.

Although multiple theories have examined the attitude-behavior relationship, this study builds on previous research which examined the utility of the Theory of Reasoned Action (TRA) as a predictive model of HIV vaccine community engagement outcomes among a small sample

of Southern African Americans (Frew, Archibald, del Rio et al., 2007). Although the findings suggested that TRA was a valuable tool in assessing differences across constructs to the participatory outcomes, key effects among variables were not realized as proposed by the model progenitors (i.e., subjective norms on intention) (Ajzen & Fishbein, 1980). While these effects may signify true theoretical deviations, it is important to address the shortcomings observed from the previous work to ascertain its explanatory potential. This study therefore addresses key limitations observed with previous research in similar populations, such as small sample size and measurement concerns, to determine the applicability of the model to community engagement.

Additionally, this study further explores the role of "consumer involvement" (Traylor & Joseph, 1984; Zaichkowsky, 1985) as translated to the current context. Many researchers, including those in consumer research and social psychology, have expanded the scope of TRA inquiry to include the relative influence of other possible factors in combination with the central components of attitude and subjective norm (Eagly & Chaiken, 1993; Perugini & Bagozzi, 2001). As noted by those in public health and marketing fields, the model is cognitively-oriented and lacks any assessment of emotional commitment, a component that may be necessary to understand likelihood of behavioral engagement in controversial product purchases and health decision-making (Bargh, 2002; Cox & Blount, 2000; Fitzmaurice, 2005; Xu, Summers, & Belleau, 2004).

Similar health volunteerism behaviors such as bone marrow and kidney donation, and clinical trials participation among healthy adults, indicate a greater degree of affective involvement in the health issue may increase intention to perform the behavior (Bagozzi, Lee, & Van Loo, 2001; Curbow, Fogarty, McDonnell et al., 2006). That is, the greater the perceived relevance and importance of the endeavor to the individual and community, the more likely it is

that engagement will ensue. Thus, within this context, the influence of external variables on intention, the research site ("the brand"), and the personal relevance of HIV vaccine research volunteerism ("the offering"), are of interest. As described by Ajzen & Fishbein (1980), any assessment of "attitudes towards brands or products are external variables" can be added to their model (p. 172). With these new dimensions, the study recognizes and extends previous findings which specifically highlighted the importance of favorable public impressions of the study site and its activities within the HIV vaccine community engagement milieu (Frew, del Rio, Clifton et al., 2007). The application of structural equation modeling in combination with a theory-driven model, allows for a very powerful assessment of simultaneous effects realized from community engagement efforts (Figure 1).

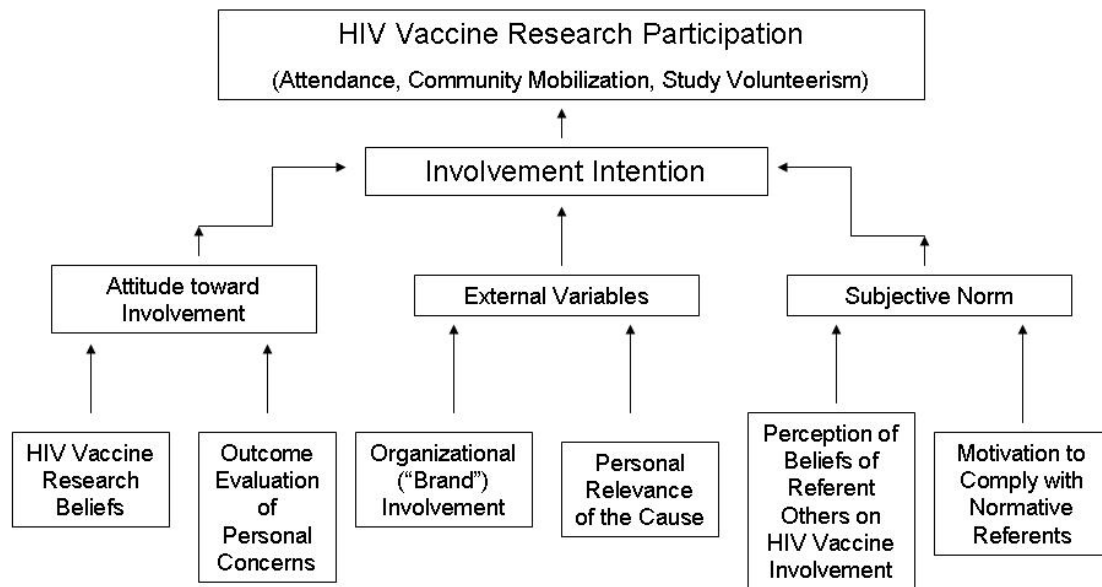


Figure 1: Variables Hypothesized to Influence Participant Engagement in HIV Vaccine Research

Purpose of the Study

The purpose of this dissertation study is to assess the potential of the AHVCC model in realizing greater community engagement in HIV vaccine research. Consequently, the overarching question for the study is: What key outcomes can be expected from a culture-centered HIV vaccine community engagement model? The combined analytic strategy using theory-driven approaches, factor analyses, and structural equation modeling of 3 potential outcomes was designed to provide useful information for future HIV vaccine community engagement endeavors and to assist in determining resource allocation for research sites involved in efforts. Specifically, the study addresses questions pertaining to the value of community engagement through a temporally-sensitive framework for assessment. The study was designed to capture short term effects such as sustained participation in partnership-organized events and activities to increase informational exchange and improve knowledge. Other "mid-range" objectives such as increasing community mobilization are also of interest, as are longer-term realization of study recruitment goals.

Research Questions

To address the AHVCC goals, this study was developed to understand the aggregate effect of multiple partnership-sponsored activities. The following questions informed the general aim of the inquiry.

1. Will the TRA and the external variables explain participatory intentions arising from the culture-centered HIV vaccine community engagement model?
2. Do the constructs vary according to outcome of interest within a structural equation model (SEM) context?

Confirmatory factor analysis and structural equation models investigated the structural underlying beliefs, attitudes, normative referents, and involvement expectancies toward behavioral intentions. The specific hypotheses include:

H1: Beliefs and attitudes about HIV vaccines and medical research that favor participatory behavior will more likely lead to intentions to participate in future activities, generate greater community mobilization, and study volunteerism.

H2: Reduced personal concern and fear of health and social consequences will more likely result in greater participatory intention.

H3: Perception of subjective norm approval of involvement will favorably influence greater participatory intention toward HIV vaccine research.

H4: Greater organizational ("brand") involvement will favor participatory intentions.

H5: Greater personal relevance of HIV vaccine volunteerism will favorably influence participatory intention.

H6: An expanded TRA model will explain various HIV vaccine community engagement outcomes.

Research Implications

Developing a greater understanding of the role of and outcomes associated HIV vaccine community engagement in promoting HIV vaccine research has the potential to impact the development of public health programs and health communication initiatives. Based upon literature review and practice experience, very little inquiry has been dedicated to inquiry in this context.

Although a call for a consumer-focused HIV vaccine research agenda has been made (Newman, 2006) to develop and sustain the interest of priority populations, this current study is

significant because it is the first of its kind to examine predictors and correlates that may be useful in developing community engagement interventions in support of HIV vaccine research, specifically for women and minorities whose participation is needed in the effort. In addition, it fills a gap in the literature with information gathered with important target populations attending HIV vaccine-related events and activities. Specifically, this study extends what has been learned about the motivational factors affecting participation in HIV vaccine research and facilitates the development of a theoretically-driven, culturally-appropriate community engagement model to achieve desired participatory goals.

CHAPTER 2

LITERATURE REVIEW

This Literature Review chapter has 4 sections. Section 1 describes the need for an HIV vaccine in the United States and details key phases in product development. Section 2 reviews why HIV vaccine community engagement is essential in the search for a vaccine and for testing phases. Section 3 provides an overview of behavioral research related to HIV vaccine research and similar forms of health volunteerism. This section focuses on the identification of sociobehavioral factors affecting health research participation. It also highlights themes identified as important to the promotion of product acceptability. Section 4 concludes the chapter with a description of how the various factors may be incorporated into the Theory of Reasoned Action model to explain important community engagement outcomes (i.e., sustained participatory behavior, community mobilization, and study volunteerism).

The Need for an HIV Vaccine: The US Context

As previously described in Chapter 1, the global need for an HIV vaccine is critical. With over 6,800 new infections occurring every day worldwide (UNAIDS/WHO, 2007), the impact of the pandemic is of profound concern across societies. Domestically, in the fifty states and the District of Columbia, the number and proportion of HIV/AIDS cases,¹ particularly among minorities (e.g., African Americans) and women, continue to highlight the need for new and

¹ *HIV/AIDS*: This term is used to refer to (1) a diagnosis of HIV infection without the presence of AIDS, (2) a diagnosis of HIV infection with a later diagnosis of AIDS, and (3) concurrent diagnoses of HIV infection and AIDS. (CDC definition)

effective prevention strategies. From 1982 to 2005, Black/African Americans encompassed approximately 42% of all AIDS cases. In 2005 alone, Black/African Americans comprised 50% of the AIDS burden (CDC, 2007) while making up only 12.8% of the general population (U.S. Census Bureau, 2005). The AIDS rate among Black/African American men (95.1/100,000) is eight times higher than that of white men (12.1/100,000) (Kaiser Family Foundation, 2007)

Among women this difference is even greater. AIDS rates are approximately 23 times higher for Black/African American women (45.5/100,000) than for white women (2.0/100,000) (CDC, 2007). An estimated 66% of new AIDS cases in women during 2005 were among Black/African Americans (CDC, 2007). Regional HIV/AIDS data shows that the South has the highest proportion of newly reported AIDS cases among Black/African Americans in the country, constituting 56% of all AIDS cases in 2005; as well as over half (51%) of all Black/African Americans living with AIDS in the US (Kaiser Family Foundation, 2007).

HIV counseling and testing, as well as other evidence-based behavioral interventions, are available in many communities, but these measures alone have been unsuccessful in preventing the spread of HIV (Janssen, Holtgrave, & Valdiserri, 2001). A safe, effective, and acceptable method of HIV prevention is therefore needed to decrease HIV transmission. Potential options include the development of preventive and therapeutic HIV vaccines, microbicides, and other forms of pre-exposure prophylaxis (D'Cruz & Uckun, 2004; Duerr, Wasserheit, & Corey, 2006; Gallo, 2005; Woodsong, 2004). As women have become increasingly infected by HIV through heterosexual transmission during the past decade, these new biomedical prevention options would be of great benefit. Inequitable decision-making and compromised power have been identified as primary obstacles to women's ability to demand male condom use (Aral & Wasserheit, 1995; Jemmott, Catan, & Nyamathi, 1995; O'Leary & Wingood, 2000; Wingood &

DiClemente, 2002). Domestic violence and economic dependency on men have been recognized as key forces of this problem (Aral & Wasserheit, 1995).

However, with over 20 years of activity, HIV vaccine research has been a complicated and disappointing endeavor (Gallo, 2005; Solomon, 2005; Tonks, 2007; Tramont & Johnston, 2003). The general consensus is that realization of an even partially-effective vaccine will be of value in controlling the pandemic (Anderson & Hanson, 2005; Stover, Bollinger, Hecht et al., 2007). It has been asserted that a vaccine with "50 percent efficacy provide to 30 percent of the population would reduce new annual infections by 34 percent" (or 17 million potential infections) (Stover, et al., 2007, p. 1147).

Vaccine Development Strategies

HIV is not like other viruses, and therefore vaccines cannot be designed as they typically have in the past using live, whole killed, or attenuated strains to of viral particles to induce immune responses. In short, the development of a vaccine cannot use actual HIV components to "train" the immune system to protect human cells against the invading antigen. The nature of HIV has eluded typically effective vaccine design strategies such as inducing broad neutralizing antibodies (Berkley & Koff, 2007). More recent scientific consensus favored other possibilities such as stimulating cell-mediated responses (Excler, 2005). Yet, the recent failure of the leading candidate vaccine in September 2007, which used the cell-mediated approach, also proved to be an unsuccessful strategy (Altman & Pollack, 2007; Merck/HVTN, 2007). By any account, the failure of this latest Merck product tested in the large-scale, international "Step Study" demonstrated that a greater understanding of the correlates of protection against HIV is needed to develop a vaccine that will prevent HIV infection (Berkley & Koff, 2007).

The development of immunizations ranks as one of the ten greatest achievements in public health in the past century (CDC, 1996; Orenstein, Douglas, Rodewald et al., 2005). As noted by Orenstein and colleagues (2005) "smallpox has been eradicated; polio is on the verge of eradication; and measles has been controlled or eliminated in numerous countries around the world" (p. 599). Table 1 demonstrates the impact of vaccines on annual morbidity for a variety of diseases. It should be noted that morbidity declined by at least 87 percent, with the majority of diseases realizing at least a 99 percent decline, with these new immunizations. The burden of invasive *Streptococcus pneumoniae* infections has also been alleviated in minority communities with the development of the pneumococcal vaccine and its widespread administration (Flannery, 2004).

Table 1: Comparison Of Representative Twentieth-Century Annual Morbidity And Current Morbidity From Vaccine-Preventable Diseases, United States

Disease	Twentieth-century annual cases	2004 cases ¹	Percent Decrease
Smallpox	48,164	0	100.00 ²
Diphtheria	175,885	0	100.00 ²
Measles	503,282	37	99.99 ²
Mumps	152,209	236	99.85
Pertussis	147,271	18,957	87.13
Polio (paralytic)	16,316	0	100.00 ²
Rubella	47,745	12	99.97
Congenital rubella syndrome	823	0	100.00 ²
Tetanus	1,314	26	98.02
<i>H. influenzae</i> , type b and unknown (<5 years)	20,000	172	99.14
<i>SOURCE: Courtesy of Walter A. Orenstein and colleagues originally published in Health Affairs (2005); As adapted from U.S. Centers for Disease Control and Prevention, "Achievements in Public Health, 1990–1999: Impact of Vaccines Universally Recommended for Children—United States, 1990–1998," Morbidity and Mortality Weekly Report 48, no. 12 (1999): 243–248; and information provided by Barry Sirotkin, statistician, National Immunization Program, CDC, personal communication, 14 February 2005.</i> ¹ Provisional data from CDC, "Notifiable Diseases/Deaths in Selected Cities Weekly Information," Morbidity and Mortality Weekly Report 53, no. 52 (2005): 1218. ² Record low.			

Those in the vaccine industry readily acknowledge that the realization of effective immunizations for any disease problem is fraught with difficulties. The timelines to realize new vaccine products is long. Although the search for an HIV vaccine has been underway for over two decades, the current timeframe for discovery is still reasonable given vaccine development in historical perspective. Table 2 details the length of time to realize vaccines examples currently available on the market.

Table 2: Vaccine Research and Development Timelines

Vaccine	Discovery of Cause	Vaccine Development	Years Elapsed
Pertussis	1906	1926	20
Polio	1908	1955	47
Measles	1953	1983	30
Hepatitis A	1973	1995	22
HIV	1983	???	As of 2007, 24 years and counting
<i>Source: HIV Vaccine Trials Network</i>			

Clinical Trials

The first stage in vaccine development is recognition of a health burden in populations. Typically, international health agencies (i.e., UNAIDS, the World Health Organization, and others) and federal (i.e., U.S. Centers for Disease Control and Prevention and National Institutes of Health) support surveillance to monitor disease status in the population. This is the first step in determining that an infectious disease is "worth preventing" (Orenstein et al., 2005, p. 601). Recognition of the disease burden spawns basic vaccine research usually within the laboratories

at the NIH, universities, and the pharmaceutical industry. From bench, the process moves to preclinical testing of animal models (i.e., mice-to-monkeys), to human clinical trials (Phase I).

The first phase of a human clinical trial typically involves small groups of healthy adult persons (e.g., 20 to 80 participants), to assess safety and tolerability of the product (Baylor & Midthun, 2004). Assuming that these objectives are met in Phase I testing, a Phase II trial typically is implemented. In this stage the product is evaluated with larger numbers of participants (i.e., hundreds to thousands) and may be used as a "proof-of-concept" study to determine potential efficacy of the vaccine product.

For example, in late 2004 a new HIV vaccine advanced after successful Phase I testing and was considered the most promising HIV vaccine candidate in recent years (Merck/HVTN, 2005). The "Step study" was a Phase II trial that requires the involvement of 3,000 high risk persons over four years at sites throughout North and South American, the Caribbean, and Australia (in regions of the world where HIV subtype B is the predominate strain of HIV). The goal of the study was to determine the vaccine's ability to prevent HIV infection or suppress HIV viral load in subjects that become infected during the trial period. Those populations recruited included men and women who are between the ages of 18 and 45, and who were HIV negative at inception of the study. Men who engaged in unprotected anal sex were included in the risk definition, as were women who have heterosexual relations with an HIV-positive man or an injection drug user, or women who engaged in sex work or crack cocaine drug use (Moriarty, 2005). The outcome was disappointing (Chase & Schoofs, 2007). The vaccine was demonstrated to be futile as it did not protect the individuals against infection or reduce viral loads among those who acquired HIV during the trial (Merck/HVTN, 2007).

Had the product succeeded in showing some potential benefit, it would have moved to Phase III trial testing, of which reduction of incident infection would have been the outcome of interest for the tens of thousands of participants. The only previously completed Phase III HIV vaccine study (the "VAXGEN" trial) accrued a study population comprising men-who-have-sex-with-men (MSM) (N = 5,108) and at-risk women (N = 309) (Francis, Heyward, Popovic et al., 2003). As with the "Step" trial, the vaccine also was shown to be ineffective in protecting individuals from disease. If, however, the vaccine study met its endpoints (i.e., reduction in HIV incidence), the US Food and Drug Administration (FDA) would have been charged with the post-product development licensing process (Thomas, 2001). Table 3 details the complete continuum of the U.S. vaccine system (Orenstein, Douglas, Rodewald et al., 2005).

Table 3: Major Components of and Participating Groups In The U.S. Vaccine System

Component	Major participating groups
Health burden determination	Federal government
Vaccine discovery	Federal government, academe, vaccine industry
Vaccine development	Vaccine industry, academe, federal government
Vaccine production and distribution	Vaccine industry, commercial distributors, state and local governments
Regulation	Federal government
Vaccine policy	Federal government, professional medical societies
Vaccine financing	Federal government, state and local governments, insurance companies, individuals
Vaccine administration	Private health care providers, state and local governments
Monitoring vaccine use	Federal government, vaccine industry, state and local governments
Monitoring vaccine effectiveness	Federal government, state and local governments, vaccine industry
Monitoring vaccine safety	Federal government, vaccine industry
Vaccine injury compensation and liability	Federal government
<i>Source: Courtesy of Walter A. Orenstein and colleagues</i>	

Currently, investment in all phases of HIV vaccine research is approximately \$800 million per year (Berkley & Koff, 2007). Although meager in comparison to the AIDS treatment development budgets, this amount has grown with the organization of the Global HIV Vaccine Enterprise, EuroVacc, and the South African AIDS Vaccine Initiative, the concurrent expansion of operations at the NIH Vaccine Research Center (VRC) and International AIDS Vaccine Initiative's scientific consortia, along with investment by the Gates Foundation (Collaboration in AIDS Vaccine Discovery) (Berkley & Koff, 2007).

Despite decades of setbacks and disappointments in the HIV vaccine realm (Thomas, 2001), the pipeline of preventive vaccines in clinical trials remains robust with more than 39 candidate vaccines in the testing process worldwide (IAVI, 2007). Although the scientific challenges are considerable, these ongoing clinical trials necessitate the involvement of diverse global populations to ensure social justice aims of the effort are fulfilled, to maintain scientific integrity, and to claim generalizability of study findings. Therefore, cultivating relationships with local communities are critical to the success of HIV vaccine research and to potential vaccine dissemination efforts. These issues are of particular concern for minority populations who have been underrepresented in HIV vaccine clinical trials and where research suspicion has been a significant barrier (Corbie-Smith, Thomas, Williams et al., 1999; Djomand, Katzman, di Tommaso et al., 2005).

HIV Vaccine Community Engagement

Public support and involvement in HIV vaccine research are necessary to realize a safe and effective product. To succeed, several obstacles have to be overcome. Among the first, is recognition of the HIV/AIDS problem, particularly by individuals and communities that are impacted by the disease burden (Bracht, 2001; Butterfoss, Goodman, & Wandersman, 1996;

CDC, 2003; Corbie-Smith, Thomas, & Marie, 2002; Wohlfeiler, 1998). Additionally, the public needs to be convinced of the importance of HIV vaccine research in the prevention armamentarium (Weiss, 1997). In other words, its potential value needs to be highlighted. Personal, relationship, and cultural issues have to be reframed. Messages highlight the vaccine's potential benefit to society and to those who may be involuntarily exposed to HIV (e.g., healthcare workers, pediatric populations, assault victims), for women for whom condom negotiation barriers are an issue (van der Straten, King, & Grinstead, 1995), and other individuals who may be unable or unwilling to protect themselves with existing methods (Woody, Metzger, & Mulvaney, 1994) (Vlahov, Astemborski, Solomon et al., 1994).

Public understanding that the individual, community, and society – along with the scientific community – play essential and intermingled roles in HIV vaccine development processes is paramount. With long timelines for development and the likelihood of failure of several candidate vaccines in advance of discovery, public interest must be sustained in the potential of the prevention strategy. Additionally, concerns need to be addressed with respect to the clinical trials process (Villarosa, 2003).

Even with sustained interest in the product, the effort can fail with a lack of participation in studies. To realize a large and representative volunteer participant pool, other issues related to trust of the medical entities and their personnel conducting the studies must be addressed (Weiss, 1997). Medical advances require the involvement of thousands of people – advocates and activists, investors and supporters, health research volunteers, and scientists – all working together to realize a goal. Thus, the role of effective community engagement is essential for the achievement of an HIV vaccine.

Community engagement is a dynamic process that is cultivated at several levels as depicted in Figure 2. The individual, community, and society all play roles in its realization. Consistent with the recommendations of the CDC/ATSDR principles of community engagement, and the working definition proposed in Chapter 1, "best practices" include consultation, dialogue, and collaboration with communities (MacQueen, McLellan, Metzger et al., 2001) to develop shared understanding and meanings associated with the research programs (Swartz & Kagee, 2006), and to foster a sense of empowerment and voice in the research endeavor (Dickert & Sugarman, 2005; MacQueen, McLellan, Metzger et al., 2001). These methods have been effective in reaching minority communities and women and sustain their involvement of in medical research studies (Boulware, Ratner, & Cooper, 2002; Brown-Peterside, Chiasson, Ren et al., 2000; Brown-Peterside, Rivera, Lucy et al., 2001; Crawley, 2001) and to promote favorable health outcomes in the population (Djomand, Katzman, di Tommaso et al., 2005; Miller & Shinn, 2005; Sengupta, Strauss, DeVellis et al., 2000). Despite widespread support for the development and promotion of community engagement in HIV vaccine research, its formation, role, and outcomes have not been the focus of empirical investigations (Newman, 2006).

In many cases, the immediate communication objectives of these efforts center on building awareness through effective information dissemination along with facilitation of learning opportunities with target groups to foster public support for HIV vaccines (Allen, Liang, Salvia et al., 2005). This can be accomplished through synergistic program efforts, and with the support and active involvement of collaborating organizations and their community constituents (Frew, 2005). In the longer term, these foundational efforts may potentially contribute to the realization of recruitment objectives, although the existing evidence is ambiguous (Koblin, Holte, Lenderking et al., 2000; Swartz & Kagee, 2006). In the dynamic social setting, it

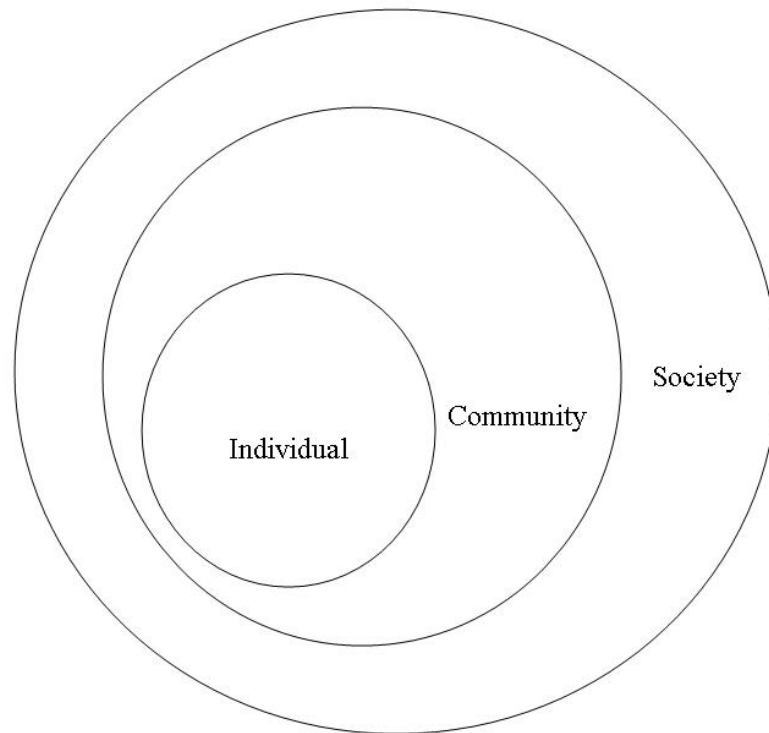


Figure 2: Community Engagement Dynamic

is critical to recognize that the amount of information, level of competition among community-oriented organizations for public involvement in various causes, and personal challenges of target audiences to participate in HIV vaccine community activities, all have an impact on sustaining interest.

The Formation of Community Engagement

The concept of "community" in HIV vaccine research has been well-defined through the Project LinCS (Linking Communities and Scientists) initiative which involved diverse communities from Durham, North Carolina (African Americans), San Francisco, California (Gay Men), and Philadelphia, Pennsylvania (Injection Drug Users) (MacQueen, McLellan, Metzger et al., 2001). It is:

A group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.

As the LinCS team noted, although HIV vaccine research programs and policy are "defined at regional and national levels" the "community is, literally, where prevention and intervention take place" (MacQueen, McLellan, Metzger, 2001, p. 1929). Across contexts, the study found five core elements contributing to the essence of community: joint action (cohesion and identity), locus (sense of place), sharing (common interests and perspectives), social ties (the community foundation), and diversity (heterogeneous social complexity) (MacQueen, McLellan, Metzger et al., 2001). With this understanding of how community is conceptualized, it is equally important to understand the needs of the communities within the local context in order to form effective engagement programs.

As noted by Newman (2006), the end of the HIV tenofovir trials in Cambodia, Cameroon, and Nigeria, brings the needs of the community to light in the planning, implementation, and conduct of clinical trials (Page-Shafer, Saphonn, Sun et al., 2005). Although the research team assigned to Cambodia attempted to bring sex workers into a community advisory group for the study, the efforts failed because of strong community mistrust (Page-Shafer, Saphonn, Sun et al., 2005). On its surface, it appeared that the research team followed World Health Organization (WHO) guidelines on community participation to ensure adequate informed consent, study material translation, and advisement on recruitment and retention practices (Page-Shafer, Saphonn, Sun et al., 2005; WHO, 2002). Yet, the community felt patronized. In particular, community representatives expressed concern that the participants felt a lack of power in the situation. They also perceived a lack of sensitivity of the research team to engage in dialogue with the community on their needs and concerns prior to study implementation (Page-Shafer, Saphonn, Sun et al., 2005).

The Cambodian tenofovir study experience highlights important distinctions with respect to community engagement, community involvement, and community consultation. They are not synonymous terms. In Cambodia, the effort failed in part because important formative research was not conducted in the community prior to study implementation. Thus, the needs, desires, and concerns of the community were not viewed as important to the research team. Provisions for "community consultation" on the study protocol, recruitment and retention methods, and other research team concerns were therefore rebuffed. With a growing demand on behalf of communities to have more control in the development and conduct of research, the nuanced nature of the community's involvement has become an important issue of concern (Dickert & Sugarman, 2005; Green & Mercer, 2001; Swartz & Kagee, 2006). Thus, community engagement is an umbrella term for an encompassing endeavor of which behavioral research, community input and advisement, and empowerment and advocacy are components.

Leslie Swartz and Ashraf Kagee (2006) highlighted the need for "an agenda that critically examines the manner in which scientists and communities engage with one another" (p. 1146) within the HIV vaccine realm. They argue that responsible community interventions need to go beyond the provision of information on how vaccines work, clinical trial logistics, and study participant involvement expectations (Swartz & Kagee, 2006). With the right intervention community empowerment in the process may lead to an "informed decision" (Swartz, 2006, p. 1145) which may be for or against trial participation. Indeed, information dissemination and increases in knowledge alone may not be sufficient for realizing long-term study recruitment goals (Koblin, Holte, Lenderking et al., 2000). Although it is ethically responsible to maintain this interventional course, this approach also may yield fewer trial participants. To overcome this

"paradox," Swartz and Kagee (2006) suggest "the participation of all stakeholders from all segments of the vaccine development enterprise is necessary" (p. 1145).

Others have also made a case for sustained community engagement programs to maintain exposure to trial participation concepts, even in periods when study enrollment is closed, to reduce confusion about HIV vaccine trials and circulation of conflicting information (Brown-Peterside, Chiasson, Ren et al., 2000; O'Connell, Hogg, Chan et al., 2002). Implementation of tailored community education programs with target audiences prior to study recruitment may enhance the subsequent informed consent process and build trust in the sites conducting the research (Koblin, Holte, Lenderking et al., 2000). Thus, a concerted effort to understand, involve and assist communities is essential to overcome mistrust and misconceptions about the effort, and build interest in the effort. Figure 3 details the spectrum of potential outcomes generated by effective community engagement.

Setting the Community Engagement Agenda in HIV Vaccine Research: Toward an Integrated Theoretical Framework for Inquiry

Several studies have been conducted that specifically examine "willingness-to-participate" in HIV vaccine trials (Buchbinder, Metch, Holte et al., 2004; Colfax, Buchbinder, Vamshidar et al., 2005; Halpern, Metzger, Berlin et al., 2001; Newman, 2006) and HIV "vaccine acceptability" issues (Crosby, Holtgrave, Bryant et al., 2004b; Esparza, Chang, Widdus et al., 2003; Tello, Soong, Hunter et al., 1998). These studies provide some insight into the potential concerns and issues of target audiences, specifically for communication efforts (message development, identification of information needs) (Salazar, Holtgrave, Crosby et al., 2005), to gauge audience motivation (personal experience with HIV/AIDS, previous prevention behavior and immunization practices) (Newman, Duan, Rudy et al., 2004b; Rudy, Newman, Duan et al., 2005), and to identify possible enrollment barriers (study design and site

characteristics) (Hennessy, MacQueen, McKirnan et al., 1996; Priddy, Cheng, Salazar et al., 2006).

Community Engagement (Participatory-Collaborative Action)	Sustained Participation	Community Mobilization & Leadership	Study Volunteerism	Product Uptake (Vaccine Acceptability)
				
Goals:	Goals:	Goals:	Goals:	Goals:
a. Gain through understanding of community needs, values, diversity, and dynamics	a. Realize individual and community involvement in planned initiative activities (e.g., meetings, board participation, forums for dialogue, activity attendance, etc.)	a. Community ownership of the issue	a. Generate interest in studies	a. Vaccine dissemination
b. Build organizational and public awareness of effort through collaborative efforts	b. Recognition of the relevance of the problem in the community and desire to acquire information and knowledge on issues	b. Empower individual and community competence to take action on the issue and related causes of the health problem	b. Enroll and retain study participants	b. Vaccine purchase
c. Generate interest in and support for effort with community and organizational direction	c. Develop critical mass consciousness on importance of the cause and role of individuals and community in realization of vaccine			
d. Development, implementation, and dissemination of sustainable culture-centered informational and educational approaches through community-advised collaborative initiatives				
e. Maintain ongoing community advisement to realize joint ownership of efforts				

Figure 3: Spectrum of Potential Outcomes Related to Community Engagement

A review of the behavioral research offers valuable clues on the barriers and facilitators to participation in HIV vaccine research and to product uptake. This review of the research informs the theoretical basis for this study through examination of the key constructs that emerged from previous studies.

Socio-Behavioral Research on HIV Vaccine Participation, Vaccine Acceptability,
and Health Volunteerism

Several preparedness studies have investigated attitudes and willingness to participate (WTP) for HIV/AIDS vaccine trials in low-risk populations (primarily college students) and in high-risk groups such as homosexual men, injection drug users, and heterosexual women. The WTP literature generally examines two simple questions: Who is likely to enroll in the HIV vaccine studies? What correlates are associated with participant intention?

Early WTP Studies: The HIVNET Group

One of the largest studies, the HIVNET Vaccine Preparedness study, employed a cross-sectional study design with a sample comprising 4,892 HIV-negative, high-risk men-who-have-sex-with-men (MSM), male and female injection drug users (IDUs), and high-risk heterosexual women from eight cities. The study was conducted from April 1995 to November 1995. One-third of the persons were recruited from previous vaccine preparedness studies. Multivariate analyses were performed by study population, inclusive of demographic and risk behaviors, and WTP was assessed with logistic regression methods (Koblin, Heagerty, Sheon et al., 1998).

Overall, a substantial portion of the study population (77%) would "definitely" (27%) or would "probably" (50%) participate in a future study. Increased WTP was associated with high risk behaviors, lower educational level, uninsured health coverage status, and not having been in a previous HIV vaccine study. Motivators for WTP included a desire for protection and altruism.

Concerns included the potential of a false antibody test, vaccine safety, and insurance or travel problems. Although only 21% (1,028) of the participants were Black and 14% were Hispanic/Latino (674), WTP did not correlate with ethnicity (Seage, Holte, Metzger et al., 2001).

Another longitudinal cohort study with a nonrandom, convenience sample (N = 279), drawn from the same "Vaccine Preparedness Study" cohort described in the Koblin studies (N = 4,892), was conducted in 1995 with adults in Philadelphia at risk for HIV infection (primarily IDUs). The purpose of the study was to determine how well people's stated WTP in a hypothetical HIV vaccine trial predicted likelihood of enrollment in an actual study, and to determine the extent to which study subjects' WTP changed over time (Halpern , Metzger, Berlin et al., 2001). The investigators also examined the role of knowledge on WTP through assessment of vaccine trial concepts (14 statements) at baseline and at 18-months. Demographic and risk behavior data were also collected at 4 time points in the study.

The findings indicate that enrollment rates were 6.8%, 8.3%, 15.8%, and 29.0% among those who would "definitely not," "probably not," "probably," and "definitely" participate in a future study. Baseline WTP among these groups was 7.9%, 19.5%, 49.8%, and 22.8%, respectively. These findings suggest that WTP assessment was a good predictor of future enrollment; however, the statistically significant change in knowledge gains over time was unrelated to enrollment. Whites who expressed baseline WTP were also more likely to enroll than African Americans. The authors concluded that other factors not assessed in this study may influence final enrollment decisions (Halpern , Metzger, Berlin et al., 2001).

WTP in the South and Among Minority Communities

A few studies have examined WTP among minorities and in the South. In-person interviews were conducted with 90 high-risk persons (MSMs, IDUs, Blacks) identified through 3

HIVNET sites in the US (Philadelphia, San Francisco, Durham), including 20 Blacks in North Carolina (Strauss, Sengupta, Kegeles et al., 2001). The sample was purposive. Overall WTP was 46% and the remaining proportion stated that they were unsure (12.6%) or not willing (41.4%). Of those WTP, 17.5% wanted more information as an assurance in their decision-making process. Specifically, they had questions "about assistance with vaccine-related complications," "trust and confidentiality in the research process," and "availability of vaccine to disproportionately affected communities after trial completion" (Strauss, et al., 2001, p. 70).

Major themes included self-benefits of participation (vaccine improving life, compensation), stopping the spread of AIDS in the community, and the desire to help others (altruism). Participants also believed that a preventive HIV vaccine would reduce economic burdens on communities. However, many expressed concerns on vaccine-induced side effects and the social consequences of trial participation. WTP and knowledge of HIV vaccines was lower among the Durham group (Blacks) and Philadelphia cohort (IDUs) compared to MSMs interviewed in San Francisco (Strauss, Sengupta, Kegeles et al., 2001).

Another qualitative study was conducted using focus group methodology among high-risk, HIV-negative males and females (N = 58) living in Los Angeles. Venue-based sampling was performed to identify organizations that served those with a high-risk HIV behavioral profile, minorities, and women for study recruitment. Most participants in the study were Hispanic/Latino/a or Black/African American (91%). Six focus groups were conducted (3 in Spanish) with 8 to 13 persons involved in each session. Fear of vaccine-induced seropositivity was the only concern reported across all groups, followed by side effects and uncertainty about vaccine efficacy and characteristics. Potential protection from HIV (vaccine-induced) was a

commonly mentioned benefit of trial participation, as well as free medical care, altruism, and compensation.

A cross-sectional, convenience sample survey involving 167 high-risk male and female, majority of Black and heterosexual STD clinic clients in Birmingham, Alabama, found 67% WTP. WTP correlated with female gender, history of having tested for HIV, but not with ethnicity (Tello, Soong, Hunter et al., 1998). Although vaccine-induced seroconversion was a concern for 41% of the volunteers in this study, WTP was not moderated by this apprehension.

More recently, racial and ethnic differences in WTP among young minorities in the South was assessed through a paper-administered cross-sectional survey at Perimeter College in Atlanta (Priddy, Cheng, Salazar et al., 2006). Prior to administration of the survey, participants were briefed about HIV vaccines and vaccine trial concepts. All surveys were administered within the classroom. The instrument included 25 items, including 12 Likert-scale items that assessed attitudes and perceptions toward participation in a future HIV vaccine study. Knowledge scores were calculated by the number of items correctly answered on an 8-point scale based on similar items reported in earlier HIVNET studies (Koblin, Holte, Lenderking et al., 2000; Koblin, Heagerty, Sheon et al., 1998). Overall findings indicate a very low WTP among the group (17%) compared to other populations (Buchbinder, Metch, Holte et al., 2004; Tello, Soong, Hunter et al., 1998). However, WTP did not differ by age, gender, ethnicity, or educational level. Factors that would influence positive WTP include compensation, location of trial site, and the time required to participate. Knowledge and altruism did not correspond with WTP, but trust in researchers was associated with WTP. African Americans and Asians indicated that it was more important to have diverse clinical trial staff and volunteers from minority groups enrolled in HIV vaccine studies than Caucasians.

Enrollment Motivations

The motivations of enrolled study participants offer additional insight on factors that play a role in participatory behavior. Those who enrolled in the VAXGEN trial indicate that they wanted to "help find a vaccine" and "help the community" (Colfax et al., 2005, p. 362), and most (75%) were motivated to "gain current information on HIV/AIDS" (Colfax et al., 2005, p. 360). Half of the volunteers (50%) joined to reduce risk behavior or to receive protection from HIV/AIDS, with a third of participants motivated by HIV/AIDS testing, a component of the study protocol. Moreover, very few individuals in the VAXGEN trial pointed to compensation or medical care as key factors influencing their decision to participate in the study. These results mirror those from other studies that have examined motivations of other HIV/AIDS vaccine trial enrollees (Colfax, Buchbinder, Vamshidar et al., 2005; Crumbo, Rybczyk, & Wagner, 1997; Francis, Heyward, Popovic et al., 2003; Halpern, Metzger, Berlin et al., 2001; Jenkins, Chinaworapong, Morgan et al., 1998; Perisse, Schechter, Moreira et al., 2000; Thapinta, Jenkins, Morgan et al., 2002).

WTP in Other Health Issue Contexts

It is also useful to review WTP for other health issues including bone marrow, blood, and organ donation. Examining WTP within other health contexts provides insight on issues affecting the motivations of specific groups, including minorities and women.

A recent cross-sectional study on organ donation knowledge and attitudes among the general Ohio population (N=1,283) reported lower willingness to donate organs or loved one's organs among African Americans compared to Whites (Siminoff, Burant, & Ibrahim, 2006). The study found that African Americans had lower scores on the "Trust in the Health Care System scale" and expressed greater mistrust in the equity of donation systems. However, the African

American participants in this study "were more favorable" about the concrete benefits provided for organ donation such as receiving money for the donation and coverage of funeral expenses for loved ones' organs (Simonoff et al., 2006, p. 995).

Similar findings from another cross-sectional random-digit dialing survey of adults living in Baltimore (N=385) found race and gender are demographic identifiers of those less willing to donate blood and cadaveric organs (Boulware, Ratner, & Cooper, 2002). Mistrust of and perceived discrimination in hospitals "explained most differences in willingness to donate blood," and respondents' beliefs related to spirituality and religion explained a large proportion of differences on willingness to donate organs (Boulware et al., 2002, p. 85). Another random-digit telephone survey examining barriers to bone marrow donation among African Americans (n = 408) and Caucasians (n = 421) living in South Carolina, found that "fear of pain" was a most common reason for unwillingness to donate and was significantly higher for African Americans (Boulware, Ratner, & Cooper, 2002; Onitilo, Lin, Okonofua et al., 2004). Additionally, African Americans expressed greater reluctance to sign up for donor registries despite "expressed willingness to donate" (Onitilo et al., 2004, p. 3212). To develop a large pool of suitable matches, the researchers indicate greater education and adequate pain control are needed to realize donations.

Studies examining communication practices and educational approaches to organ donation have focused on increasing knowledge, debunking myths, and fostering positive attitudes about donation (Merion, Vinokur, Couper et al., 2003; Morgan & Miller, 2002). Results from Morgan & Miller's investigation (2002) indicate that potential organ donor's knowledge, attitude, and altruism are related to willingness to communicate with family members about intention to donate. Another study developed an internet-based multimedia intervention to

promote family notification and donor registry participation (Merion et al., 2003). Improvement of knowledge and attitudes toward organ donation and increased communication with family members were of primary concern in this study. Among 10,884 visitors to the study's internet site, willingness to donate and willingness to register increased after exposure to the intervention. Although the findings indicate that increases in knowledge did not correspond to increases in positive attitudes on organ donation, increases in "pro-donation" attitudes was a significant predictor of organ donation registry ($p < 0.001$) (Merion et al., 2003, p. 1175).

WTP Conclusions

An overall examination of the WTP literature suggests the following constructs have an effect on health volunteerism behavior:

1. Favorable attitudes and beliefs towards health research, including HIV vaccine research (Halpern, Metzger, Berlin et al., 2001; Koblin, Holte, Lenderking et al., 2000; Morgan & Miller, 2002; Newman, Duan, Roberts et al., 2006);
2. Personal concerns (time, travel, fear of needles, false positive antibody test, safety concerns, etc.) (Colfax, Buchbinder, Vamshidar et al., 2005; Koblin, Heagerty, Sheon et al., 1998; Newman, Duan, Roberts et al., 2006; Onitilo, Lin, Okonofua et al., 2004; Siminoff, Burant, & Ibrahim, 2006; Strauss, Sengupta, Kegeles et al., 2001; Tello, Soong, Hunter et al., 1998)
3. Personal relevance of the issue may be associated with WTP (Colfax, Buchbinder, Vamshidar et al., 2005; Morgan & Miller, 2002; Strauss, Sengupta, Kegeles et al., 2001);
4. Normative factors (friends/family reactions) may influence WTP (Allen, Liang, Salvia et al., 2005; MacQueen, Vanichseni, Kitayaporn et al., 1999; Newman, Duan, Roberts et al., 2006; Nyamathi, Suhadev, Swaminathan et al., 2006).

5. WTP is influenced by the sociocultural context, such as areas or communities where prevalence and incidence of HIV are high, or the perception of the HIV/AIDS burden in the region is great (Kiwanuka, Robb, Kigozi et al., 2004; Koblin, Heagerty, Sheon et al., 1998; Strauss, Sengupta, Kegeles et al., 2001).

6. Racial and ethnic minorities' enrollment in HIV vaccine trials has increased over time but these groups are still underrepresented in trials (Djomand, Katzman, di Tommaso et al., 2005).

7. Stated WTP is the best predictor of intent (Halpern, Metzger, Berlin et al., 2001).

HIV Vaccine Acceptability

Several potential barriers to HIV/AIDS vaccine adoption exist and need to be addressed to foster uptake among high risk groups (Crosby, Holtgrave, Bryant et al., 2004a, 2004b; Rudy, Newman, Duan et al., 2005; Salazar, Holtgrave, Crosby et al., 2005; Zimet, Blythe, & Fortenberry, 2000). Severy and Newcomer (2005) characterized "acceptability" as the voluntary sustained use of a method in the context of alternatives. The acceptability literature borrows from consumer research and health marketing models to examine product attributes. In other words, this body of literature asks: if a vaccine is available or a trial is planned, what attributes will influence marketability? Exploration of this dimension provides insight on factors affecting community engagement.

The first HIV vaccine acceptability studies were conducted by Zimet and colleagues (1997; 1999) and by Liao and colleagues (1998, 2000) to examine factors influencing attitudes toward HIV vaccines. They also evaluated the relationship of health beliefs and vaccine characteristics on acceptability of hypothetical HIV immunization. In all of the studies, the four domains of the Health Belief Model were assessed including perceived susceptibility, perceived

severity, benefits, and barriers (several subscales were developed for assessment of these constructs). A key finding from the first study (N=222) is low overall probability of HIV vaccine acceptance (53.7%) (Liau, Zimet, & Fortenberry, 1998). Although many did not respond favorably to an HIV vaccine, health beliefs were independently predictive of HIV vaccine acceptability, and included perceived susceptibility to HIV, perceived nonmembership in an HIV risk group, and fear of vaccine-induced HIV infection (Liau, Zimet, & Fortenberry, 1998).

In this study, efficacy most strongly influenced acceptability, followed by type of vaccine, leading to the overall conclusion that vaccine characteristics coupled with individuals' health beliefs are likely to influence vaccine uptake. More recently, the team conducted work with a larger sample (N=549) of college students and found that all health belief domains were significantly associated with HIV vaccine acceptance (Zimet, Blythe, & Fortenberry, 2000). Based on the collective findings of the team, a recommendation emerged to develop educational strategies to address potential barriers to immunization including concerns about vaccine safety, low perceived HIV risk among target groups, and the general belief that less effective HIV vaccine is not worthwhile to the individual or to society.

Acceptability among High-Risk Populations in Atlanta, Georgia

Recent cross-sectional studies conducted by our team sought to identify factors that may preclude people from accepting an AIDS vaccine when one is developed and approved for use (Crosby, Holtgrave, Bryant et al., 2004a, 2004b). Participants completed a brief self-administered survey inclusive of sociodemographic questions and items addressing key components drawn from Health Belief Model. The findings suggest that three factors may be important intervention points for an approved AIDS vaccine (personal issues, product concerns, and normative influences including worry and associated stigma). Overcoming personal issues

such as minor side effects and the mode of vaccine administration are important for Black/African Americans, particularly those without Hepatitis B history, and for people without a high school education. Issues for women included the number of doses, past testing of the product, and risk of major side effects (i.e., perceived barriers).

The second in this series of studies with the same population investigated the demographic, behavioral, and psychosocial correlates of negative intent to receive a hypothetical AIDS vaccine (Crosby, Holtgrave, Bryant, et al., 2004b). "Negative intent" is defined as not willing to take an AIDS vaccine in the future. Twenty percent of sample reported negative intent. Negative intent was significantly more likely among people reporting they had not had sex in the past year, and those who were never diagnosed with an STD (i.e., perceived susceptibility), and among people who worried about problems caused by an AIDS vaccine (i.e., low perceived benefit). Indicators of behavioral risk were not associated with negative intent (substance abuse, having multiple partners, and a lack of condom use with new and established partners, and sexual orientation). The findings suggest that behavioral and psychosocial (rather than demographic measures) were associated with negative intent to receive an AIDS vaccine.

Acceptability among Minority Communities in Los Angeles

Another series of studies by Newman and colleagues similarly investigated consumer concerns, motivations, and adoption intentions before an HIV vaccine is publicly available (Newman, Duan, Lee et al., 2005; Newman, Duan, Roberts et al., 2006; Newman, Duan, Rudy et al., 2004b). These include two qualitative studies with the same focus groups, two quantitative studies, and one review paper.

The first of the qualitative studies involved female participants from community agencies (n = 41) and health care providers (n = 9) in Los Angeles (Rudy, Newman, Duan et al., 2005).

The purpose of this study was to explore perceived barriers and facilitators to the uptake of future HIV vaccines among women at risk for HIV. Four client groups (including one in Spanish) were conducted with 7 to 14 persons per group (N=41) and one focus group of women's health care professionals (N=9). Participants were recruited from diverse community agencies and health care clinics in LA using purposive, venue-based sampling.

Gendered roles and power dynamics emerged. Women reported men were often in denial of their own risk behaviors. Latinas indicated that HIV vaccines would not be discussed among couples because it would cast doubt on male machismo. Women's communication patterns with male partners may be a barrier to uptake. Mistrust of providers, and of government, were also identified as barriers to future vaccine uptake. Providers and participants agreed that normalization of HIV vaccination in routine care would decrease stigma and overcome accessibility issues. Empowerment to protect self and children (particularly among Latinas) emerged as major reasons to get an HIV vaccine.

The study revealed concerns about vaccine-associated social harms and gender-specific issues (e.g., relationships and reproductive side-effects) (Rudy, Newman, Duan et al., 2005). The findings from this study point to the development of gender-specific interventions to increase women's power. The authors note that information for women may focus on issues of reproductive safety and side effects, relationship concerns, vaccine affordability, and empowerment to discreetly protect oneself against infection (Rudy, Newman, Duan et al., 2005).

The complementary qualitative study by the same group also utilized bilingual focus group interviewing formats (Newman, Duan, Rudy et al., 2004b). The sample (N = 99) was similarly recruited from high risk venues in Los Angeles. A semistructured interview guide elicited participant concerns, motivators, and adoption intentions regarding a hypothetical HIV

vaccine and HIV vaccine knowledge and beliefs. Participants were asked to give their own opinions as well as their perceptions of the opinions and responses of their peers.

The Newman team's findings are remarkably similar to other acceptability studies (Crosby, Holtgrave, Bryant et al., 2004b; Hennessy, MacQueen, McKirnan et al., 1996; Zimet, Blythe, & Fortenberry, 2000). Emergent concerns about potential vaccines included efficacy issues, potential vaccine-induced infection, side effects, trust of researchers, impact on relationships, and vaccine-induced seropositivity. The authors note a general ambivalence about immediate adoption of the vaccine until a critical mass of demand is realized. Therefore, future marketing of HIV vaccines needs to account for women's needs (interpersonal concerns and reproductive issues), the general "health promoting benefits" of vaccines to protect people from infectious diseases, and incorporation of parents, providers, and family members' endorsement of HIV vaccines (Newman, Duan, Rudy et al., 2004b).

Vaccine Trial Acceptability

To date, only one study has aided in the design of HIV vaccine trials to enhance study participation (Hennessy, MacQueen, McKirnan et al., 1996). A factorial survey design was devised for this purpose that incorporated "hypothetical descriptions" (p. 210) that manipulated essential trial design features. The design allowed for exploration and identification of "consumer preferences" and "decision-making processes" to optimize enrollment in future HIV vaccine studies. Gay men (N = 73) participating in a larger study assessing HIV vaccine trial feasibility at sites in Denver, Chicago, and San Francisco were selected to participate in this cross-sectional study.

The study findings indicate that trial design may drive future WTP, and that negative HIV vaccine study features have larger effects on discouraging participation than positive

features have on encouraging participation. General findings suggest that higher prevalence of enduring antibody responses and a lack of diversity among enrolled participants (heterosexual, IDU, narrowly defined risk groups) may be central obstacles among future groups of HIV vaccine volunteers. The study implications focus on the development of positive messages and educational materials to overcome perceived negative characteristics of a future HIV vaccine trial. In particular, the authors note the importance of highlighting the positive attributes associated with vaccine-induced immunologic activity (generation of antibody responses against HIV) in educational efforts. They underscore the importance of showcasing the sociodemographic diversity of HIV vaccine volunteers to assure future participants that similar persons have contributed to the cause.

Acceptability Conclusions

Although HIV/AIDS vaccines may be years from introduction to the market, the literature suggests varying levels of potential adoption. Acceptability research draws upon marketing research examples, particularly "purchase behavior" measurement and prediction. The following has been observed in this body of research:

1. Personal relevance of the product is a motivator to uptake. Specifically, the extent to which a vaccine would serve as a means of self-empowerment (women, minorities) (Rudy, Newman, Duan et al., 2005);
2. Reduced personal concerns will likely facilitate uptake (e.g., the benefits of vaccine-induced antibody responses) (Hennessy, MacQueen, McKirnan et al., 1996; Newman, Duan, Rudy et al., 2004a; Newman, Duan, Rudy et al., 2004b);
3. "Organizational" involvement is important to overcome issues of mistrust. In particular, the volunteers and study personnel involved in the effort to achieve a vaccine are of

concern (Crosby, Holtgrave, Bryant et al., 2004b; Hennessy, MacQueen, McKirnan et al., 1996; Rudy, Newman, Duan et al., 2005);

4. Compliance with and concern of normative referent opinion may influence adoption within minority communities (e.g., relationship issues) (Rudy, Newman, Duan et al., 2005).

Preliminary Studies: The AHVCC Model of Community Engagement in HIV Vaccine Research

With translation of these WTP and acceptability research findings into AHVCC programmatic efforts (Crosby, Holtgrave, Bryant et al., 2004a, 2004b; Frew, Crosby, Salazar et al., 2008; Priddy, Cheng, Salazar et al., 2006; Salazar, Holtgrave, Crosby et al., 2005), our team conducted preliminary studies on factors influencing community engagement in the urban South (Frew, Archibald, del Rio et al., 2007; Frew, Crosby, Salazar et al., 2008). The first of the two exploratory studies examined personal characteristics, socio-environmental conditions, and motivational factors that potentially influence HIV vaccine research community engagement with ethnically diverse populations (N = 452 adults, ≥ 18 years) attending 2006 HIV vaccine awareness-building and community education gatherings in Atlanta.

This study examined predictors and correlates associated with repeat attendance at AHVCC program events, and specifically examined motivational influences observed among women (n = 251) and minorities (n = 224), two priority populations for our efforts. In multivariate analysis, the overall logistic regression model was significant, with a resulting coefficient of determination (Nagelkerke R^2) of 0.505. Highly significant factors included the activity/event rating (log odds $\beta = 4.521$, $p < .001$) and perception of the study site ($\beta = 2.131$, $p < .001$). Subgroup analyses of women ($R^2 = 0.513$) and minorities ($R^2 = 0.634$) revealed similar findings. Previous research on AIDS volunteerism within the African American community

suggests a combination of factors (e.g., gaining knowledge and helping others) fuels participatory motivation (Reeder, Davison, Gipson et al., 2001; Simon, Sturmer, & Steffans, 2000). Moreover, identification with an AIDS service organization significantly increases the likelihood of volunteerism, a finding similar to our own (Simon, Sturmer, & Steffans, 2000).

At a minimum, the results show that investment in cultivating a unique study site "brand identity" and "brand personality" that is consistent with the values of target groups attains requisite community awareness and fosters greater interest on the subject matter (Allen, Liang, Salvia et al., 2005; Percy & Elliott, 2005; White & Miles, 1996). These data demonstrate the importance of building a favorable study site image and gaining familiarity in the community to aid in the promotion of HIV vaccine research on an ongoing basis. Consistent with this concept, the results suggest that the site-sponsored community programs are fulfilling a tacit need for inclusion and information among women and minorities (Crawley, 2001; Dickert & Sugarman, 2005; IOM, 2003; King, 2003; Koblin, Holte, Lenderking et al., 2000; Priddy, Cheng, Salazar et al., 2006). Overall, the study highlights the role of an effective culture-centered community collaborative to promote HIV vaccine research engagement.

More recently, we conducted a study utilizing an established behavioral theory (TRA) in predictive modeling of HIV vaccine community engagement. Although considerable evidence has been accrued in the past few decades on the application of the Theory of Reasoned Action (TRA) to an array of health behaviors including exercise (Blanchard, 2002; Blue, 2001; Jones, 2004), HIV prevention (Koniak-Griffin, 2006, 2003) including condom use (McClaws, 1996; Sneed, 1998), diabetes adherence (Syrialala, 2002), and pneumococcal vaccination (Zimmerman, 2005), only one study to date has employed the constructs in examination of HIV vaccine research (Gagnon & Godin, 2000). The TRA model is motivational in nature, with integration of

individual (behavioral attitudes) and social (subjective norms) components in the formation of intentions which are predictive of behavioral outcomes of which persons have full volitional control (Ajzen & Fishbein, 1980; Ajzen & Madden, 1986; Fishbein & Ajzen, 1975). This predictive model was selected for preliminary testing given the body of WTP and acceptability evidence indicating the importance of favorable attitudes and perceived normative support in the formation of intent.

According to TRA, formation of individual attitude is affected by behavioral beliefs and evaluation of behavioral outcome (Montano & Kasprzyk, 2002). The salience of these beliefs (attitude), combine with the social factors - normative beliefs and motivation to comply (subjective norm formation) – and are weighted in relation to the other (Ajzen & Madden, 1986). The addition of the social component is useful for prediction of health behavior outcomes, particularly as the approval or disapproval of referent others (family, friends, colleagues), and importance afforded to these opinions can be important (counter)persuasive factors. In total, all of these form the basis for intention. As intention increases, the likelihood of realizing the behavioral outcome improves.

Therefore, the goal of the recent study was to examine the TRA covariates predictive of potential outcomes from AHVCC community engagement efforts specifically targeting African Americans. Overall, the hypotheses were mostly supported, with the exception of subjective norms and outcome evaluations. Important relationships materialized among constructs especially those related to self-empowerment beliefs on attitude, and counter-resistance (motivation to comply) to negative normative pressure (subjective norms). In particular, belief in one's participation resulting in positive, tangible outcomes for the community, research, and HIV/AIDS mediated through the attitude construct had a profound impact on the potential to

mobilize the community for action (.698) and participate in HIV vaccine trials (.687). Attitude formation clearly is evidenced by the lower coefficient (.311) on future attendance, indicating the critical role of effective communication and community engagement programming in fostering positive attitudes towards the cause. Moreover, the set of self-empowering perceptions (.667) on attitude outweighed more generic beliefs related to involvement (.346) such as "I benefit from health science research."

These findings support the need for the AHVCC to clearly articulate as many concrete outcomes that can be expected from involvement in HIV vaccine research. A key assumption of the value-expectancy theories (i.e., TRA) is that some end will be achieved through the performance of a behavior. Yet, in the context of HIV vaccine development, it is unclear exactly what end will be met – for example, "will my efforts result in a vaccine that partially or fully prevents infection?" Or, some may ask, "Will my participation help achieve a vaccine that will help those living with HIV?" Although it is possible that one of these outcomes will be achieved in the future, participatory behaviors do not yet have clear consequences. In other words, people do not know what to expect of their involvement. Thus, the findings point to a need for effective communication citing specific examples of the role of African Americans in the realization of ethical oversight (i.e., participation on CABs, Institutional Review Boards, etc.), improving community trust, and preventing AIDS (e.g., risk reduction through greater condom use among study enrollees). Communication emphasis should be on individual self-empowerment to affect collective change.

In contrast to previous studies examining willingness-to-participate among predominantly minority populations (Corbie-Smith, Thomas, Williams et al., 1999; Newman, Duan, Roberts et al., 2006; Priddy, Cheng, Salazar et al., 2006) and among women (Mills, Nixon, Singh et al.,

2006), logistical concerns did not materialize. With respect to inconvenience, time constraints, risk perception, and use of needles in studies, these items as related to the "outcome evaluation" construct, did not impact attitudes. The findings related to outcome evaluation may be indicative of other issues. A lack of thorough consideration may have been afforded to these issues of practical concern given the high first time attendance rate of the majority of respondents (85.4%, n=146). Furthermore, the HIV vaccine messages promoted in these situations may have strengthened individuals' resolve to manage any concerns or logistical issues likely to be encountered in the future.

Obviously, the relationship of subjective norms to intention was not significant in this study population. This finding is consistent with a previous HIV vaccine study that tested TRA effects (Gagnon & Godin, 2000). The result could be due to a manifestation of measurement issues associated the items designed to measure subjective norms ($\alpha = .64$, $n = 3$ items) in combination with a small sample size. With consideration given to these shortcomings, the nonsignificant pathways between subjective norms to intention could represent a theoretical deviation. That is, negative normative influences may not causally impact community engagement outcomes. In contrast with other studies citing social harms (Francis, Heyward, Popovic et al., 2003) and negative social judgments (Fuchs, Durham, McLellan-Lemal et al., 2007; Koblin, Heagerty, Sheon et al., 1998) as barriers to participation, our nonsignificant finding suggests the possibility that our participants rejected the negative views of others related to behavioral intention.

Alternatively, the findings suggest the possibility that those who become engaged in HIV vaccine research exhibit a degree of independent thinking to resist counterattitudinal messages. Surprisingly, the strength of the relationship of the (lack of) motivation to comply with

subjective norms resulted in powerful pathway effects (.814-future attendance, .811-community mobilization, .818-study volunteerism). Moreover, approval of doctors, family, pastors, work colleagues, and others in HIV vaccine research weakly, but significantly, offset negative opinion on involvement. Thus, it is possible that a degree of social support is valuable in promoting involvement, but not required for the formation of participant intention.

It merits consideration that the emphasis on issue-relevant thinking (e.g., ending HIV/AIDS) in community engagement activity may result in greater psychological resiliency to withstand counterpersuasive normative thinking. Within this culture-centered context, albeit a supportive situation, it is likely that the conditions favorably predispose individuals to resist negative normative pressure encountered in "real world" conversations with others.

Incorporating Participant Motivations into the Theory of Reasoned Action

Although our findings indicate the importance of the site and event perceptions in cultivating community engagement intention (Frew, del Rio, Clifton et al., 2007), and the TRA as a useful theoretical framework for evaluation of key outcomes of interest, the studies have been constrained by several factors. Among them are the use of a small purposive samples and a limited set of items that were not subjected to reliability or validity testing. Additionally, the exclusion of a number of cases with missing data and uncertainty expressed on outcome responses (e.g., "don't know"), may have resulted in reduced construct validity with the inability to detect pathway effects within the TRA model (McKnight, McKnight, Sidani et al., 2007).

The study conducted in 2006 indicates that development of a strong brand image, with an emphasis on increasing an emotional connection to the cause, has great potential for successful HIV vaccine community engagement. The results indicate that through collaboration with the AHVCC entities, the evaluation of the Hope Clinic (i.e., the "brand") emerged as an important

factor in sustained public involvement. Thus, in positioning the clinic as a volunteer organization of choice, among others in the AIDS-related arena, greater acceptance of the vaccine endeavor was realized with that study population.

Research pertaining to HIV/AIDS volunteerism, clinical trials participation, and other forms of elective health behavior (i.e., bone marrow donation) suggest the decisional pathways are complex and have a strong affective component (Bagozzi, Lee, & Van Loo, 2001; Curbow, Fogarty, McDonnell et al., 2006; Davis & Randhawa, 2006; Reeder, Davison, Gipson et al., 2001). In short, the emotional commitment accompanying the health behavior may sufficiently explain the decision to become a health research volunteer or support a cause (Eagly & Chaiken, 1993). Others have argued that TRA is compromised in its ability to predict intention and behavior in the face of alternative options (Sheppard, Hartwick, & Warshaw, 1988).

To assess the affective components in consumer decision-making, Julie Fitzmaurice (2005) and others have pointed to the value of measuring "involvement" constructs within the framework of TRA (Xu, Summers, & Belleau, 2004; Zaichkowsky, 1985). This dimension, as defined by Judith Zaichkowsky (1985) is "A person's perceived relevance of the object based on inherent needs, values, and interests" (p. 342). Thus, a measurement model with these components is potentially useful for the AHVCC framework. The community engagement model (AHVCC) encourages participants to actively search for information, gain education, and make informed choices on their form of participation. The process assumes reasoned decision-making while promoting the personal relevance of the cause.

In several studies, it has been observed that degree of importance afforded to the product or purchase decision leads to different intentions and behaviors. Given its influence on attitude, incorporation of "involvement" as an external variable has been recommended for the TRA

model within consumer decision-making contexts (Shim, Morris, & Morgan, 1989).

"Involvement" has been conceptualized as connection or engagement to individual's values and commitment to brand choice (Lastovicka & Gardner, 1979). Traylor and Joseph (1984) view it as a "consumer response to a product, message, medium, or situation" that "reflects an individual's sense of self or identity and is activated by external stimuli" (p. 65). Bloch, Sherrell, and Ridgeway (1986) stated that it is "enduring in character, representing a continuing interest or enthusiasm" (p. 119). Involvement is the process of "'stirring one up' to engage in a new behavior" (Fitzmaurice, 2005, p. 915).

Yet, Ajzen and Fishbein (1980) claim that TRA's focus on identifying influential salient beliefs is more powerful in its predictive validity compared to most market research which emphasizes attribute correlation in consumer preference and purchase decisions. They contend:

Attitudes towards brands or products are external variables that need not have any systematic relation to consumer intentions or behaviors. Like other external variables, brand attitudes are related to purchase intentions only when they are related to attitudes towards the behavior or to the subjective norm. That is, their effects on intentions and behavior are indirect, being mediated by the attitudinal and normative components. (Ajzen & Fishbein, 1980, p. 172)

Therefore, this study builds on previous findings observed with the TRA model and recognizes the potential mediating role of affective involvement on community engagement decision-making. Thus, the study incorporates new external "involvement" variables with the TRA to explain HIV vaccine community engagement outcomes.

This study allows for specification and testing of structural models that reflect a priori assumptions on the direct and indirect effects among observed variables (Kline, 2005). Using structural equation model (SEM) approaches in estimating the relationships among endogenous (attitudes, subjective norms, and intentions) and exogenous theory-derived variables (behavioral beliefs, outcome evaluations, normative beliefs, and motivation to comply) in combination with

external variables (personal relevance, organizational involvement), enables simultaneous estimation analyses of community engagement (Figure 4). It is anticipated that the study will provide a more insightful and precise understanding of the causal pathways of influence on participatory behaviors.

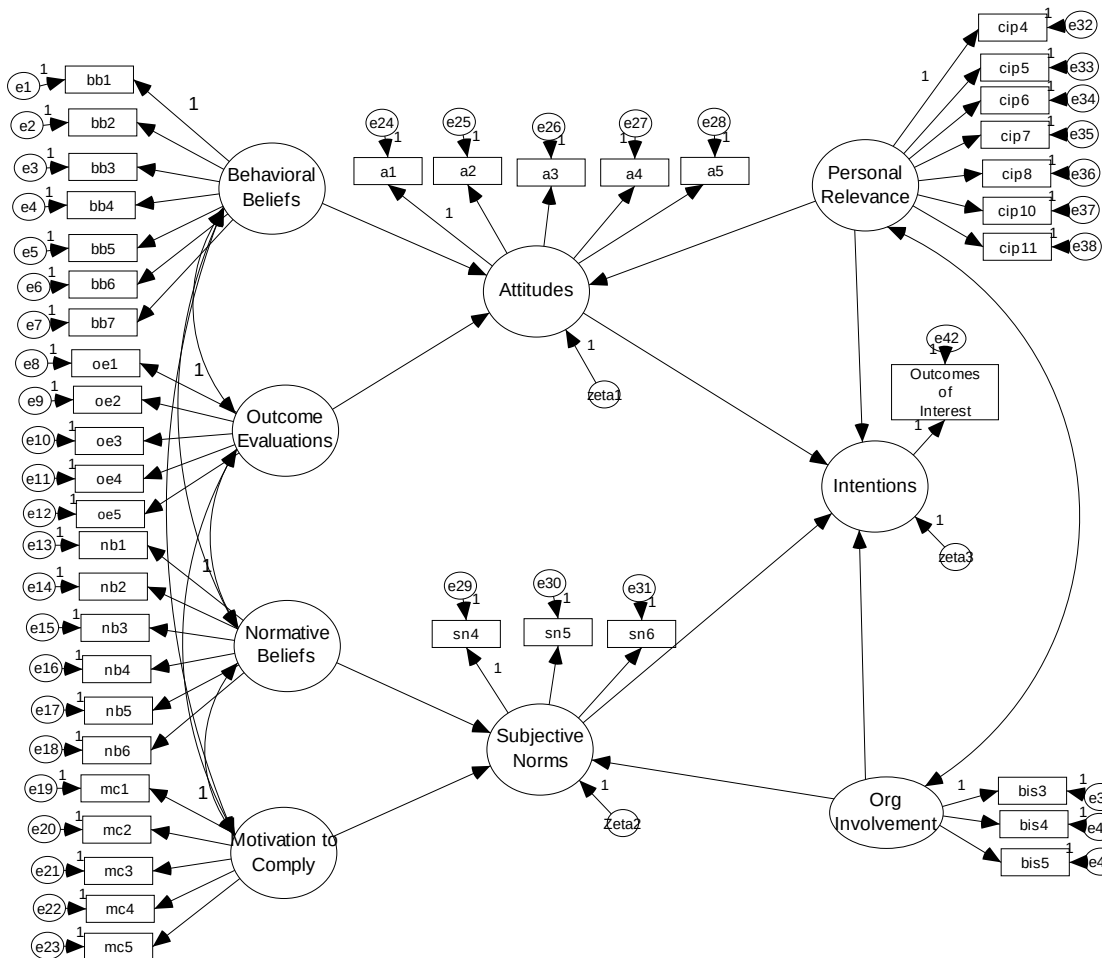


Figure 4: Future Attendance, Community Mobilization, and Study Volunteerism Intention

CHAPTER 3

RESEARCH METHODS

The current study utilizes an established behavioral theory (TRA) with external variables, personal relevance and organizational involvement, to assess community engagement outcomes related to the AHVCC initiative. The goal of the current study is to examine the theoretical covariates influencing respondents' willingness to participate in future HIV vaccine-related activities and events, mobilize their communities to action on the cause, and participate in research studies. Therefore, the study explores the importance of theoretical guidance in predicting community engagement. The sections that follow provide information on the survey instrument development and refinement procedures, data collection approaches, data management strategies, and confirmatory factor analysis and structural equation modeling for this study.

Research Design

To evaluate the research questions for this study, quantitative survey data from a cross-section of adults, ages 18 or older, was collected through a self-administered questionnaire at AHVCC partnership functions. Structural equation modeling (SEM) can be applied to nonexperimental data (i.e., cross-sectional), and is best suited for larger samples ≥ 200 cases (Kline, 2005). Using SEM techniques, the following conditions lead to greater power to reject the null hypothesis: a large sample, a .05 level of statistical significance, a one-tailed (directional) H_1 , a parametric test statistic (e.g., t), and "scores that are very reliable" (Kline, 2005, p. 42).

Study Sample

Because this research examined TRA/involvement construct interrelations, guidance from the literature indicated that at least 400 cases would be appropriate for the research aims of this study (Breckler, 1990; Kline, 2005; MacCallum & Austin, 2000). The survey design enabled this study to attain a representative sample of the populations attending events and activities and achieve adequate response rates. The goal was to accrue a total of 400 completed surveys from participants.

Ethical conduct of survey research respects the decisions of those who elect against participation (Salant & Dillman, 1994). Valid SEM analyses, however, require large datasets and nonresponse to questionnaire items can impact estimates. Therefore, accurate projection of response rates and questionnaire completion were evaluated prior to study implementation. Steps were taken to reduce nonresponse bias and other issues in advance of administration by notifying sponsoring agency representatives of the intent to conduct the study at the event or activity (Fowler, 2002). This method is not only good practice, but it enlists the cooperation of the organizers to ensure access to the population and explain to participants how their help is important.

Based on previous experience with similar populations, it was anticipated that the study would be proposed to at least 600 persons to achieve a response rate of at least 80% (Frew, Archibald, del Rio et al., 2007; Frew, del Rio, Clifton et al., 2007). Persons typically refuse to participate based on a lack of availability (time constraints), disinterest, or language barriers (i.e., English as a second language or illiterate). Experience with similar questionnaires and nearly identical populations set the expectation that about 80% of those who agreed to participate (i.e.,

500) would fully complete the survey. It was anticipated that the analyses would be conducted with a dataset representing a sample of ≥ 400 cases.

Survey Instrument/Measurement Overview

All psychosocial items related to the conceptual model were developed based on previous quantitative and qualitative research findings, literature review, as well as HIV vaccine clinical and community experience. Qualitative research focusing on HIV vaccine issues among women and minorities was content analyzed to form the basis of questions regarding beliefs and attitudes (Frew, Crosby, Salazar et al., 2008; Salazar, Holtgrave, Crosby et al., 2005). This procedure helped ensure that beliefs salient to the populations of interest were incorporated in the measurement scales. Moreover, this approach was employed to increase the content validity of the proposed survey.

New items were developed for most of the domains based on recommendations provided by TRA theory progenitors (Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975). TRA variables cover volunteers' intentions or willingness to participate in HIV related events, and their subjective norms, attitudes, motivations and beliefs about engaging in HIV-related events. The personal relevance and organizational involvement scales were adapted from marketing measures (Lastovicka & Gardner, 1979; Traylor & Joseph, 1984; Zaichkowsky, 1985). A team of clinicians, psychometricians, and health behavior researchers reviewed the complete instrument for adequacy of the measures.

Scale Construction

The inventories used the summative response format, a 5-point Likert scale, to assign meaningful values to an underlying continuum of ratings (Meyers, Gamst, & Guarino, 2006). The following section details the development of each scale for this study.

Intentions. Three outcome variables were used to measure volunteers' willingness to participate in future activities and events, to mobilize others in the cause of HIV vaccine research, and to contact organizers about participating in the vaccine trials. Outcome options were measured on a continuous rating scale. Participants were asked to rate the probability that they would return to HIV vaccine community engagement activities on a 0 (definitely not) to 10 (definitely will) continuum.

Attitudes. The influence of attitudes on the three outcome intentions was explored. Communication, particularly persuasive forms (Petty & Cacioppo, 1983; Petty, Strathman, Cacioppo et al., 1994), plays a powerful role in attitude formation and alteration, and are central to culture-centered approaches. It was therefore hypothesized that favorable responses to attitudinal items covering HIV vaccine research would increase intentions. Respondents indicated positive attitudes with statement agreement on 5 items within a scale including "I like to do good for others," "I like getting involved with HIV vaccine research," "HIV is a serious concern in my immediate community," "HIV testing is a benefit of an HIV vaccine study," and "I would benefit from the medical care associated with an HIV vaccine study."

Subjective Norms. Perceived "social pressure" (Ajzen & Fishbein, 1980, p. 246) to perform a behavior or forego it, is reflected in the "subjective norm" construct. In this study, participants were also asked if they thought people, including family and friends, would support their participation. It was hypothesized that favorable social opinion of research involvement would increase participatory intention. Influential normative concerns were directly measured through items including "most people who are important to me think I should participate in the HIV vaccine effort," "most people who are important to me would approve of my involvement

in this cause," and "most people who are important to me would support my interest in this cause."

Behavioral Beliefs. Several questions measured volunteers' salient beliefs about their role in health research related to HIV/AIDS. It was hypothesized that beliefs about medical research favoring participatory behavior would increase intentions to participate in future activities, generate greater community mobilization, and study volunteerism. The items included "My community would really benefit from an HIV vaccine," "My actions can inspire others to act," "I benefit from health science research," "My participation in an HIV vaccine study would be very good," "My involvement in this cause will result in more ethical research," "My involvement in this cause will improve my community's trust in medical research," and "I would participate in an HIV vaccine research study because it would help to prevent AIDS."

Outcome Evaluations. Consideration of outcomes related to study participation was uniquely assessed to understand negative salient beliefs related to volunteerism. Previous studies indicated logistical, physical, and psychological as barriers with respect to involvement in HIV vaccine research among ethnic minorities (Newman, Duan, Roberts et al., 2006; Priddy, Cheng, Salazar et al., 2006). It was therefore hypothesized that reduced personal concerns, and decreased concern of negative health and social consequences specifically related to HIV vaccine study participation, would more likely result in greater participatory intention. Items therefore included in the scale were "My participation in an HIV vaccine research study would be more trouble than it's worth," "Even if I wanted to participate in an HIV vaccine research study, I just don't have the time," "Participating in an HIV vaccine research study seems risky," "I would participate in an HIV vaccine research study, but I don't like needles" and "I am concerned that an HIV vaccine will cause me to test HIV positive."

Normative Beliefs. Two aspects of normative beliefs were considered. Those connected to beliefs about the effects of research on a community and beliefs about the effects of ones' own participation in research for the greater good. It was hypothesized that these motives would influence subjective norms and participatory intentions. Normative beliefs consisted of six questions based on these two dimensions. They include reference to specific individuals within the social realm who may affect individual decision-making. Items on the 5-point scale therefore included "I think my doctor would approve of my involvement in HIV vaccine research," "I think my work colleagues would approve of my involvement in this cause," "My immediate family is supportive of my involvement in HIV vaccine research," "Most people important to me think my involvement in HIV vaccine research is good," "Most people important to me usually support my interests," and "If my pastor supported HIV vaccine research, I would be inclined to get involved."

Motivation to Comply. Lastly, individuals might declare a willingness to participate or reluctance to get involved due to general compliance with referent opinion. The theorized influence of family, friends, and others on behavioral performance will exert social pressure to act or engage in avoidance. It was hypothesized that greater self agency would lead to greater participatory intention. The items measuring this domain therefore include "I tend to be concerned about what people think of me, even if I don't know them," "I generally do what my family expects of me," "I would not want to do something my friends disapproved of," "If my superiors told me to do something I disagreed with, I would obey their wishes," "Sometimes I do what my friends say to do, even though I know they are wrong."

Organizational Involvement. Traylor and Joseph (1984) conceptualized involvement as a consumer response to a product, message, medium, or situation. They indicated that

"Involvement" is a response that reflects an individual's "sense of self or identity and is activated by external stimuli" (Traylor & Joseph, 1984, p. 66). Based on a review of their "General Scale to Measure Involvement" (GMSI), three items were selected that could be "translated" into the current context to measure involvement with the Hope Clinic. The domain may independently predict or mediate the influence of subjective norms on intent. The items drawn from Traylor & Joseph's scale originally were: "This product helps me express who I am," "Seeing someone else use this product tells me a lot about that person," and "When I use this product, others see me the way I want them to see me." The items for this study now include: "Being active with the Hope Clinic would help me to express who I am," "Hearing that someone else is involved with the Hope Clinic tells me a lot about that person," and "Others would view me favorably if I volunteered for a study at the Hope Clinic."

Personal Relevance of Volunteerism. Finally, "Personal Relevance" incorporates specific attitudes about participatory behavior and belief expectancy to identify the degree to which consumer involvement reflect a broader pattern of values, identity, perceived empowerment, and personal connection to the issue are aligned with intention to perform a participatory behavior. The "purchase decision" measurement work of Zaichkowsky (1985) informed the development of this scale. She theorized involvement as being closely linked to values and interests, along with inherent needs.

To account for the influence of persuasive communication within the context of community engagement, it is theorized that positive attitudes toward involvement in the cause may have a strong influence on behavioral intention. Items such as "Being involved with the Hope Clinic helps me to feel empowered," "I experience a sense of community in this cause," "I feel a sense of belonging through my participation in this effort," "My involvement is helping to

protect the rights of others," "I am advancing the public's health and well-being through my support of this cause," "Getting involved with the HIV vaccine effort is liberating," and "I feel a sense of purpose in this cause" are associated with HIV vaccine social marketing efforts that promote involvement in the cause from a socially appealing advocacy perspective. Agreement with these statements is theorized to be associated with general attitude toward HIV vaccine community engagement. Notably, this dimension augments the TRA model which solely focuses on attitudes toward behavior and not toward other objects (i.e., HIV vaccine research).

Data Collection Procedures

Pilot Phase

From May 2007 through August 2007, the questionnaire was administered to 212 participants at similar events and activities to hone the instrument, ensure consistency and adequate reliabilities of scales, and address any potential health literacy issues prior to implementation of this study. The pilot study was conducted in a similar manner to the current one. Results from that study specifically assisted with improvements of scale internal consistency.

Prior to the administration of the survey, all data collection assistants were required to obtain Collaborative Institutional Training Initiative (CITI) certification in biomedical and social and behavioral sciences modules, and each member was subsequently added to the study protocol that was submitted to the Emory University institutional review board (IRB). Survey team members were briefed about the survey purpose and consent procedures, and the instrument was reviewed in the event that clarification was needed in advance of the field administration. Research assistants were instructed not to "lead" participants in their responses if questions arose during the administration. Assessments were conducted on the degree to which persons were

willing, capable, and qualified to answer the questionnaire before giving them the opportunity to complete it. Typically, this meant ensuring that the person could read and understand English, was over 18 years of age, and had sufficient time to complete the survey. Finally, the provision of incentive items for participation in the study was discussed. All participants received a t-shirt or some other health promotion item after the questionnaire was returned to the field research team.

Participants completed the survey in the field setting which contained 41 TRA and involvement items via the self-administered questionnaire. Respondents were provided with a semi-private area, or directed to nearby quiet spots (such as picnic tables) in outdoor locations, to complete the questionnaire. Every effort was made to manage any potential literacy issues in advance of administration by ensuring that all persons understood the written informed consent document. During questionnaire completion, the principal investigator and research assistants were available to help participants in the event that any of the instrument language required clarification.

Good survey research approaches were employed to write clear and understandable questions that were pilot tested with similar audiences prior to inclusion in this study's instrument (Salant & Dillman, 1994). The study protocol allowed for assessment of participant reactions on the survey and respondent feedback on item language, as well as issues with completion (i.e., length of instrument originally containing 110 items). The original instrument had a Flesch reading ease score of 61.4, and the corresponding Flesch-Kincaid grade level was 6.7. This corresponds with a 6 - 8th grade reading level fluency. The formative results indicated difficulty with questionnaire completion given participant fatigue and time constraints; therefore, the items were later reduced for the current study (N = 101). The study instrument retained its

reading level (6.7), and with items deleted, the resulting Flesch reading ease score was 61.8. The time to completion averaged approximately 15 to 20 minutes.

The pilot study population comprised 212 participants recruited at 9 AHVCC partnership functions. Details of the events and activities from this period are in Table 4. The mean age of this sample was 41.7 years old. The sample was predominantly female and non-white, with African American/Black being the most commonly identified ethnic group ($n = 120$, 58.8%). Most respondents were not in school ($n = 160$, 78.4%). The majority of respondents had some form of post-secondary education ($n = 152$, 74.2%), with many having received their Bachelor's degree ($n = 60$, 29.3%). Most respondents identified as heterosexual ($n = 128$; 61.5%), and the remaining 38.5% ($n = 80$) identified themselves as lesbian, gay, bisexual, or unsure (i.e., "questioning"). Most were single ($n = 96$, 46%) and an additional 40% ($n = 83$) reported being married or having a domestic partner. A clear majority was employed full-time ($n = 126$, 60.6%), but many reported incomes of less than \$40,000 per year ($n = 99$, 49.0%). A demographic profile of this sample is included in Table 5.

The results from the pilot phase indicated that, with the exception of "subjective norms" (Cronbach's $\alpha = 0.525$), the reliabilities of the initial subscales had moderate to high internal consistency (Cronbach's $\alpha = 0.714$ - 0.925) (Table 6). Assessment of the "personal relevance" of HIV vaccine volunteerism scale ($n = 7$ items) resulted in the highest level of internal consistency among scales (Cronbach's $\alpha = 0.925$). Item total correlations ranged from 0.708 to 0.811. Construct validity was also assessed for the new "personal relevance" scale using principal components analysis with the varimax rotation technique. The subsequent factor analysis confirmed the unidimensional nature of the measure, with the 7 items comprising a distinct factor that explained 70% of the variance in the data. This result is similar to those observed with

the "personal involvement" inventory developed by Zaichkowsky (1985) which measured "the perceived relevance of the object based on inherent needs, values, and interests" (p. 342).

The subjective norms measure was previously problematic in our earlier study ($\alpha = 0.644$) and may contributed to the inability to detect a pathway effect from subjective norms to intent as predicted by TRA model (Frew, Archibald, del Rio et al., 2007). Influential normative concerns were directly measured through items including "people negatively judge those who participate in HIV vaccine research," "I think some of my family members would be upset if I participated in an HIV vaccine research study," and "I think my friends would negatively judge me if I joined in an HIV vaccine study." Given concerns about these items, new items were created for this study based on the wording suggested by Ajzen & Fishbein (1980, p. 262). The previous items were deleted from the measurement. The three new subjective norms items were therefore added including: "most people who are important to me think I should participate in the HIV vaccine effort," "most people who are important to me would approve of my involvement in this cause," and "most people who are important to me would support my interest in this cause." Item and scale statistics from the pilot study are provided in Table 6.

With this sample, the "Organizational Involvement" measure containing 4 items resulted in a coefficient $\alpha = 0.714$. Traylor and Joseph's (1984) 6-item version achieved a coefficient $\alpha = 0.920$ with a sample of 280 graduate and undergraduate persons. Methods to improve scale reliability include increasing items or improving the Cronbach alpha by removing "poor" items (Warner, 2008b). Because instrument length was a concern, a decision was made to drop the item "you can tell a lot about a person by their community affiliations" (thus increasing Cronbach's α to 0.733) for this study.

One other decision was made with respect to the "Outcome evaluation" scale to maintain content validity given new evidence of concerns related to the potential for false antibody testing among study populations (Fuchs, Durham, McLellan-Lemal et al., 2007). Therefore, one item was added to that scale for this study's instrument, "I am concerned that an HIV vaccine will cause me to test HIV positive." The total items for "Outcome Evaluation" was increased to 5, thereby increasing the potential internal consistency of this measure (Warner, 2008b).

Table 4: Pilot Phase AHVCC Collaborative Partner Sample

Collaborative Partner	AHVCC Activity/Event	Date	Estimated Attendance	Surveys	Study Sample Percent (N=212)
Hopewell Baptist Church/SisterLove, Inc./AID Atlanta/AID Gwinnett/AIDS Alliance for Faith & Health/Emory Center for AIDS Research/Centers for Disease Control & Prevention (CDC)/National AIDS Education and Services for Minorities (NAESM)/Institute for Health Protection/Atlanta Harm Reduction Center/AIDS Survival Project/AIDS Research Consortium of Atlanta	"There's Hope in Our Soul" faith-based HIV vaccine leadership symposium	5/18/07	150	72	34.0
Atlanta Voice	Health Expo	5/19/07	150	16	7.5
AID Atlanta	AIDS 101	6/16/07	150	9	4.2
Atlanta Harm Reduction Center	Prevention "House Party"	6/22/07	75	24	11.3
Atlanta Pride Committee/Atlanta Gay & Lesbian Chamber of Commerce	Pride	6/23-24/07	50,000	59	27.8
Americorps/ Hands On Atlanta	HIV Vaccine 101 Workshop	6/29/07	20	8	3.8
New Mercies Church	Vaccine 101 Small Group Meeting	7/17/07	25	10	4.7
Grady Infectious Disease Program (Ponce Clinic)	Community Advisory Board Meeting	7/17/07	20	5	2.4
Atlanta Black Nurses Association	Health Information Day	7/24/07	100	9	4.2

Table 5: Pilot Phase AHVCC Sample Characteristics

Sample Demographics (N = 212)	Pilot Phase Study Population (Total %)
Age (mean = 41.7 years)	
18-29	42 (19.8)
30-39	51 (24.1)
40-49	45 (21.2)
50-59	52 (24.5)
60 and over	12 (5.6)
Gender	
Male	63 (30.6)
Female	142 (68.9)
Transgender: M→ F	1 (0.5)
Race	
White	66 (32.2)
Non-white	139 (67.8)
Ethnicity	
Asian/Asian-American/Pacific Islander	5 (2.5)
Hispanic/Latino/Chicano	6 (2.9)
African-American/Black	120 (58.8)
Caucasian/White	56 (27.5)
Native American/American Indian/Alaskan Native	2 (1.0)
Multiracial/Multicultural	15 (7.4)
Sexual Orientation	
Straight (heterosexual)	128 (61.5)
Lesbian, Gay, Bisexual, Queer, Questioning (LGBTQQ)	80 (38.5)
Educational Attainment	
K-12 grade	53 (25.8)
Technical/Vocational/ Associates	42 (20.5)
Bachelor	60 (29.3)
Master's	39 (19.0)
Doctorate	11 (5.4)
Household Income	
Less than \$40,000	99 (49.0)
\$40,001- \$60,000	42 (20.8)
\$60,001- \$80,000	27 (13.9)
\$80,001- \$100,000	18 (8.9)
Over \$100,000	15 (7.4)

Table 6: Pilot Phase Internal Consistency Measures (N=212)

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	7	4	3	6	5	4	7
Observations (%)	194 (91.5)	177 (83.5)	188 (88.7)	193 (91.0)	181 (85.4)	188 (88.7)	189 (89.2)	179 (84.4)
Cronbach's α	.741	.850	.785	.525	.808	.842	.714	.925
Cronbach's Standardized α	.750	.853	.789	.527	.811	.842	.720	.927
Item Mean	1.689	1.818	3.191	3.016	2.375	3.447	2.410	2.156
Item Range	.789	.655	.479	1.031	.735	.660	.275	.441
Item Variance	.097	.072	.039	.280	.077	.064	.019	.008
Scale Mean	8.443	12.723	12.766	9.047	14.249	17.234	9.640	15.162
Scale Variance	8.310	18.304	14.341	6.399	16.143	20.565	6.636	21.204
Scale SD	2.883	4.278	3.787	2.530	4.018	4.535	2.576	4.605

Current Study

From August 2007 through October 2007, venue-based convenience sampling was conducted. Project assistants randomly approached members of attendee populations about the survey. When feasible, persons were also simultaneously introduced the study at the Hope Clinic booth at the public events. The complete event roster for the data collection period includes eighteen unique activities and events hosted by AHVCC partners and the Hope Clinic. They included: the Atlanta Executive Network Meeting, the Hope Clinic volunteer appreciation event, the "REACH for Wellness" community health day, Congressman David Scott's annual health fair, Project LINK's health and wellness community day, the "In the Life Atlanta" Black Gay Pride festival, an Atlanta Gay & Lesbian Chamber of Commerce luncheon, an Emory University Volunteer Fair, AID Atlanta's "AIDS 101," the CHAMPS event (Black Men's Health Fair), a Faith-based leadership event on health issues at Hopewell Baptist Church, PALS Bingo, "For Sisters Only," the African American MSM Summit, the AIDS Survival Project clinical trials forum, Everest Institute's health fair, an Outwrite Bookstore special event, and a Macy's employee presentation featuring HIV vaccine research at the Hope Clinic. The events were organized and sponsored by the study site (The Hope Clinic of Emory Vaccine Center) and its partner organizations (i.e., AID Atlanta, SisterLove, Inc., NAESM, AIDS Survival Project, and others) with a specific focus on building HIV vaccine awareness and providing community education on HIV vaccine research. Table 7 details the sampling frame for the study, of which the study population was drawn.

Table 7: AHVCC Collaborative Partner Sampling Frame

Collaborative Partner	AHVCC Activity/Event	Date	Estimated Attendance
Atlanta Executive Network (AEN)	Monthly meeting	8/16/07	100
Hope Clinic & Community Advisory Board	Volunteer Appreciation Event	8/17/07	150
REACH for Wellness Coalition	Community Health Fair	8/18/07	200
Center for AIDS Research (CFAR)	Congressman David Scott's Annual Health Fair	8/18/07	250
Atlanta AIDS Partnership Fund/Neighborhood Fund's "Project LINK"	NPU-L Community Health and Wellness Day	8/25/07	100
In the Life Atlanta (ITLA)	Black Gay Pride	9/1-2/07	20,000
Atlanta Gay & Lesbian Chamber of Commerce (AGLCC)	Luncheon	9/4/07	15
Emory Healthcare/Morehouse School of Medicine/Pfizer, Inc.	CHAMPS	9/8/07	1,000
Hopewell Baptist Church	Faith-Community-based Health Partnership Symposium	9/10/07	125
Volunteer Emory	Volunteer Fair	9/11/07	200
Pets are Loving Support (PALS)	Monthly Bingo & Community Partner Information Session	9/12/07 & 10/10/07	400
Everest Institute	Health Fair	9/14/07	400
AID Atlanta	AIDS 101	9/15/07	150
SisterLove, Inc. & AID Atlanta	For Sisters Only	9/16/07	2,000
Our Common Welfare	African American MSM Summit	9/22/07	400
AIDS Survival Project	Clinical Trials Forum	9/27/07	100
Outwrite Bookstore	Evening of "Hope"	9/27/07	100
Macy's	HIV Vaccine Lunch & Learn	10/18/07	10

Recruitment occurred at arbitrary times and days of each week, and throughout the duration of the activities. The recruitment area was limited to Atlanta, Georgia. Persons were eligible for study participation if they were at least 18 years of age and could read and speak English. Data collection assistants made an effort to ensure that surveys were completed only once at each event by attendees. Approximately six hundred people were invited to participate in

the study. Of these, 542 were eligible and provided written informed consent (yielding a response rate of 90.3%). A t-shirt or health promotion incentive for participation was provided. The Emory University Institutional Review Board approved the protocol amendment on May 8, 2007. The University of Georgia Institutional Review Board approved the study on October 26, 2007.

Data Management

Data were collected through a paper questionnaire. All questionnaires were returned to the Hope Clinic's administrative office, where data entry was performed by members of the research team. An entry key was developed for the assignment of codes and recommendations for ambiguous responses (e.g., "other" responses were given separate categories). Each questionnaire was assigned an event number and case number which corresponded to its appearance in the SPSS dataset. All data were entered in a timely manner. Cases were systematically cross-checked by two members of the research team to reduce any error, a process that helps to ensure excellent quality control (Fowler, 2002).

The next steps included identifying cases with missing data, specifically the type and extent of missing outcome values and scaled items. Descriptive frequencies, means, and standard deviations for all variables of interest were also calculated. Additional examination of the Little's chi-square tests for scaled item responses indicated whether patterns of missing data were observed among cases. Diagnoses of systematic nonresponses would indicate if single or multiple imputation procedures could be applied (i.e., mean maximum likelihood estimation) (Brown, 2006; McKnight, McKnight, Sidani et al., 2007).

Data Analysis

SPSS version 15.0 and AMOS 7.0 software were used for all analyses (SPSS, Inc., Chicago, IL., USA). These packages were used because they have the capability to automatically screen data for multivariate normality (i.e., skewness and kurtosis) and for outlier cases (Brown, 2006). AMOS also employs the complete case method procedure through its default of listwise deletion to handle missing cases if imputation is not appropriate (McKnight, McKnight, Sidani et al., 2007). Scale internal consistency was assessed at $p < .05$ levels.

Internal Scale Consistency

Reliability and validity were assessed for all scales to measure internal consistency of the measures. Given the reliability coefficients obtained in the pilot sample, it was expected that the coefficients would be similar or improve with this larger study sample. Once these measures were obtained, confirmatory factor analyses were performed to determine if the subscales were reflective of the latent constructs.

Confirmatory Factor Analysis

According to Brown (1996), confirmatory factor analysis (CFA) measures "relationships between observed measures or indicators (e.g., test items, test scores, behavioral observation ratings) and latent variables or factors" (p. 1). It is typically used in scale development to verify item-factor relationships, to determine construct and convergent validity. This study included a confirmatory factor analysis of measurement fit to establish the components of the factors by estimating the strength of the relationships between indicators and constructs (Brown, 2006).

A confirmatory factor analysis using maximum likelihood estimation was specifically undertaken to test the adequacy of the model measuring the underlying factors. Each latent construct (intentions, attitudes, subjective norms, behavioral beliefs, outcome evaluations,

normative beliefs, personal relevance, and organizational involvement) was identified by its corresponding measured variables. One indicator per construct was fixed to define the scales of the indicators. An a priori alpha level was set at $p < .05$ for all factor patterns.

This study generated fit indices for the measures. A chi-square statistic was produced for each outcome iteration to indicate absolute measurement fit, along with the Standardized Root Mean Square Error of Approximation (RMSEA). The RMSEA produces an average covariance residuals value observing differences between the sample and the population estimate (Byrne, 1998; Meyers, Gamst, & Guarino, 2006). This measure has been recognized as "one of the most informative criteria in covariance structure modeling" (Byrne, 1998, p. 112). Values less than 0.08 are acceptable (Meyers, Gamst, & Guarino, 2006, p. 559). The comparative fit index (CFI) is also considered "the fit statistic of choice in structural equation modeling research" (Meyers, Gamst, & Guarino, 2006, p. 560). CFI good fit guidelines suggest that a good fit is > 0.90 , an adequate/marginal fit is 0.80 to 0.90 (Knight, Virdin, Ocampo et al., 1994; Meyers, Gamst, & Guarino, 2006). SPSS' AMOS 7.0 was the software package used to generate maximum likelihood estimates of the parameters (Arbuckle, 2006). The resulting maximum likelihood χ^2 values are provided in Chapter 4.

Structural Model

The covariance structure model was used to test the causal relationships between factors implied by TRA with the addition of the involvement constructs. For this study, the effects of behavioral and normative beliefs, outcome evaluations and motivation to comply were tested on attitudes and subjective norms. At the same time, attitudes and subjective norms, along with personal relevance and organizational involvement, were used to explain respondents' intentions

with respect to future involvement in HIV research, whether through attending future events, mobilizing others, or participating in vaccine trials.

A structural equation model was determined to be well-suited for this type of analysis because (1) it examines both direct and indirect paths to willingness to participate in an efficient (simultaneous) manner, (2) random measurement error can be taken into account, reducing its effect on parameter estimates, (3) non-random error can be explicitly accounted for, and (4) it can explicitly investigate the fit of these measures to the constructs thereby promoting their more general definition.

The basic structural equation model follows Jöreskog and Sörbom (1993):

$$\eta = \beta\eta + \gamma\xi + \zeta$$

where η and ξ are latent constructs based on vectors of observed variables (y and x); β is a matrix of coefficients expressing the mutual effects of endogenous variables; γ represents the effects of latent exogenous on endogenous variables, and ζ is a vector of random error. One underlying assumption of the model is that the errors are uncorrelated with latent constructs and uncorrelated among themselves.

It was also essential to obtain standardized regression coefficients. Assessment of the causal model implied by the theory of reasoned action and its corresponding external variables of "personal relevance" and "organizational involvement," necessitates an examination of the resulting standardized regression coefficients to ascertain the relationships among the theoretical constructs. Standardized coefficients can be interpreted as standard deviation unit changes in the outcome of interest for a unit change in its precursor. They also permit comparisons of the degree to which one variable influences another.

The overarching aim of this study was to examine what could be expected from the AHVCC partnership community engagement model. Directional hypotheses for the key constructs of interests were investigated using structural equation models. This approach allowed for evaluation of the explicitly hypothesized and complex relationships among theoretical variables. The results of the study indicate the usefulness of the TRA model in explaining HIV vaccine community engagement outcomes. The investigation also evaluates the role of the external variables, "personal relevance of volunteerism" and "organizational involvement," as influencers of these outcomes. The results detailed in Chapter 4 present the results of the confirmatory factor analyses and the full structural models.

CHAPTER 4

RESEARCH FINDINGS

All analytical findings are presented in this chapter. Preliminary data analyses are detailed in the first section, inclusive of descriptive statistics and measures of internal consistency for each of the study scales. The subsequent sections describe the analyses which confirmed the theory of reasoned action factor structure and it details the steps taken to ensure measurement equivalence of the populations by gender. The findings related to the research hypotheses are addressed through the structural equation analyses presented in the conclusion of the chapter.

Preliminary Data Analyses

Following the pilot period of data collection (May to August 2007), a new sample of data was obtained for this study (late August to mid October 2007). Interest in the study was excellent with approximately 600 persons invited to participate in the various venue settings. Of these, 542 persons were determined to be eligible to participate and subsequently completed the questionnaire, resulting in a very high response rate (90.3%). Table 8 details the survey return yield from each partner function.

Following data entry, code and value cleaning functions were undertaken. Frequency tables were produced for all sociodemographic variables and scanned for accuracy by members of the research team. Anomalous case values were cross-checked against the corresponding paper questionnaire, and when appropriate, codes were replaced with the correct value.

Table 8: AHVCC Collaborative Partner Study Sample

Collaborative Partner	AHVCC Activity/Event	Date	Estimated Attendance	Surveys	Study Sample Percent (N=542)
Atlanta Executive Network (AEN)	Monthly meeting	8/16/07	100	8	1.5
Hope Clinic & Community Advisory Board	Volunteer Appreciation Event	8/17/07	150	38	7.0
REACH for Wellness Coalition	Community Health Fair	8/18/07	200	37	6.8
Center for AIDS Research (CFAR)	Congressman Scott Annual Health Fair	8/18/07	250	1	0.2
Atlanta AIDS Partnership Fund "Project LINK"	Community Health and Wellness Day	8/25/07	100	2	0.4
In the Life Atlanta (ITLA)	Black Gay Pride	9/1-2/07	20,000	92	17.0
Atlanta Gay & Lesbian Chamber of Commerce (AGLCC)	Luncheon	9/4/07	15	6	1.1
Emory Healthcare/Morehouse School of Medicine/Pfizer, Inc.	CHAMPS	9/8/07	1,000	37	6.8
Hopewell Baptist Church	Faith-Community-based Health Partnership Symposium	9/10/07	125	22	4.1
Volunteer Emory	Volunteer Fair	9/11/07	200	26	4.8
Pets are Loving Support (PALS)	Bingo/Community Partner Information Session	9/12/07 & 10/10/07	400	30	5.5
Everest Institute	Health Fair	9/14/07	400	64	11.8
AID Atlanta	AIDS 101	9/15/07	150	42	7.7
SisterLove, Inc. & AID Atlanta	For Sisters Only	9/16/07	2,000	34	6.3
Our Common Welfare	African American MSM Summit	9/22/07	400	48	8.9
AIDS Survival Project	Clinical Trials Forum	9/27/07	100	24	4.4
Outwrite Bookstore	Evening of "Hope"	9/27/07	100	26	4.8
Macy's	HIV Vaccine Lunch & Learn	10/18/07	10	5	0.9

The study sample is remarkably similar to the pilot sample with respect to most sociodemographic characteristics (Table 9). The mean age of this sample was slightly younger (37.0 years of age) than the pilot sample (41.7 years). This sample was predominantly female (n = 296, 54.6%) and non-white (n = 381, 72.8%), with Black/African American being the most commonly identified ethnic group (n = 308, 58.3%). Other ethnic groups included Asian/Asian-American/Pacific Islander (n = 20, 3.8%), Hispanic/Latino/Chicano (n = 14, 2.7%), multiracial or multicultural (n = 44, 8.3%), Native American/American Indian/Alaskan Native (n = 3, 0.6%). A small percentage of this sample reported transgender status (n = 10, 1.8%). Because the current identified gender was selected by these individuals, they were subsequently added to male (n = 232, 42.8%) or female gender categories (n = 302, 55.7%) for subsequent analyses. Most respondents were not in school (n = 353, 66.2%). The majority of respondents had some form of post-secondary education (n = 367, 68.9%), with many having received their Bachelor's degree (n = 141, 26.5%). Most respondents identified as heterosexual (n = 326, 60.7%), and the remaining (n = 211, 39.2%) identified themselves as lesbian, gay, bisexual, or unsure (i.e., "questioning"). Most were single (n = 311, 57.8%) and an additional 162 persons (30.1%) reported being married or having a domestic partner. A clear majority were employed full-time (n = 310, 57.6%), but many reported incomes of less than \$40,000 per year (n = 285, 54.2%).

Assessment of provider utilization, attendance motivations, previous forms of health volunteerism, and participant impressions complemented the demographic measures. Most items were close-ended selection sets, with "specify" options. Because trust in healthcare providers and clinical entities is a key barrier to health volunteerism, particularly among minority populations, an item queried recent access to care. The majority of respondents (n = 349) indicated that they sought healthcare at a provider's office in the past year (65.4%), with 87

persons having sought care at a community clinic or health center (16.3%), or hospital (n = 60, 11.2%). Therefore, it appeared that most participants had a level of engagement with the healthcare system.

Table 9: Study Sample Characteristics

Sample Demographics (N = 542)	Study Population (Total %)
Age (mean = 37.0 years old)	
18-29	163 (31.0)
30-39	136 (25.9)
40-49	143 (27.2)
50-59	70 (13.3)
60 and over	13 (2.5)
Gender	
Male	228 (42.1)
Female	296 (54.6)
Transgender: M → F	6 (1.1)
Transgender: F → M	4 (0.7)
Race	
White	142 (27.2)
Non-white	381 (72.8)
Ethnicity	
Asian/Asian-American/Pacific Islander	20 (3.8)
Hispanic/Latino/Chicano	14 (2.7)
African-American/Black	308 (58.3)
Caucasian/White	139 (26.3)
Native American/American Indian/Alaskan Native	3 (0.6)
Multiracial/Multicultural	44 (8.3)
Sexual Orientation	
Straight (heterosexual)	326 (60.1)
Lesbian, Gay, Bisexual, Queer, Questioning (LGBTQQ)	211 (39.3)
Educational Attainment	
K-12 grade	166 (31.1)
Technical/Vocational/ Associates	130 (24.4)
Bachelor	141 (26.5)
Master's	72 (13.5)
Doctorate	24 (4.5)
Household Income	
Less than \$40,000	285 (54.2)
\$40,001- \$60,000	97 (18.4)
\$60,001- \$80,000	63 (12.0)
\$80,001- \$100,000	32 (5.9)
Over \$100,000	49 (9.0)

Previous forms of health volunteerism were also of interest as an indicator of potential involvement in HIV vaccine research. Most respondents indicated some form of medical volunteerism (n = 308, 60.2%). In the past year, they performed “multiple” health-oriented volunteer behaviors (n = 113, 22.1%). Many noted that they donated money to a healthcare cause (n = 151, 29.5%), gave blood (n = 139, 27.1%), signed an organ donor card or donated an organ (n = 83, 16.2%), gave bone marrow (n = 6, 1.2%), donated their body to science (n = 10, 2.0%), participated in a health research study (n = 71, 13.9%), or gave sperm or eggs (n = 2, 0.4%). With respect to health decision-making, most agreed that they typically act on their intentions (n = 441, 83.2%).

Existing community involvement was also assessed to identify and expand alliances with organizations of which the target population is already affiliated. The study population was generally observed to exhibit community involvement, with 452 (83.3%) having commitments to other groups. Membership in a faith-based organization was a common source of community involvement (n = 299, 55.8%), followed by volunteer organization (n = 151, 28.2%), social organization (n = 127, 28.2%), and professional organization (n = 120, 22.4%). Very few reported affiliations with activist organizations (n = 47, 8.8%) which have been instrumental in sustaining HIV/AIDS advocacy. Many came away from the functions agreeing that they would like their communities to be more involved in HIV vaccine research (n = 457, 85.6%).

With respect to the Hope Clinic, a significant proportion of respondents indicated a degree of familiarity prior to the event (n = 207, 38.4%) having heard about the clinic through “multiple sources” (n = 73, 13.5%). Others reported hearing about the clinic from friends (n = 73, 13.5%), family (n = 23, 4.3%), health provider (n = 31, 5.8%), television (n = 14, 2.6%), radio (n = 16, 3.0%), Internet (n = 29, 5.4%), newspaper/magazine (n = 25, 4.6%), community

event (n = 42, 7.8%), flyer/poster (n = 27, 5.0%), community organization referral (n = 30, 5.6%), or “other” sources (n = 25, 4.6%). Most agreed that they are “active health information seekers” (n = 425, 79.1%).

The majority (n = 305, 57.5%) correctly identified “prevention research” as the primary function of the site. Some indicated that its main purpose was “health promotion or health education” (n = 58, 10.9%), clinical care (n = 42, 7.9%), multiple or “other” functions (n = 19, 3.6%). Some simply did not know its main mission (n = 106, 20.0%). Most of the respondents were not Hope Clinic study volunteers (n = 502, 93.7%). The overall organizational rating was “excellent” (n = 236, 44.5%), “very good” or “good” (n = 196, 37.0%), with some assessing it as “fair” (n = 98, 18.5%).

Motivation to attend the event was also of interest given indications from the WTP and AIDS volunteerism literature of a desire to help others, get information, and obligation to the community (Colfax, Buchbinder, Vamshidar et al., 2005; Reeder, Davison, Gipson et al., 2001). Many of the participants came "to get the latest scientific-medical information" (n = 152, 29%), and of "my sense of obligation to my community" (n = 90, 17.1%), for "volunteer opportunities" (n = 52, 9.9%), and "to meet others that share my concerns" (n = 82, n = 15.6%). Consistent with the AHVCC’s objectives, the majority of participants perceived that the focus of their event was "to raise awareness about a health issue (n = 235, 44.6%) or provide education (n = 142, 26.9%). Some indicated "study recruitment" was the goal (n = 37, 7.0%), while some stated the functions were conducted for multiple reasons (n = 45, 8.5%), or some other reason not specified (n = 68, 12.9%).

People traveled from all over the metropolitan Atlanta area and beyond to attend the events in nearly equation proportions (≤ 5 miles: n = 149, 28.1%; 6-9 miles: n = 106, 20.0%; 10-

20 miles: $n = 127$, 23.9%; and ≥ 20 miles: $n = 149$; 28.1%). Most found the functions easily accessible ($n = 429$, 80.8%) or somewhat easy to locate ($n = 77$, 14.5%). They favorably rated the events or activities as "excellent/outstanding" ($n = 296$, 55.8%) or "good/very good" ($n = 211$, 39.8%). Less than 1% of the study population rated them as "fair or poor" ($n = 5$, 0.9%). A corollary measure of expectancy found that the functions exceeded their anticipations ($n = 148$, 29.7%) and that they met expectations of many ($n = 335$, 67.1%). About a quarter of participants reported having been at one of the partner organization activities in the past year ($n = 129$; 24.4%), and a smaller proportion ($n = 47$, 8.9%) specifically reported having been at a similar Hope Clinic activity in the past year. Most agreed with the statement that they wanted to learn more about HIV vaccine research ($n = 420$, 78.5%) and ethical issues ($n = 406$, 76.3%).

Subscale Reverse Coding

Subsequent analysis of the items for each scale included a review of those phrased with negative expressions for reverse-coding. Items from the "Outcome Evaluation" (e.g., "My participation in an HIV vaccine study would be more trouble than its worth") and "Motivation to Comply" (e.g., "Sometimes I do what my friends say to do, even though I know they are wrong") subscales were phrased in a negative direction. Therefore, items were subsequently reverse coded for the analyses, resulting in 1 (strongly agree) being assigned a value of 5 (strongly disagree) to positively align with intention. The valence is therefore consistent with the hypotheses.

Study Scale Internal Consistency

The results from this study indicated that the reliabilities of all subscales had moderate to high internal consistency (Cronbach's $\alpha = 0.732$ - 0.922) (Table 10). The scales also achieved greater completion rates for the 41 items (92.4% to 95.6%) compared to the pilot phase (83.5%

to 91.5%). Consistent with the pilot study, the "personal relevance" of HIV vaccine volunteerism scale ($n = 7$ items) resulted in the highest level of internal consistency among scales (Cronbach's $\alpha = 0.922$). The "Attitudes" scale ranked lowest with $\alpha = 0.732$ which is still acceptable by most standards (Warner, 2008b). Most scales exhibited stability in their estimates compared to the pilot phase and improvements were noted with respect to "Outcome Evaluation," "Subjective Norm," and "Organizational Involvement." The subjective norms measure was previously problematic in the pilot study ($\alpha = 0.525$), but improved dramatically with the new items ($\alpha = 0.843$). Thus, the modification of this scale improved the likelihood of detecting a pathway effect from subjective norms to intent as predicted by TRA model. Item and scale statistics from this study are provided in Table 10.

Management of Outliers

In addition to the demographic descriptives, the preliminary data analysis phase included generation of item descriptives for outcome variables and scaled measures to assess normality, and degree of skewness and kurtosis of each item. Histograms with normal distribution for continuous variables and bar graphs were produced for categorical scaled items to identify potential outliers. Upon review of the output files, extreme and out-of-range values were inspected against the raw data (i.e., paper questionnaire), and data entry errors were corrected as deemed appropriate.

Factor analyses and structural equation models typically assume normal distributions for variables of interest. Therefore, subsequent steps had to be taken to ensure that resulting values were reasonable and representative of participant opinion after data cleaning. Histograms with normal curves were produced for the continuous outcome variables (Appendix B). The results

Table 10: Internal Consistency Measures (N=542)

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	7	5	3	6	5	3	7
Observations (%)	515 (95.0)	508 (93.7)	514 (94.8)	518 (95.6)	506 (93.4)	502 (92.6)	508 (93.7)	501 (92.4)
Cronbach's α	.732	.854	.826	.843	.806	.840	.808	.922
Cronbach's Standardized α	.739	.853	.828	.843	.807	.841	.808	.922
Item Mean	1.808	1.887	2.728	2.368	2.362	2.449	2.535	2.303
Item Range	.835	.565	.424	.554	.727	.653	.106	.433
Item Variance	.119	.050	.041	.085	.070	.054	.004	.028
Scale Mean	9.041	13.210	13.640	7.104	14.170	12.245	7.604	16.124
Scale Variance	8.635	19.286	21.915	5.173	13.520	21.147	4.291	20.869
Scale SD	2.938	4.392	4.681	2.274	3.677	4.599	2.071	4.568

indicated a high mean for future attendance (8.47; $n = 504$), and moderate means for community mobilization (5.52; $n = 491$) and study volunteerism (4.70, $n = 486$). The standard error for future attendance also was considerably less (0.09) than the other variables, community mobilization (0.14) and study volunteerism (0.15). Therefore, symmetry of the distributions (skewness) for outcome and scaled item variables required closer inspection. This was clearly necessary for the future attendance outcome. Additionally, kurtosis estimates were examined to determine normality of the distributions. The final step was a test of normality (Shapiro-Wilk) to assess skewness. Q-Q plots were also generated. A significant normality test resulted ($p = <.001$) indicating data skew on the first outcome (attendance).

Various thresholds have been recommended for determination of data skewness (George & Mallery, 2003; Morgan, Griego, & Gloeckner, 2001). Because perfectly normal and symmetrical distributions have a skewness value of 0, some recommend using ± 1.0 as a guide for detecting skewness (Meyers, Gamst, & Guarino, 2006; Warner, 2008b). A visual inspection of the data suggested negative skewness on the future attendance variable, with a long tail on the lower end of the distribution. The descriptive statistics indicated a skew statistic of $z = -1.67$ for this variable, compared to community mobilization ($z = -0.23$) and study volunteerism ($z = 0.01$).

Based on procedures described by Hair et al. (1998) for identification of continuous variable outliers, outcome values were converted to standard (i.e., z) scores. Scores exceeding ± 3.30 are generally considered outliers (Hair, Anderson, Tatham et al., 1998; Meyers, Gamst, & Guarino, 2006; Warner, 2008b). Kline (2005) argues "there is less consensus about the kurtosis index...A conservative rule of thumb, then, seems to be that absolute values of kurtosis index greater than 10.0 may suggest a problem" (p. 50). The kurtosis estimates on the raw scaled

outcomes were acceptable for community mobilization ($z = -0.90$) and study volunteerism ($z = -1.22$). However, the z score on the attendance outcome may suggest a marginal departure from normality by some standards ($z = 3.33$).

Heteroscedasticity can be usually found in regression models that utilize cross-sectional data and can be expected for certain types of data (Kline, 2005). Additional sources of heteroscedasticity may include skewed data, the presence of outliers, specification errors, and incorrect data transformations. The structural equation models for this study include maximum likelihood estimates (MLE) which maximize the values of unknown parameters while diverging from some ordinary least squares (OLS) assumptions (e.g., homoscedasticity). Therefore, the examination of potential outliers was important in assuring that individual cases did not unduly bias the results.

The same steps were taken with all of the subscale indicator items ($n = 41$). Skewness and kurtosis estimates, along with histograms, were generated and each item was inspected. Of the 41 variables, only 2 items exhibited evidence of skewness or kurtosis. On the "attitudes" scale, the item "I like to do good for others" kurtosis estimate was 4.798 with a skew statistic of 1.865. The low mean of 1.39 suggested that the data was skewed toward the "strongly agree" and "agree" end of the scale. Of the 527 responses to this question, only 2 indicated "strongly disagree" and 3 selected "disagree." "My community would really benefit from an HIV vaccine" on the "behavioral beliefs" scale resulted in a skew statistic of 1.716 toward agreement; however, the kurtosis value was not excessive (2.899).

Categorical Transformations

As an additional assurance of maintaining the propriety of the subsequent regression analysis, any potential issues arising from heteroscedasticity and normality violations

(particularly with respect to the attendance variable) were also managed by collapsing the continuous outcome measures to interval level response categories (Meyers, Gamst, & Guarino, 2006). This method is clearly justified for the attendance outcome because many points within the lower level of the continuum had very few cases (i.e., ≤ 6 on the 0, 1, 2, 3, and 4 values) (Warner, 2008a). Therefore the revised outcome variables included response categories of 1 to 4 for attendance, with 1 = definitely, 2 = likely/very likely, 3 = neutral/no opinion, and 4 = definitely not/unlikely/very unlikely. The raw scores from the other outcomes displayed a greater degree of normality and acceptable clustering; therefore, the 0 to 10 scales were collapsed to 1 (definitely) to 5 (definitely not) categories. Table 11 details the frequencies and percentages of the revised outcome variables. Appendix B shows the histograms of the raw and recategorized data.

Table 11: Community Engagement Outcomes

Outcomes	Frequency	Percent
Sustained Involvement (n = 504)		
Definitely	235	46.6
Very likely/Likely	218	43.3
Neutral/No opinion	36	7.1
Very unlikely/Definitely not	15	3.0
Community Mobilization (n = 491)		
Definitely	78	15.9
Likely	161	32.8
Neutral/No opinion	99	20.2
Unlikely	99	20.2
Definitely not	54	11.0
Study Volunteerism (n = 486)		
Definitely	63	13.0
Likely	135	27.8
Neutral/No opinion	84	17.3
Unlikely	100	18.5
Definitely not	104	21.4

Subsequent inspection of the standardized scores (i.e., z) showed improvements in the degree of kurtosis on attendance ($z = 1.10$) compared to the continuous raw score ($z = 3.33$). Community mobilization remained relatively similar ($z = -0.99$) to its previous version ($z = -0.90$), as did study volunteerism ($z = -1.29$ compared to previous -1.22). The degree of skewness of the attendance outcome also was reduced with this procedure. The raw version was $z = -1.66$ compared to the new value of -1.07 . Community mobilization ($z = -0.28$) remained remarkably similar to its previous value ($z = -0.23$). Study volunteerism also remained close ($z = 0.01$ to -0.03). The resulting outcome variables were therefore deemed acceptable for subsequent SEM analyses given the improved kurtosis and skewness estimates. Within the context of structural modeling, MLE also has the ability to handle a large sample (i.e., ≥ 300 cases) containing non-normal data, assuming that extreme kurtosis is not a problem (Gorsuch, 1983; Kline, 2005).

Missing Case Data

A goal of the preliminary analyses was to assess the degree of ignorable missing data which is characterized by its randomness (hence, MAR = missing at random or MCAR = missing completely at random) (Kline, 2005). A number of procedures are recommended for analysis of nonresponse to items (McKnight, McKnight, Sidani et al., 2007). One of the most powerful techniques includes the Little MCAR chi-square test with variables to determine if missing data is systematic or random.

For this study, an "expectation maximization" (EM) imputation was used to estimate missing values and parameters (Meyers, Gamst, & Guarino, 2006). This EM approach uses maximum likelihood techniques to assess differences in observed data and theoretical distributions (McKnight, McKnight, Sidani et al., 2007). When the Little MCAR test is found to

be significant, data are not assumed to be MCAR. Thus, multiple imputations for missing values identified under these circumstances may be appropriate. Therefore, a series of tests were performed for all indicator variables included in the analysis ($n = 41$) to assess whether there was a difference in observed response patterns from the model-based expected values. At a 95% confidence interval, the results revealed a significant pattern, $\chi^2_{(2894)} = 3412.594$, $p < .001$.

Multiple mean imputation procedures are recommended if missing data accounts for less than 5% of the dataset (McKnight, McKnight, Sidani et al., 2007; Roth, 1994). Among the 41 indicator variables, all items met the criteria (Appendix D details the item means, standard deviations, missing values, and related expectation maximization statistics). The multiple imputation procedure was conducted for the missing indicator values. This resulted in 504 cases with complete data for the attendance outcome, 491 cases for the community mobilization outcome, and 486 cases for the study volunteerism outcome, and 3 datasets with a complete set of 41 independent variables for the subsequent analyses.

Measurement Model Analyses

The assessment of the measurement model included a review of the bivariate correlations among items and factors, followed by confirmatory factor analysis. Bivariate correlations were computed first for all indicators as a first step in factor structure validity. The results indicated that multicollinearity was not a concern for individual items with the intercorrelation threshold set at ≥ 0.85 as recommended by Kline (2005, p. 56).

With respect to the first outcome (attendance), the correlation matrix indicated only four items strongly correlated from the Subjective Norms scale ("Most people important to me would support my interest in this cause" and "Most people important to me would approve of my involvement in this cause") with a resulting Pearson value 0.786, $p \leq .01$. These same items

repeated the pattern on the second outcome (community mobilization), ($r = 0.798$, $p \leq .01$) and on study volunteerism ($r = 0.786$, $p \leq .01$). The others, from the Normative Beliefs scale, included "My involvement in this cause will improve my community's trust in medical research" and "My involvement in this cause will result in more ethical research" ($r = 0.748$, $p \leq .01$). These same items repeated the pattern on the second outcome (community mobilization), ($r = 0.767$, $p \leq .01$) and on study volunteerism ($r = 0.773$, $p \leq .01$).

A subsequent check of correlations among factors ensued with calculations of composite factor scores for all items on each scale following principal components analysis with Eigenvalues ≥ 1.0 . This method also validated the unidimensionality of each factor. Correlations of the eight factors' composite scores were assessed. The results indicated that multicollinearity was not a concern for the various factors. Overall, the highest intercorrelation was 0.829 between Behavioral Beliefs and Attitudes, and Normative Beliefs and Subjective Norms (0.777) on the Study Volunteerism outcome. However, these fell below the ≥ 0.85 estimate needed to combine redundant variables into one factor. Appendix C shows the correlation matrix among constructs for the three outcomes of interest.

Additional analyses of the eight domain composites and the three corresponding outcomes revealed the magnitude of the relationships among endogenous and exogenous variables. The results indicate low to moderate strength relationships among the exogenous and endogenous variables. Overall, it appears that the correlations are weakest on future attendance in comparison to the other outcomes. "Behavioral Beliefs" (0.243), "Normative Beliefs" (0.245), "Attitudes" (0.251), and "Personal Relevance" (0.277) are the strongest in comparison to others on attendance intention. This evidence of nearly identical strength among the "background variables" (i.e., beliefs) on endogenous variables (i.e., "Attitudes" and "Subjective Norms")

suggests a mediating role of these factors which is consistent with the theory. However, the stronger external variable correlation of 0.277 (i.e., "Personal Relevance") on attendance intention also indicates a more proximate relationship to the outcome. This effect would stand in contrast to the theorized mediating role of such variables on the endogenous TRA constructs as claimed by Ajzen and Fishbein (1980).

More robust associations are clearly evidenced on the community mobilization outcome with much stronger evidence of the role of the new exogenous involvement variables on intention (e.g., personal relevance = 0.485). In this case, "Behavioral Beliefs" exerts a stronger influence on the outcome, suggesting its mediating role on attitudes. With respect to the third outcome, moderately weaker correlations are also observed. The correlations indicated that "Outcome Evaluation" and "Motivation to Comply" had very weak, nonsignificant relationships with the outcomes.

Table 12: Composite Variable Correlation Matrix

	Attendance (N = 504)	Community Mobilization (N = 491)	Study Volunteerism (N = 486)
Behavioral Beliefs	0.243**	0.489**	0.339**
Outcome Evaluation	0.050	0.039	0.077
Motivation to Comply	-0.004	-0.077	-0.091*
Normative Beliefs	0.245**	0.387**	0.278**
Attitudes	0.251**	0.417**	0.253**
Subjective Norms	0.204**	0.393**	0.274**
Personal Relevance	0.277**	0.485**	0.345**
Organizational Involvement	0.195**	0.333**	0.293**
* Correlation is significant at the 0.05 level (2-tailed)			
** Correlation is significant at the 0.01 level (2-tailed)			

Confirmatory Factor Analysis

Confirmatory factor analysis is a deductive approach for "predicting an outcome from a theoretical framework" (Meyers, Gamst, Guarino, 2006, p. 548). With the proposed TRA model

as a basis for covariance evaluation, a confirmatory factor analysis using maximum likelihood estimation was undertaken to test the adequacy of the model measuring the underlying factors (Figure 2.3, page 56). Each latent construct (intentions, attitudes, subjective norms, behavioral beliefs, outcome evaluations, normative beliefs, personal relevance, and organizational involvement) was identified by its corresponding measured variables. One indicator per construct was fixed to define the scales of the indicators.

Results of the factor analysis generally support the validity of the constructs for all outcomes of interest. Factor loadings were consistent across all analyses with most items in the range of $\geq .450$ to $\leq .895$. The only low factor loading ($\leq .50$) across all three models was the attitude measure of HIV being a serious community concern. Appendix F details the item descriptive statistics and factor loadings for each outcome analysis.

The model estimation and fit measures indicate good matches between the predicted interrelationships between the hypothesized variables to the observed measures. The χ^2 values judge the overall fit of the models, with nonsignificance preferred to approximate little difference between the observed and predicted relationship. However, given sample size sensitivity concerns with the use of the chi square test, it is not advisable to use this statistic as a sole measure of absolute model fit (Bentler, 1990; Joreskog & Sorbom, 1989). As noted by Meyers, Gamst, and Guarino (2006), "the chi-square test can return a statistically significant outcome even when the model fits the data reasonably well" (p. 559) with a large sample size (≥ 200 cases). They add, "for models with more cases, chi square will usually be statistically significant, suggesting a poor fit when there really are only trivial differences between the model and the data" (Meyers, Gamst, & Guarino, 2006, p. 561). In addition to the chi square "absolute fit"

measure, relative fit statistics are also useful to compare independent (no relationships observed) and "saturated" (perfect fit) models.

Among the more widely used fit measures is the root mean square error of approximation (RMSEA) which analyzes the residual averages between the observed and expected covariance model values. As noted by Byrne (1998), the RMSEA is "one of the most informative criteria in covariance structure modeling" (p. 112) and is therefore suggested by others as a valuable measure for confirmatory factor analysis (Meyers, Gamst, & Guarino, 2006). Additionally, the use of the "comparative fit index" (CFI) is highly recommended as the "fit statistic of choice" (Meyers, Gamst, & Guarino, 2006, p. 560; Byrne, 1998). Adequate model fit is commonly judged at the $\geq .80$ threshold (Meyers, Gamst, & Guarino, 2006).

Table 13 details the fit statistics for all tested outcomes. With respect to the first model (attendance), the $\chi^2 = 2507.493$, $df=803$, $p=.000$ indicating the model fit was not a reasonable match. However, the root mean square error, RMSEA, resulted in a measure of .065 and the CFI was comparatively good (0.842). Similar statistics resulted from tests of the other models, with community mobilization resulting in $\chi^2 = 2583.161$, $df=803$, $p<.05$ (RMSEA = .067; CFI = 0.834) and the study volunteerism measures being $\chi^2 = 2582.154$, $df=803$, $p<.05$ (RMSEA = .068; CFI = 0.835). For complex model assessment, these multiple fit measures indicated sufficient support for the use of the eight-factor model in testing the relationships hypothesized to influence HIV vaccine community engagement outcomes (Appendix G).

Structural Model Analyses

The next set of findings refers to the causal model implied by the TRA. Table 13 provides estimates of standardized regression coefficients measuring relationships among the theoretical constructs. Standardized coefficients can be interpreted as standard deviation unit

changes in the outcome of interest for a unit change in its precursor. They also permit comparisons of the degree to which one variable influences another.

The pattern of significant and nonsignificant TRA path coefficients is similar across the three different measures of intention to engage in action around HIV research. Attitudes but not subjective norms had a positive affect on the likelihood of community mobilization (1.367), study volunteerism (1.013), and to a lesser extent, future attendance at HIV-related events (.328). Respondents' favorable attitudes about the importance of HIV vaccine trials were in turn shaped by their positive beliefs about their role in HIV research. The strength of the relationship was greater for beliefs linked to how respondents' viewed their own actions (e.g., .797 for the model with future attendance as the intention variable). Negative beliefs (defined as outcome evaluations) were not related to attitudes, except in the case of study volunteerism (.028). Normative beliefs and motivations to comply, however, were related to subjective norms. The effect of respondents' noncompliance to others wishes in general (e.g., "I would not want to do something my friends disapproved of") was linked to their subjective norms regarding participation in HIV research (e.g., "Most people important to me think I should participate in the HIV vaccine effort"). Nonconformity with others' expectations was evident across models (i.e., .108, .107, .096, respectively). Not surprisingly, normative beliefs about doctors' and colleagues' encouragement to participate were likely to be associated with positive judgments of others (i.e., 1.093, 1.071, 1.086, respectively). The pathways suggest that independent cognitive appraisal of the HIV vaccine effort has an effect on the formation of subjective norms. However, these are less likely to be influenced by compliance with normative pressure, and they are unlikely to shape intentions to participate in HIV research when other beliefs and attitudes are taken into account.

Table 13: SEM Maximum Likelihood Standardized Regression Coefficients of Endogenous Variables on Theory of Reasoned Action Covariates

		Dependent Variables				
Independent Variables		Future Attendance		Community Mobilization		Study Volunteerism
Attitudes		0.328*		1.367***		1.013***
Subjective Norms		0.047		0.111		0.038
Personal Relevance		0.183*		0.412***		0.177
Organizational Involvement		0.034		0.108		0.323*
Independent Variables	Attitudes	Subjective Norms	Attitudes	Subjective Norms	Attitudes	Subjective Norms
Behavioral Beliefs	0.797***	--	0.819***	--	0.806***	--
Outcome Evaluations	0.025	--	0.025	--	0.028*	--
Normative Beliefs	--	1.093***	--	1.071***	--	1.086***
Motivation to Comply	--	0.108***	--	0.107***	--	0.096***
Personal Relevance	0.027	--	0.031	--	0.035*	--
Organizational Involvement	--	0.108**	--	0.109**	--	0.093**
RMSEA	0.065		0.067		0.068	
CFI	0.842		0.834		0.835	
Chi-Square	2507.493		2583.161		2582.154	
N	504		491		486	
Note: * p < 0.05; ** p < 0.01; *** p < 0.001, 2-tailed tests						

The external variables, personal relevance and organizational involvement, added new dimensions to the understanding of the standard TRA model effects. Although attitudes exerted greater weight on future attendance intention (.328), the personal relevance of HIV vaccine volunteerism added a significant direct effect on the outcome (.183). Thus, with respect to future

attendance, the personal relevance of the cause did not mediate the attitudinal pathway effect. It stood as an independent effect on intention. Organizational involvement also realized a significant mediating effect on subjective norms; however, unlike personal relevance, it did not have a significant independent predictive value on behavioral intention.

With respect to community mobilization, personal relevance also resulted in a highly significant direct effect on intention. It also had a positive mediating effect on attitudes towards the HIV vaccine research endeavor. As with the attendance outcome, organizational involvement positively mediated subjective norms. However, its direct effect on the community mobilization outcome did not result in a significant correlation.

Finally, the effect of personal relevance on the study volunteerism outcome disappeared in favor of its mediating role on attitudes (.035). In contrast, organizational involvement increased in its effect on the outcome (.323), while maintaining an influence on subjective norms (.093). Therefore, the distinct patterns within the correlational models suggest varying pathways on decisional intention with respect to this cause.

Summary of Findings: Research Questions and Hypotheses

To address the AHVCC goals, this study was developed to understand the aggregate effect of multiple partnership-sponsored activities. The following questions informed the general aim of the inquiry:

1. Will the TRA and the external variables explain participatory intentions arising from the culture-centered HIV vaccine community engagement model?
2. Do the constructs vary according to outcome of interest within a structural equation model (SEM) context?

The results from this study support the explanatory potential of the modified TRA model within the realm of HIV vaccine community engagement. Therefore, both of the overarching research questions can be answered in the affirmative.

The theoretical model is a useful tool in predicting various intentions related to the cause. In contrast to our previous study (Frew, Archibald, del Rio et al., 2007), the model incorporated all theoretical variables proposed by Fishbein and Ajzen (1975), along with new external constructs drawn from marketing research, and it simultaneously measured the relative importance of each in predicting various intentions. The TRA "background variables" of behavioral and normative beliefs, along with motivation to comply, exhibited significant effects on endogenous variables, subjective norms and attitudes. Attitudes toward the three behavioral intentions was the most significant and consistent determinant among the models. External variables of personal relevance and organizational involvement also had significant mediating, and direct, influences on the outcomes. However, the effects differed with respect to each of the decisional outcomes.

Confirmatory factor analysis and structural equation models investigated the structural underlying beliefs, attitudes, normative referents, and involvement expectancies toward behavioral intentions. The specific hypotheses are therefore assessed as follows:

H1: *Beliefs and attitudes about HIV vaccines and medical research that favor participatory behavior will more likely lead to intentions to participate in future activities, generate greater community mobilization, and study volunteerism.*

H1 Result: Respondents' beliefs and attitudes toward the various outcomes had significant influences on their behavioral intentions. The more favorable the attitude toward HIV

vaccine research, the higher the intentions for each decisional situation. Therefore, hypothesis 1 is accepted.

H2: *Reduced personal concern and fear of health and social consequences will more likely result in greater participatory intention.*

H2 Result: Negative salient beliefs related to HIV vaccine volunteerism (i.e., outcome evaluations) resulted in nonsignificant values on the attitude domain for two of the three outcomes (i.e., attendance and community mobilization). With respect to study volunteerism, a significant mediating effect on attitude was realized. The other component of social consequences, "motivation to comply," resulted in highly significant pathway effects on subjective norms in all models. Therefore, hypothesis 2 is partially accepted.

H3: *Perception of subjective norm approval of involvement will favorably influence greater participatory intention toward HIV vaccine research.*

H3 Result: The subjective norm was not significantly related to intentions for all three of the models. Social pressure to become involved in HIV vaccine research did not increase the likelihood of participatory intention. Therefore, hypothesis 3 is rejected.

H4: *Greater organizational ("brand") involvement will favor participatory intentions.*

H4 Result: The organizational component of HIV vaccine research had a significant, and favorable, mediating influence on subjective norms. Respondents' who perceived a greater sense of identity in relation to the Hope Clinic "brand," were more likely to indicate favorable perception of support from normative influences. The direct effect of the variable on intention was realized only with respect to the third outcome (study volunteerism). Therefore, hypothesis 4 is partially accepted.

H5: *Greater personal relevance of HIV vaccine volunteerism will favorably influence participatory intention.*

H5 Result: The component factor reflecting the linkage to individual values, interests, and needs (personal relevance) had a significant direct influence on future attendance and on community mobilization intentions. With respect to study volunteerism, a significant mediating effect on attitudes was realized. Therefore, hypothesis 5 is partially accepted.

H6: An expanded TRA model will explain various HIV vaccine community engagement outcomes.

H6 Result: The factors realized consistent pathway effects across the outcomes with respect to behavioral beliefs on attitudes, attitudes on intentions, and normative beliefs, motivation to comply, and organizational involvement on subjective norms. Outcome evaluations, personal relevance, organizational involvement, and subjective norms experienced variance across outcomes of interest. Thus the components of the model experienced some instability. For these reasons, hypothesis 6 is partially accepted.

CHAPTER 5

DISCUSSION

This final chapter is organized into five main sections. Summary findings, discussion, and general study conclusions are presented first. These are followed by a review of limitations affecting the study's generalizability. Finally, implications for future research and practice are detailed at the end of this section.

Summary of Findings

This current study is significant because it utilizes an established behavioral theory (TRA) in predictive modeling of HIV vaccine community engagement. It augments the explanatory power of the theory with affective appraisal measures of HIV vaccine volunteerism and of the clinical trial site. This study specifically focused on the behavioral intentions of diverse participants with respect to various forms of HIV vaccine involvement. In this study, special emphasis has been placed on the engagement of women and minorities who are greatly affected by HIV/AIDS, and whose participation and support is needed within the realm of HIV vaccine research (Djomand, Katzman, di Tommaso et al., 2005; Moutsiakakis & Chin, 2007). Thus, the pilot study for instrument development included 212 participants, and the larger study included 542 persons, mostly female and non-White.

This study also adds to the literature with information gathered among those attending HIV vaccine-related events and activities. As favorable attitudes, perceptions, and beliefs are theorized to be critical predisposing factors influencing future behavioral outcomes (Ajzen, 1991; Fishbein & Ajzen, 1975; Maiman & Becker, 1974), these attendees have the potential, at a

minimum, to serve as allies in expanding needed social support for HIV vaccine research (Allen, Liang, Salvia et al., 2005). The results from this study offer evidence to reinforce this notion.

Specifically, this study extends our earlier findings on factors influencing community engagement formation (Frew, Archibald, del Rio et al., 2007; Frew, del Rio, Clifton et al., 2007) with the addition of theory-driven assessment of outcomes anticipated with targeted community approaches. Greater emphasis also was placed on obtaining good psychometric measures with strong internal consistency for all subscales to evaluate the explanatory power of the model in this realm. The results indicate achievement of this goal with the development of the "HIV Vaccine Community Engagement Questionnaire" (HVCEQ) used in this study.

The goal of the current study was to examine the Theory of Reasoned Action covariates impacting respondents' willingness to participate in HIV vaccine research. The study expands the model applicability and contributes to a better understanding of its predictability. Overall, the hypotheses were mostly supported, with the exception of subjective norms. By incorporating all six TRA variables along with two external affectively-oriented variables in one model, the relative importance was effectively determined. The findings suggest the importance of theoretical guidance in predicting community engagement outcomes.

Discussion

This study addressed the validity of using an established theoretical model in combination with new evaluative measures to predict various outcomes from a "culture-centered" community engagement program model in HIV vaccine research. This section details the study's findings with respect to the TRA constructs as well as the utility of the "involvement expectancy" factors that influence the various outcomes of the AHVCC endeavor.

Theory of Reasoned Action

As predicted, important relationships materialized among most of the TRA constructs especially those related to beliefs and attitudes. Overall, the model yields consistent effects with respect to the "chain of relations" previously observed on outcome predictions (Frew, Archibald, del Rio et al., 2007). In particular, belief in one's participation resulting in positive, concrete outcomes for the community, research, and HIV/AIDS. This was mediated through the attitude construct had a profound impact on the potential to mobilize the community for action (1.367) and participate in HIV vaccine trials (1.013). A lower attitudinal coefficient (.328) was obtained on future attendance, signifying the dynamic of reciprocal influence between individuals and the community context. That is, positive attitudes toward health research and, more specifically HIV vaccine research, may be subject to active evaluation by participants within the context of activity. Alternatively, preexisting attitudes could be activating intention motivation.

In contrast to previous studies examining willingness-to-participate among predominately minority populations (Corbie-Smith, Thomas, Williams et al., 1999; Newman, Duan, Roberts et al., 2006; Priddy, Cheng, Salazar et al., 2006) and among women (Mills, Nixon, Singh et al., 2006), logistical concerns relating to the formation of community engagement outcomes did not materialize on two of the outcomes. With respect to inconvenience, time constraints, risk perception, use of needles in studies, and false positive concerns, the items as related to the "outcome evaluation" construct, did not impact attitudes except with respect to study volunteerism. Given the orientation of the questions measuring the "Outcome Evaluation" construct, these findings are not surprising. These study volunteer-oriented concerns may not be salient with respect to future attendance or intention to mobilize one's community. Thus, the lack

of effect on attitudes may be more reflective of the limited scope of items ($n = 5$) which tapped the most critical concerns expressed in the WTP and acceptability literature.

Obviously, the relationship of subjective norms to intention was not significant in this study population. This finding is consistent with a previous HIV vaccine study that tested TRA effects (Gagnon & Godin, 2000) as well as our own (Frew, Archibald, del Rio et al., 2007). The result is not likely due to a manifestation of measurement issues or sample size concerns. The nonsignificant pathways between subjective norms to intention may instead represent a theoretical deviation. That is, negative normative influences may not causally impact community engagement outcomes. In contrast with other studies citing social harms (Francis, Heyward, Popovic et al., 2003; Fuchs, Durham, McLellan-Lemal et al., 2007) and negative social judgments (Koblin, Heagerty, Sheon et al., 1998) as barriers to participation, our nonsignificant finding suggests the possibility that our participants rejected the views of others in their decision-making. The choice to become involved may be intensely personal, rendering other social concerns as insignificant in comparison.

The findings suggest the possibility that those who become engaged in HIV vaccine research exhibit a degree of independent thinking on involvement in health research related to HIV/AIDS. It also may reflect ambivalence on the part of the study population. The relationship of motivation to comply on subjective norms resulted in significant pathway effects (.108-future attendance, .107-community mobilization, .096-study volunteerism). Moreover, approval of doctors, family, pastors, work colleagues, and others in HIV vaccine research significantly amplified positive normative opinion on involvement. Thus, it is likely that some general sense of support for health decision-making may promote involvement, but not required for the formation of participant intention.

It merits consideration that the emphasis that stronger attitudes may invoke greater psychological resiliency to withstand counterpersuasive norms. Within the AHVCC culture-centered context, situational conditions may favorably predispose individuals to resist negative normative pressure encountered with others. The perception among attendees may be of changing community norms with the active sponsorship and promotion of the functions by trusted community entities and key opinion leaders. Additionally, the AHVCC messages promote individual decision-making. That is, the consistent message from partners has been on getting involved, but doing what's personally suitable given individual circumstances. Future research may uncover the nature of and degree to which normative concerns are factored into health participation decisions.

Finally, it is useful to frame the TRA findings within a historical perspective to understand the community norms structuring the participant responses. Social networks arising from race and ethnicity powerfully construct the context in which knowledge, information, social experiences, attitude formation and sociopolitical action take place (McPherson, Smith-Lovin, & Cook, 2001; Putnam, 2000). Solidaristic networks generate a sense of trust and promote civic engagement based on concern for community (Knack, 2003). Thus, as applied in this study, the TRA model is useful in understanding how the social arrangement of minority communities impact individual decision-making.

Central to this notion is collective protection motivation. The study findings indicate that social forces are shaping attitudes. These can be characterized as significant short-term effects respective to the outcomes. However, normative concerns related to medical mistreatment are deeply embedded within the culture and they may be more resistant to change. This is especially true for African American communities. Thus, a collective norm of mistrust and suspicion within

these communities may be temporally sensitive. Therefore, it may be precluding the simultaneous realization of normative shifts within the TRA model.

Involvement Expectancies

According to TRA, intentions are formed based on cognitive operational sequences (Albarracin & Wyers, 2000). The role of affect in "reasoned" decision-making is also evidenced in the literature with respect to clinical trials, HIV/AIDS, and HIV vaccine research (Colfax, Buchbinder, Vamshidar et al., 2005; Curbow, Fogarty, McDonnell et al., 2006; Frew, del Rio, Clifton et al., 2007; Igartua, Cheng, & Lopes, 2003; Verheggen, Nieman, & Jonkers, 1998). A criticism of the TRA model is that it does not contain a mechanism to directly assess affective "involvement" in decision-making (Fitzmaurice, 2005). However, the literature clearly indicates the important role of affective appraisal and emotion as causal constructs in acceptance or rejection of behavior-related messages in the clinical trials realm (Curbow, Fogarty, McDonnell et al., 2006). Within a persuasive communication context, the promotion of favorable attitudes and expectancies may ensue (Albarracin & Kumkale, 2003; Albarracin, McNatt, Klein et al., 2003).

A call has been made for greater "consumer-oriented" evaluation of community engagement in HIV vaccine research with comprehensive scientific inquiry on decisional determinants (Newman, 2006). Taking a cue from market researchers who have incorporated new variables into the TRA framework, this study similarly explored the interchange of affective and cognitive appraisal in a complex "purchase decision" environment (Xu, Summers, & Belleau, 2004). Scales were adapted to measure the motivational influence of affect, resulting in varying effects across the outcomes.

With respect to future attendance, the personal relevance of health research volunteerism (.183), in combination with attitudes (.328), has significant and direct effects on intention. These effects increased in relative weight on the community mobilization outcome. It is important to note that, in contrast to Ajzen and Fishbein's assertion, this affective evaluation domain did not mediate through attitudes. Thus, the benefit of volunteerism is perceived as being of independent value in the decisional calculus. The importance afforded to empowerment, inclusion, advocacy, liberation, self-purpose, and well-being of the community (factors associated with HIV vaccine volunteerism) are given special consideration by participants. These contrast with general attitudes on altruism ("doing good for others"), health research benefits (medical care and HIV testing), the perceived severity of HIV/AIDS in the community, and other behavioral beliefs related to HIV vaccine research. These ideas are promoted by the AHVCC. Therefore, affective response to the perceived "latent characteristics" of HIV vaccine volunteerism resonated with this study population.

In contrast to these effects observed on the first two outcomes, a decisional adjustment was made on study volunteerism with respect to the role of personal relevance in favor of organizational involvement. While the direct path from attitudes to intention remained robust, the effect of organizational involvement was realized. Personal relevance disappeared as a direct effect in this context. Affective response in the form of a positive attribution given to the site (i.e., "brand"), resulted in greater likelihood of study volunteerism. This finding corresponds with the literature on role of heuristic evaluation of physicians, clinical trial sites, and HIV vaccine communication campaigns in decisional processes (Curbow, Fogarty, McDonnell et al., 2006; Frew, Macias, & Harding, 2008; Verheggen, Nieman, & Jonkers, 1998).

In the consumer mindset, entities that are perceived to be honest, altruistic, competent, and reliable are favored (Hupp & Powaga, 2004; Mangini, 2002). Previous work on clinical trials acceptance provided evidence that study participation may not be "based on nonrational factors" (Curbow, Fogarty, McDonnell et al., 2006, p. 215). Others have found that "The patient's preference for university hospitals over general hospitals also has a substantial indirect effect on trial participation. Participants with high trust in university hospitals will expect higher personal comfort in the trial..." (Verheggen, Nieman, Jonkers, 1998, p. 121).

This study similarly found that favorable attribution toward the site clearly shape expectations toward volunteerism. Involvement with the site is regarded as a form of self-expression. Participatory behavior is also perceived as garnering social approval. Thus the findings are supportive of previous work that has linked site attributes to volunteerism (Verheggen, Nieman, & Jonkers, 1998).

Within the HIV vaccine context, the "mental picture" associations with study sites develop through ongoing involvement and visible presence of the research effort in the community (Brown-Peterside, Chiasson, Ren et al., 2000; Colfax, Buchbinder, Vamshidar et al., 2005). Through intensive "on-the-scene" AHVCC activity, the study also highlights the importance of persuasive communication in promoting favorable opinion of "source characteristics" such as the site being perceived as "being responsive, respectful, and caring" (Curbow, Fogarty, McDonnell et al., 2006, p. 215). The degree of reliance on AHVCC message cues in the attribution evaluation process merits additional research. Given the sizeable proportion of participants who were newly introduced to the clinic's concept in the field setting, the nature of affective appraisal is unclear and should be subjected to further scrutiny.

Limitations

Findings are limited by several factors, including the inherent limitations of a cross-sectional study design. The design does not allow for causal conclusions to be drawn. The study was concerned with relational modeling of various theoretical constructs thereby only allowing for covariant evaluation. Additionally, the venues where the participants were recruited may have resulted in bias. Clearly, the people attending AHVCC functions may have already had a vested interest in HIV/AIDS or the HIV vaccine cause. The use of a small purposive sample consisting of primarily minority women may not be representative of others attending AHVCC functions. Consequently, generalizability is limited to mostly non-White women who attend AVHCC events and activities and volunteer to participate in survey research. The results therefore cannot be generalized to all groups.

Instrument changes were made subsequent to pilot testing of the HVCEQ. Although the resulting subscale internal consistencies appeared to improve with the study sample, the adjustments could have altered the reliability and validity of the HVCEQ. Additionally, items were developed from existing TRA scales, marketing instruments, and were informed via a review of the literature. They may not be ideally representative of the latent constructs of interest to this study. Despite these potential issues, confirmatory factor analyses indicated good respective loadings of items on various constructs. Cronbach's alpha measures were suggestive of good internal consistencies across scales, even with mean multiple imputation application.

An important limitation is that intent may not be strongly associated with future participatory behavior. It should also be noted that participation bias in a study of HIV vaccines and health behaviors is particularly likely (i.e., it is conceivable that people having strong beliefs and attitudes on HIV vaccine research may be the least inclined to complete the study

questionnaire). Thus, even though the study achieved a response rate of approximately 90%, participation bias may have affected the results. This may be especially important for low-literacy or non-English speaking populations who did not have the opportunity to complete the questionnaire. Additionally, given that data collection occurred in the noncontrolled field setting, testing variations may have occurred. Interferences may have therefore occurred outside of investigative control that may threaten the validity of the data.

Finally, as with any self-administered questionnaire, self-reported data may not be entirely accurate and therefore, should be viewed with caution. However, it is not anticipated that any of these limitations resulted in large or systematic errors in data collection.

Conclusions

This study is one of the few "consumer-oriented" community engagement investigations addressing HIV vaccine research. The analyses from this study revealed differences in the pathway influences to various intentions. The results from this study indicate the importance of favorable beliefs and attitudes toward health research among AHVCC attendees. Attitudes are clearly an important predictor of future behavioral intention for all outcomes of interest in this study. The behavioral belief and attitude constructs yielded strong intentions related to community mobilization and study volunteerism intent. The external variable of "personal relevance" resulted in significant direct effects on future attendance and community mobilization. Thus, the latent characteristics associated with future personal or community-level involvement resonate with this population. An additional finding of the significance of organizational involvement suggests the importance afforded to the clinical trial site in study volunteer decision-making. This result suggests that first impressions or previous interactions with the site may be used as a heuristic for decision-making on study volunteerism.

Surprisingly, positive normative pressure had no effect on intentions. Despite this finding, there is powerful evidence of self-deterministic thinking and appraisal of perceived normative support in relation to these influences. Additionally, organizational involvement also influences subjective norms, thus signaling potential ambiguity in the appraisal of normative concerns. The present research also points to the valuable benefit of theory-driven inquiry, yet it also highlights its limitations in understanding a complex array of relationships between the individual and his/her environment.

Implications for Research and Practice

The findings from this study indicate the importance of future research on HIV vaccine community engagement. Additional programmatic recommendations can also be offered to others in the field.

Future Research

The endeavor of HIV vaccine research requires the sustained commitment and support of the global population. Since very little is known about the development and formation of community engagement within this context, a primary goal of future research is to gain greater familiarity with its role. New research could explore additional theoretical dimensions, individual-, community-, and societal-level differences impacting its role in motivating people to action on this cause. Given the current situation in which a highly anticipated vaccine proved a recent failure, it would be useful to measure public opinion at community engagement functions. This would shed light on changes in engaged population viewpoints over time as products in testing phases reach milestones of success or failure. Moreover, this type of design would be beneficial in assessing organizational involvement and its perceived attributes. This would offer

a gauge on the level of trust and confidence in the entity built by the partnership collective, particularly in times when the vaccine research agenda is challenged.

Additional exploration of other "culture-centered" models developed across contexts would be highly beneficial in furthering understanding of the intersectional influences of persuasive communication and socio-ecological dynamics on individual behavior. It would also be helpful to gauge the extent of community engagement programming within various geographic locales where HIV incidence and prevalence are greatest. Additionally, targeted engagement efforts within communities outside of urban centers without HIV vaccine clinical research sites warrant further investigation (e.g., rural Southern communities). This may inform our nascent understanding of the interaction of situational, cultural, and psychosocial variables in community settings where HIV/AIDS are heavily stigmatized and resources not given to community engagement.

In this study, intentions were evaluated. A body of research has demonstrated that intentions are good predictors of future behavior (Ajzen & Fishbein, 1980; Albarracin & Wyers, 2000; Halpern, Metzger, Berlin et al., 2001). However, it would be highly beneficial to the field to examine the role of intentions to behavior among HIV vaccine attendees. This would offer additional insight on the factors which are truly motivating on achievement of each of the outcomes of interest. Thus, a longitudinal cohort design would be beneficial. Further testing of the HVCEQ would also improve its validity and reliability with multiple population samples.

In this study, the influence of attitudes resulted in significant effects for all of the tested outcomes. However, cognitive and situational factors may alter attitude toward behavior, highlighting the role of affect in the decision-making continuum (Albarracin & Wyers, 2000). Previous persuasive communication studies have shown that when people have time to consider

message content, greater cognitive appraisal influences attitudes and subsequent behavior. Within the highly stimulating community engagement setting, it is possible that people are distracted from careful message evaluation. In these situations, affective appraisal may be responsible for informing attitude (Albarracin & Wyers, 2000). Thus future research could explore the mechanisms of cognitive and affective processing with respect to HIV vaccine message evaluation in a more controlled environment.

Programmatic Recommendations

The findings from this study may inform HIV vaccine community engagement programming for various audiences. The body of research dedicated to inquiry may assist with the development of effective community engagement models.

Targeted Model

Although HIV/AIDS is a health issue that affects the global population, the results from this study suggest that priority populations can be effectively engaged in HIV vaccine research. Sponsored functions using a culture-centered format and conducted within community venues realized attendance of women and minorities. Therefore, the role of the partners in identifying appropriate spokespersons, locations, scheduling, and type of activity for each targeted group is beneficial to the engagement of diverse segments.

Partnerships

The findings have additional programmatic implications for the initiation of community engagement via a coalition of partnership organizations. Although the various agencies formed a collective to promote HIV vaccine research in their respective communities, the organizations have well-established track records in offering health promotion functions and services for public health problems. Therefore, each entity has its own view of the health issues faced by the

populations they serve. Recognition of HIV/AIDS as an important issue signifies a normative concern for each entity. In bringing HIV vaccine research to the agency agenda, the importance of new prevention options to reduce HIV transmission is signified. With experience in building trusting relations among their respective communities, the partners therefore bring enormous credibility to the endeavor. Thus, agencies with stable histories in the community and for whom HIV prevention is a concern are ideal allies for collective collaborative action.

Additionally, relationships to the collective's spearheading organizations are important in building a strong programmatic structure. The AVHCC entities all formed relationships to the Hope Clinic and/or SisterLove prior to activity planning and implementation. Thus, an understanding of the respective organizational roles and programmatic objectives allowed for effective partnership action with clear conceptualizations of goals. Foundational efforts given to partnership development therefore have longer term value in promoting synergy among multiple organizations. Ongoing dialogue between and among agencies and evaluation of expectations is highly beneficial to collaborative success.

Health Communication

The key role of positive attitude on the outcomes also highlights the importance of effective health communication. More specifically, the function of grassroots, community-generated interpersonal networks of communication are of interest to this study in comparison to "top-down" social marketing approaches. William Smith (2002) identified four markers of health communication effectiveness including strategy, execution, measurement, and expectation. Each of these "best practices" elements has been explored in this study.

Communication efforts depend on solid structural foundations. Under this rubric is the provision of services and programs to address the needs of target populations (Smith, 2002). If

this element of "strategy" is not in place prior to the development and delivery of communication strategies, messages will fail. Therefore, the AHVCC partnership was created with entities that delivered essential programs and services in their communities. This strategic decision facilitated the development of a partnership structure which would augment existing community apparatus, not take the place of community assistance provisions or compete for fundamental resources.

The second element of "execution" involves assessment of determinants of behaviors, message design, and exposure. Within this domain, communication can be compromised if the efforts are not aligned with behavioral outcomes of interest. More specifically, the use of theoretically-based inquiry has been of value in setting program objectives. The key AHVCC organizing agencies, the Hope Clinic and SisterLove, have recognized the importance of identification of positive influencers on behavioral outcomes. As such, the organizations focused on setting an agenda with favorable attitude and normative change as priority and positive attribution afforded to the relevance of HIV vaccine volunteerism through direct involvement with clinical research. With this in place, the AHVCC was positioned to address the critical determinants of effective community engagement in a variety of contexts.

If messages are poorly constructed or fail to gain adequate exposure, these elements of "execution" can also compromise communication program success. The value of "culture-centered" approaches is evidenced by this study's findings. With messages informed by behavioral research with women and minorities, and extensive experience in various community settings, the AHVCC messages were tailored for the specific audiences. Moreover, a body of formative research and consultation with community members on messages assisted in the honing processes. As a result, the specific emphasis of the AHVCC messages has been on the articulation of the role of women and minorities in the realization of ethical oversight (i.e.,

participation on CABs, IRBs, etc.), improving community trust (e.g., increases in study participation rates), and the value of new prevention technologies in achieving a reduction in HIV/AIDS incidence. Additionally, with consistent, intensive communication efforts in the community, adequate exposure to the messages was achieved. Thus, the overall findings from this study on the attitude construct suggest that the persuasive messages have been internalized and have, in varying degree, positively affected the attitude-intention relationship.

Inadequacy of measures can also result in communication failure. As noted by William Smith (2002) instruments can measure wrong changes or fail to capture communication effects over time. Thus, instruments must be sensitive to long-term strategy. In this study, careful consideration was given to the development of an instrument (HVCEQ) with adequate psychometric properties for ongoing investigation of community engagement outcomes. Emphasis was placed on measuring the behavioral determinants implied by the TRA and corresponding external variables. Therefore, the instrument was useful in theoretical assessment and was developed to measure AHVCC changes for the duration of the funding cycle (2007 – 2009).

Finally, expectations of planners and funders impact the determination of communication success. The complex nature of HIV vaccine research promotion must account for the intersecting issues of HIV/AIDS, clinical trials, and vaccines. Each of these areas is fraught with controversies and passionate convictions on behalf of individuals and communities. The recognition that promotion of HIV vaccine research is a difficult, highly-charged endeavor is therefore critical to the success of communication and program efforts.

Realization of changes in attitudes, normative concerns, and embracement of the cause necessitates sustainable action to detect changes over time. Thus, the AHVCC agencies set forth

a realistic agenda of long-term communication goals and objectives to change deeply held beliefs, attitudes, and concerns in the community. The allocation for the three year period (2007 to 2009) similarly reflects the commitment on behalf of funders to assess communication changes. Although this study captured "baseline" measures, the study revealed important influences on achievement of various outcomes. Thus, the investment in the grassroots, "culture-centered" AHVCC model will yield valuable information for future community engagement endeavors.

REFERENCES

- Aggleton, P. (1997). Behavior change communication strategies. *AIDS Education and Prevention*, 9(2), 111-123.
- Aggleton, P. (1998). What works best? *AIDS Action*, 39, 2.
- AIDS at 25. (2006). *AIDS at 25: An overview of the major trends in the US epidemic*. Retrieved July 20, 2006, 2006
- Airhihenbuwa, C. (1995). *Health and culture: Beyond the Western paradigm*. Thousand Oaks, CA: Sage Publications.
- Ajzen, I. (1991). The theory of planned behavior. *Organizational Behavior and Human Decision Processes*, 50, 179-211.
- Ajzen, I., & Fishbein, M. (1980). *Understanding attitudes and predicting behavior*. Englewood Cliffs, NJ: Prentice-Hall.
- Ajzen, I., & Madden, T. J. (1986). Prediction of goal-directed behavior: attitudes, intentions, and perceived behavioral control. *Journal of Experimental Social Psychology*, 22, 453-474.
- Albarracin, D., & Kumkale, G. T. (2003). Affect as information in persuasion: A model of affect identification and discounting. *J Personality and Social Psychology*, 84(3), 453-469.
- Albarracin, D., McNatt, P. S., Klein, C. T. F., & Ho, R. M. (2003). Persuasive communications to change actions: An analysis of behavioral and cognitive impact in HIV prevention. *Health Psychology*, 22(2), 166-177.
- Albarracin, D., & Wyers, R. S. (2000). The cognitive impact of past behavior: Influences on beliefs, attitudes, and future behavioral decisions. *J Personality and Social Psychology*, 79(1), 5-22.

- Allen, M., Liang, T., Salvia, T., Tjugum, B., Gulakowski, R., & Murguia, M. (2005). Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. *Journal of Acquired Immune Deficiency Syndrome*, 40(5), 617-624.
- Altman, L. K., & Pollack, A. (2007, September 22). Failure of Vaccine Test is Setback in AIDS Fight. *New York Times*.
- Anderson, R., & Hanson, M. (2005). Potential public health impact of imperfect HIV type I vaccines. *J. Infectious Diseases*, 191(1), S86-S96.
- Aral, S., & Wasserheit, J. (1995). Interactions among HIV, other sexually transmitted diseases, socioeconomic status, and poverty in women. In A. O'Leary & L. Jemmott (Eds.), *Women at Risk: Issues in the Primary Prevention of AIDS* (pp. 13-42). New York, NY: Plenum Press.
- Arbuckle, J. L. (2006). *Amos 7.0 User's Guide*. Chicago: SPSS.
- Bagozzi, R. P., Lee, K., & Van Loo, M. F. (2001). Decisions to donate bone marrow: The role of attitudes and subjective norms across cultures. *Psychology & Health*, 16, 29-56.
- Bargh, J. A. (2002). Losing consciousness: Automatic influences on consumer judgment, behavior, and motivation. *J. Consumer Research*, 29, 280-286.
- Baylor, N. W., & Midthun, K. (2004). Regulation and testing of vaccines. In S. A. Plotkin & W. A. Orenstein (Eds.), *Vaccines* (4th ed., pp. 1539-1556). Philadelphia: Elsevier.
- Bentler, P. M. (1990). Comparative fit indexes in structure of models. *Psych Bulletin*, 107, 238-246.
- Berkley, S. F., & Koff, W. C. (2007). Scientific and policy challenges to development of an AIDS vaccine. *The Lancet*, 370, 94-101.
- Blanchard, C. M., Courneya, K.S., Rodgers, W.M., & Murnaghan, D.M. (2002). Determinants of exercise intention and behavior in survivors of breast and prostate cancer: An application of the theory of planned behavior. *Cancer Nursing*, 25(2), 88-95.

- Blue, C. L., Wilbur, J., & Marston-Scott, M. (2001). Exercise among blue-collar workers: Application of the theory of planned behavior. *Research in Nursing & Health*, 24, 481-493.
- Boulware, L. E., Ratner, L. E., & Cooper, L. A. (2002). Understanding disparities in donor behavior: Race and gender differences in willingness to donate blood and cadaveric organs. *Med Care*, 40(2), 85-95.
- Bracht, N. (2001). Community partnership strategies in health campaigns. In R. E. Rice & C. K. Atkin (Eds.), *Public Communication Campaigns* (3rd ed., pp. 323-342). Thousand Oaks, CA: Sage.
- Breckler, S. J. (1990). Applications of covariance structure modeling in psychology: Cause for concern? *Psych Bulletin*, 107, 260-273.
- Brown-Peterside, P., Chiasson, M. A., Ren, L., & Koblin, B. A. (2000). Involving women in HIV vaccine efficacy trials: lessons learned from a vaccine preparedness study in New York City. *Journal of Urban Health*, 77(3), 425-437.
- Brown-Peterside, P., Rivera, E., Lucy, D., Slaughter, I., Ren, L., Chiasson, M., et al. (2001). Retaining hard-to-reach women in HIV prevention and vaccine trials: Project ACHIEVE. *American Journal of Public Health*, 91(9), 1377-1379.
- Brown, T. A. (2006). *Confirmatory Factor Analysis for Applied Research* (1st ed.). New York: Guilford Press.
- Buchbinder, S., Metch, B., Holte, S., Scheer, S., Coletti, A., & Vittinghoff, E. (2004). Determinants of Enrollment in a Preventive HIV Vaccine Trial: Hypothetical Versus Actual Willingness and Barriers to Participation. *J Acquir Immune Def Syndr*, 36(1), 604-612.
- Butterfoss, F. D., Goodman, R. M., & Wandersman, A. (1996). Community coalitions for prevention and health promotion: Factors predicting satisfaction, participation, and planning. *Health Education Quarterly*, 23(1), 65-79.
- Byrne, B. M. (1998). *Structural equation modeling with LISREL, PRELIS, and SIMPLIS: Basic concepts, applications, and programming*. Hillsdale, NJ: Erlbaum.

- CDC. (1996). Ten great public health achievements - United States, 1900-1999. *Morbidity and Mortality Weekly Report*, 48(12), 241-243.
- CDC. (2003). Advancing HIV prevention: New strategies for a changing epidemic - United States, 2003. *Morbidity and Mortality Weekly*, 52, 329-332.
- CDC. (2006a). Epidemiology of HIV/AIDS - United States, 1981-2005. *MMWR*, 55(21), 589-592.
- CDC. (2006b). Racial/ethnic disparities in diagnoses of HIV/AIDS--33 states. *MMWR Morbid Mortal Wkly Rep.*, 55, 121-125.
- CDC. (2006c). Twenty-Five Years of HIV/AIDS - United States, 1981-2006. *MMWR*, 55(21), 585-589.
- CDC. (2007). HIV/AIDS Surveillance Report. Rev ed. Atlanta: US Department of Health and Human Services. 17, 1-54.
- CDC/ATSDR. (1997). *Principles of Community Engagement* (1st ed.). Atlanta, GA: US Dept. Health and Human Services.
- Chase, M., & Schoofs, M. (2007). AIDS effort suffers big blow as Merck vaccine fails. *Wall Street Journal*.
- Colfax, G., Buchbinder, S. P., Vamshidar, G., Celum, C., McKirnan, D., Neidig, J., et al. (2005). Motivations for participating in an HIV vaccine efficacy trial. *J Acquir Immune Def Syndr*, 39(3), 359-364.
- Corbie-Smith, G., Thomas, S. B., & Marie, D. (2002). Distrust, race, and research. *Arch Intern Med*, 162, 2458-2463.
- Corbie-Smith, G., Thomas, S. B., Williams, M. V., & Moody-Ayers, S. (1999). Attitudes and beliefs of African Americans toward participation in medical research. *Journal of General Internal Medicine*, 14, 537-546.
- Cox, W. M., & Blount, J. P. (2000). Motivational predictors of readiness to change chronic substance abuse. *Addiction Research*, 8, 121-129.

- Crawley, L. (2001). African American participation in clinical trials: Situating trust and trustworthiness. *Journal of the National Medical Association*, 93, 7S-14S.
- Crosby, R. A., Holtgrave, D. R., Bryant, L., & Frew, P. M. (2004a). Correlates of negative intent to receive an AIDS vaccine: An exploratory study. *Int J STDs & AIDS*, 14, 552-557.
- Crosby, R. A., Holtgrave, D. R., Bryant, L., & Frew, P. M. (2004b). Factors associated with the acceptance of an AIDS vaccine: an exploratory study. *Preventive Medicine*, 39(4), 804-808.
- Crotty, M. (2003). *The Foundations of Social Research: Meaning and Perspectives in the Research Process*. London: Sage.
- Crumbo, C., Rybczyk, G., & Wagner, L. (1997). Characteristics of volunteer participants in phase I HIV vaccine trials. *Journal of the Association of Nurses in AIDS Care*, 8(5), 59-65.
- Curbow, B., Fogarty, L. A., McDonnell, K. A., Chill, J., & Scott, L. B. (2006). The role of physician characteristics in clinical trial acceptance: Testing pathways of influence. *J Health Communication*, 11, 199-218.
- D'Cruz, O., & Uckun, F. (2004). Clinical development of microbicides for the prevention of HIV infection. *Curr Pharm Des*, 10(3), 315-336.
- Davis, C., & Randhawa, G. (2006). The influence of religion on organ donation and transplantation among the Black Caribbean and Black African population--a pilot study in the United Kingdom. *Ethn Dis*, 16(1), 281-285.
- Dickert, N., & Sugarman, J. (2005). Ethical goals of community consultation in research. *Am J Public Health*, 95, 1123-1128.
- Djomand, G., Katzman, J., di Tommaso, D., Hudgens, M. G., Counts, G. W., Koblin, B. A., et al. (2005). Enrollment of racial/ethnic minorities in NIAID-funded networks of HIV vaccine trials in the United States, 1988 to 2002. *Public Health Reports*, 120(5), 543-548.
- Duerr, A., Wasserheit, J. N., & Corey, L. (2006). HIV Vaccines: New Frontiers in Vaccine Development. *Clin Inf Disease*, 43(4), 500-511.

- Dutta-Bergman, M. J. (2005). Theory and practice in health communication campaigns: A critical interrogation. *Health Communication, 18*(2), 103-122.
- Eagly, A. H., & Chaiken, S. (1993). *The psychology of attitudes*. Fort Worth, TX: Harcourt Brace Jovanovich.
- Esparza, J., Chang, M.-L., Widdus, R., Madrid, Y., Walker, N., & Ghys, P. D. (2003). Estimation of "needs" and "probable uptake" for HIV/AIDS preventive vaccines based on possible policies and likely acceptance (a WHO/UNAIDS/IAVI study). *Vaccine, 21*(17-18), 2032-2041.
- Excler, J. L. (2005). AIDS vaccine development: Perspectives, challenges & hopes. *Indian J Med Res, 121*(4), 568-581.
- Fishbein, M., & Ajzen, I. (1975). *Belief, attitude, intention, and behavior*. Menlo Park, CA: Addison-Wesley.
- Fitzmaurice, J. (2005). Incorporating consumers' motivations into the Theory of Reasoned Action. *Psychology & Marketing, 22*(11), 911-929.
- Flannery, B. (2004). Impact of childhood vaccination on racial disparities in invasive *Streptococcus pneumoniae* infections. *Journal of the American Medical Association, 291*(18), 2197-2203.
- Fleischman, A. R. (2007). Community engagement in urban health research. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*.
- Fowler, F. J. (2002). *Survey Research Methods* (3rd ed. Vol. 1). Thousand Oaks: Sage Publications.
- Francis, D. P., Heyward, W. L., Popovic, V., Orozco-Cronin, P., Orelind, K., Gee, C., et al. (2003). Candidate HIV/AIDS vaccines: Lessons learned from the world's first phase III efficacy trials. *AIDS, 17*(2), 147-156.
- Frew, P. M. (2005). 'Real People, Real Progress': Improving HIV vaccine awareness & knowledge through integrated community education. *Health Education & Behavior, 32*(1), 8-9.

- Frew, P. M., Archibald, M., del Rio, C., Martinez, N., & Mulligan, M. (2007). Promoting HIV Vaccine Research in the African American Community: Does the Theory of Reasoned Action Explain Potential Outcomes of Involvement? *Challenge: The Journal of African American Men*.
- Frew, P. M., Crosby, R. A., Salazar, L. F., Gallinot, L., Bryant, L. O., & Holtgrave, D. R. (2008). Acceptance of an HIV/AIDS vaccine among minority women. *J National Medical Assn*, in press.
- Frew, P. M., del Rio, C., Clifton, S., Hormes, J., & Mulligan, M. J. (2007). *Factors influencing HIV vaccine community engagement in the urban South*. Paper presented at the AIDS Vaccine 2007.
- Frew, P. M., Macias, W., & Harding, A. C. (2008). In "Step" with HIV vaccines?: A content analysis of recruitment campaigns for an international HIV vaccine study. *J. Health and Mass Communication*, in press.
- Fuchs, J., Durham, M., McLellan-Lemal, E., Vittinghoff, E., Colfax, G., Gurwith, M., et al. (2007). Negative social impacts among volunteers in an HIV vaccine efficacy trial. *JAIDS*, 47(3), 1-7.
- Gagnon, M. P., & Godin, G. (2000). Young adults and HIV vaccine: Determinants of intention of getting immunized. *Canadian Journal of Public Health*, 91, 432-434.
- Gallo, R. C. (2005). The end or the beginning of the drive to an HIV-preventive vaccine: a view from over 20 years. *Lancet*, 366(9500), 1894-1898.
- Gamble, V. (1997). Under the shadow of Tuskegee: African Americans and health care. *Am J Public Health*, 87, 1773-1778.
- George, D., & Mallery, P. (2003). *SPSS for Windows step by step: A simple guide and reference 11.0 update* (4th ed.). Boston: Allyn & Bacon.
- Gorsuch, R. L. (1983). *Factor Analysis*. Hillsdale, NJ: Lawrence Erlbaum Associates.
- Green, L. W., George, M. A., Daniel, M., Frankish, C. J., & Herbert, C. J. (1995). *Study of participatory research in health promotion*. Vancouver: University of British Columbia, Royal Society of Canada.

- Green, L. W., & Mercer, S. L. (2001). Can public health researchers and agencies reconcile the push from funding bodies and the pull from communities? *American Journal of Public Health*, 91, 1926-1929.
- Hadi, A. (2001). Promoting health knowledge through micro-credit programme: Experience of BRAC, Bangladesh. *Health Promotion International*, 16, 219-227.
- Hair, J. F., Anderson, R. E., Tatham, R. L., & Black, W. C. (1998). *Multivariate data analysis* (5th ed.). Upper Saddle River, NJ: Prentice Hall.
- Halpern, S. D., Metzger, D. S., Berlin, J. A., & Ubel, P. A. (2001). Who will enroll? Predicting participation in a phase II AIDS vaccine trial. *Journal of Acquired Immune Deficiency Syndromes*, 27(3), 281-288.
- Hatch, J., Moss, N., Saran, A., Presley-Cantrell, L., & Mallory, C. (1993). Community research: Partnerships in Black communities. *Am J Prev Med*, 16(3), 27-31.
- Hennessy, M., MacQueen, K., McKirnan, D., Buchbinder, S., Judson, F., Douglas, J. M., et al. (1996). A factorial survey study to assess the acceptability of HIV vaccine trial designs. *Controlled Clinical Trials*, 17, 209-220.
- Hupp, O., & Powaga, K. (2004). Using consumer attitudes to value brands: Evaluation of the financial value of brands. *Journal of Advertising Research*, 225-231.
- IAVI. (2007, November 13, 2007). Ongoing Trials of preventive AIDS vaccine candidates. Retrieved November 16, from <http://www.iavireport.org/specials/OngoingTrialsofPreventiveHIVVaccines.pdf>
- Igartua, J. J., Cheng, L., & Lopes, O. (2003). To think or not to think: Two pathways towards persuasion by short films on AIDS prevention. *J Health Communication*, 8, 513-528.
- IOM. (2003). *Exploring Challenges, Progress, and New Models for Engaging the Public in the Clinical Research Enterprise*. Washington DC: Institute of Medicine of the National Academics.
- Israel, B. A., Schulz, A. J., Parker, E. A., & Becker, A. B. (1998). Review of community-based research: Assessing partnership approaches to improve public health. *Annual Review of Public Health*, 19, 173-202.

- Janssen, R., Holtgrave, D. R., & Valdiserri, R. (2001). The serostatus approach to fighting the HIV epidemic: Prevention strategies for infected individuals. *American Journal of Public Health, 91*, 1019-1024.
- Jemmott, L., Catan, V., & Nyamathi, A. (1995). African American women and HIV-risk-reduction issues. In A. O'Leary & L. Jemmott (Eds.), *Women at Risk: Issues in the Primary Prevention of AIDS* (pp. 131-158). New York, NY: Plenum Press.
- Jenkins, R., Chinaworapong, S., Morgan, P., Ruangyuttikarn, C., Sontirat, A., Chiu, J., et al. (1998). Motivation, recruitment, and screening of volunteers for a phase I/II HIV preventive vaccine trial in Thailand. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 18*(2), 171-177.
- Jones, L. W., Sinclair, R.C., Rhodes, R.E., & Courneya, K.S. (2004). Promoting exercise behavior: An integration of persuasion theories and the theory of planned behavior. *British Journal of Health Psychology, 9*, 505-521.
- Joreskog, K. G., & Sorbom, D. (1989). *LISREL 7: A guide to the program and applications* (2nd ed.). Chicago: Scientific Software.
- Kaiser Family Foundation. (2007). *HIV/AIDS Policy Fact Sheet: Black Americans and HIV/AIDS*. Washington, D.C.
- King, W. (2003). Examining African Americans' mistrust of the health care system: Expanding the research question. *Public Health Reports, 118*, 366-370.
- Kiwanuka, N., Robb, M., Kigozi, G., Birx, D., Philips, J., Wabwire-Mangen, F., et al. (2004). Knowledge about vaccines and willingness to participate in preventive HIV vaccine trials. *J Acquir Immune Def Syndr, 36*(2), 721-725.
- Kline, R. B. (2005). *Principles and Practice of Structural Equation Modeling* (2nd ed.). New York: Guilford Press.
- Knack, S. (2003). Groups, growth and trust: Cross-country evidence on the Olson and Putnam hypotheses. *Public Choice, 117*(3-4), 341-355.
- Knight, G. P., Virdin, L. M., Ocampo, K. A., & Roosa, M. (1994). An examination of the cross-ethnic equivalence of measures of negative life events and the mental health among Hispanic and Anglo American children. *Am J Community Psychology, 22*, 767-783.

- Koblin, B., Holte, S., Lenderking, B., & Heagerty, P. (2000). Readiness for HIV vaccine trials: changes in willingness and knowledge among high-risk populations in the HIV network for prevention trials. *J Acquir Immune Defic Syndr.*, 24(5), 451-457.
- Koblin, B. A., Heagerty, P., Sheon, A., Buchbinder, S., Celum, C., Douglas, J. M., et al. (1998). Readiness of high-risk populations in the HIV Network for Prevention Trials to participate in HIV vaccine efficacy trials in the United States. *AIDS*, 12(7), 785-793.
- Koniak-Griffin, D., & Stein, J.A. (2006). Predictors of sexual risk behaviors among adolescent mothers in a human immunodeficiency virus prevention program. *Journal of Adolescent Health*, 38, 297.e291-297.e211.
- Koniak-Griffin, D., Lesser, J., Nyamathi, A., Uman, G., Stein, J.A., & Cumberland, W.G. (2003). Project charm: An HIV prevention program for adolescent mothers. *Family Community Health*, 26(2), 94-107.
- Lastovicka, J. L., & Gardner, D. M. (1979). Components of Involvement. In J. C. Maloney & B. Silverman (Eds.), *Attitude research plays for high stakes* (pp. 53-73). Chicago: American Marketing Association.
- Lawler, A., & Cohen, J. (1997). AIDS Research: A Deadline for an AIDS Vaccine. *Science*, 276(5316), 1184-1185.
- Leung, M. W., Yen, I. H., & Minkler, M. (2004). Community-based participatory research: A promising approach for increasing epidemiology's relevance in the 21st century. *Int J Epidemiology*, 33, 499-506.
- Liau, A., Zimet, G. D., & Fortenberry, J. D. (1998). Attitudes about Human Immunodeficiency Virus immunization: the influence of health beliefs and vaccine characteristics. *Sexually Transmitted Diseases*, 25(2), 76-81.
- MacCallum, R. C., & Austin, J. T. (2000). Applications of structural equation modeling in psychological research. *Annual Review of Psychology*, 51, 201-236.
- Mace, D. (2003). *Southern States Manifesto - HIV/AIDS and STDs in the South: A Call to Action*. Retrieved May 22, 2007. from <http://www.nastad.org>.
- MacQueen, K., Vanichseni, S., Kitayaporn, D., Lin, L., Buavirat, A., Naiwatanakul, T., et al. (1999). Willingness of injection drug users to participate in an HIV vaccine efficacy trial

- in Bangkok, Thailand. *Journal of Acquired Immune Deficiency Syndromes*, 21(3), 243-251.
- MacQueen, K. M., McLellan, E., Metzger, D., Kegeles, S., Strauss, R. P., Scotti, R., et al. (2001). What is community? An evidence-based definition for participatory public health. *Am J Public Health*, 91(12), 1929-1937.
- Maiman, L., & Becker, M. H. (1974). The health belief model: Origins and correlates in psychological theory. *Health Education Monographs*, 2, 387-408.
- Mangini, M. K. (2002). Branding 101: It's time for healthcare to embrace this marketing mainstay. *Marketing Health Services*, 20-23.
- McKnight, P. E., McKnight, K. M., Sidani, S., & Figueredo, A. J. (2007). *Missing data: A gentle introduction*. New York: Guilford Press.
- McLaws, M. L., Irwig, L.M., Oldenburg, B., Mock, P., & Ross, M.W. (1996). Predicting intentions to use condoms in homosexual men: An application and extension of the theory of reasoned action. *Psychology & Health*, 11(5), 745-755.
- McPherson, M., Smith-Lovin, L., & Cook, J. (2001). Birds of a feather: homophily in social networks. *Annual Review of Sociology*, 27, 415-444.
- Merck/HVTN. (2005). Merck's investigational HIV/AIDS vaccine candidate advances to Phase II efficacy testing in collaborative clinical trial. Retrieved January 25, 2005, from http://www.hvtn.org/media/press_releases.sht?id=41
- Merck/HVTN. (2007). Vaccination and Enrollment Are Discontinued in Phase II Trials of Merck's Investigational HIV Vaccine Candidate: Interim Analysis of STEP Study Shows Vaccine was not Effective. Retrieved September 22, 2007, from www.hvtn.org
- Merion, R., Vinokur, A., Couper, M., Jones, E., Dong, Y., Wimsatt, M., et al. (2003). Internet-based intervention to promote organ donor registry participation and family notification. *Transplantation*, 75(8), 1175-1179.
- Meyers, L. S., Gamst, G., & Guarino, A. J. (2006). *Applied Multivariate Research: Design and Interpretation*. Thousand Oaks: Sage Publications.

- Miller, R. L., & Shinn, M. (2005). Learning from communities: Overcoming difficulties in dissemination of prevention and promotion efforts. *Am J Community Psychology*, 35(3/4), 169-183.
- Mills, E., Nixon, S., Singh, S., Dolma, S., Nayyar, A., & Kapoor, S. (2006). Enrolling women into HIV preventive vaccine trials: An ethical imperative but a logistical challenge. *PLoS Med*, 3(3), e94.
- Mittlemark, M. B. (2001). Promoting social responsibility for health: Health impact assessment and healthy public policy at the community level. *Health Promotion International*, 16, 269-274.
- Montano, D. E., & Kasprzyk, D. (2002). The theory of reasoned action and the theory of planned behavior. In K. Glanz, B. Rimer & F. Lewis (Eds.), *Health Behavior and Health Education: Theory, Research, and Practice* (3rd ed., pp. 67-98). San Francisco: Jossey-Bass.
- Morgan, G. A., Griego, O. V., & Gloeckner, G. W. (2001). *SPSS for Windows: An introduction to use and interpretation in research*. Mahwah, NJ: Erlbaum.
- Morgan, S., & Miller, J. (2002). Beyond the organ donor card: The effect of knowledge, attitudes, and values on willingness to communicate about organ donation to family members. *Health Communication*, 14(1), 121-134.
- Moriarty, E. (2005, October 28-November 3, 2005). Emory part of landmark HIV vaccine trial. *Atlanta Business Chronicle*, 8A.
- Morin, S. F., Maiorana, A., Koester, K.A., Sheon, N.M., & Richards, T.A. (2003). Community consultation in HIV prevention research: a study of community advisory boards at 6 research sites. *Journal of Acquired Immune Deficiency Syndromes*, 33(4), 513-520.
- Moutsiakis, D. L., & Chin, N. P. (2007). Why Blacks Do Not Take Part in HIV Vaccine Trials. *Journal of the National Medical Association*, 99(3), 254-257.
- Newman, P. A. (2006). Toward a science of community engagement. *The Lancet*, 367, 302.
- Newman, P. A., Duan, N., Lee, S.-J., Rudy, E. T., Seiden, D., Kakinami, L., et al. (2005). HIV vaccine acceptability among communities at risk: The impact of vaccine characteristics. *Vaccine*, 24, 2094-2101.

- Newman, P. A., Duan, N., Roberts, K. J., Seiden, D. S., Rudy, E. T., Swendeman, D., et al. (2006). HIV vaccine trial participation among ethnic minority communities. *J Acquir Immune Def Syndr*, 41(2), 210-217.
- Newman, P. A., Duan, N., Rudy, E. T., & Anton, P. (2004a). Challenges for HIV vaccine dissemination and clinical trial recruitment: if we build it, will they come? *AIDS Patient Care and STDs*, 18(12), 691-701.
- Newman, P. A., Duan, N., Rudy, E. T., Roberts, K. J., & Swendeman, D. (2004b). Posttrial HIV Vaccine Adoption: Concerns, Motivators, and Intentions Among Persons at Risk For HIV. *J Acquir Immune Def Syndr*, 37(3), 1393-1403.
- Nyamathi, A., Suhadev, M., Swaminathan, S., & Fahey, J. (2006). Perceptions of a community sample about participation in future HIV vaccine trials in South India. *AIDS Behav*, 1-9.
- O'Connell, J., Hogg, R., Chan, K., Strathdee, S., McLean, N., Martindale, S., et al. (2002). Willingness to participate and enroll in a Phase 3 preventive HIV-1 vaccine trial. *J Acquir Immune Def Syndr*, 21(5), 521-528.
- O'Leary, A., & Wingood, G. (2000). Interventions for sexually active heterosexual women. In J. Peterson & R. DiClemente (Eds.), *Handbook of HIV Prevention* (pp. 179-200): Kluwer/Plenum Press.
- Onitilo, A. A., Lin, Y. H., Okonofua, E. C., Afrin, L. B., Ariail, J., & Tilley, B. C. (2004). Race, education, and knowledge of bone marrow registry: Indicators of willingness to donate bone marrow among African Americans and Caucasians. *Transplant Proc*, 36(10), 3212-3219.
- Orenstein, W. A., Douglas, R. G., Rodewald, L. E., & Hinman, A. R. (2005). Immunizations in the United States: Success, structure, and stress. *Health Affairs*, 24(3), 599-610.
- Page-Shafer, K., Saphonn, V., Sun, L. P., & al., e. (2005). HIV prevention research in a resource-limited setting: The experience of planning a trial in Cambodia. *The Lancet*, 366, 1499-1503.
- Percy, L., & Elliott, R. (2005). *Strategic Advertising Management* (Second ed.). Oxford: Oxford University Press.

- Perisse, A., Schechter, M., Moreira, R., do Lago, R., Santoro-Lopes, G., & Harrison, L. (2000). Willingness to participate in HIV vaccine trials among men who have sex with men in Rio de Janeiro, Brazil. Projeto Praca Onze Study Group. *J Acquir Immune Def Syndr*, 25(5), 459-463.
- Perugini, M., & Bagozzi, R. P. (2001). The role of desires and anticipated emotions in goal-directed behaviours: Broadening and deepening the theory of planned behaviour. *British Journal of Social Psychology*, 40, 79-98.
- Petty, R. E., & Cacioppo, J. T. (1983). Central and peripheral routes to persuasion: Application to advertising. In L. Percy & A. Woodside (Eds.), *Advertising and Consumer Psychology* (pp. 3-23). Lexington, MA: Lexington Books.
- Petty, R. E., Strathman, A. J., Cacioppo, J. T., & Priester, J. R. (1994). To think or not to think: Exploring two routes to persuasion. In S. Shavitt & T. C. Brock (Eds.), *Persuasion: Psychological insights and perspectives* (pp. 113-147). Boston: Allyn and Bacon.
- Priddy, F. H., Cheng, A. C., Salazar, L. F., & Frew, P. M. (2006). Racial and ethnic differences in knowledge and willingness to participate in HIV vaccine trials in an urban population in the Southeastern US. *Int J STDs & AIDS*, 17(2), 99-102(104).
- Putnam, R. D. (2000). *Bowling Alone: The Collapse and Revival Of American Community*. New York: Simon and Schuster.
- Reeder, G. D., Davison, D. M., Gipson, K. I., & Hesson-McInnis, M. S. (2001). Identifying the motivations of African American volunteers working to prevent HIV/AIDS. *AIDS Education and Prevention*, 13(4), 343-354.
- Reif, S., Geonnotti, K. L., & Whetten, K. (2006). HIV infection and AIDS in the Deep South. *Am J Public Health*, 96, 970-973.
- Roth, P. L. (1994). Missing data - A conceptual review for applied psychologists. *Personnel Psychology*, 47, 537-560.
- Rudy, E., Newman, P., Duan, N., Kelly, E., Roberts, K., & Seiden, D. (2005). HIV vaccine acceptability among women at risk: Perceived barriers and facilitators to future HIV vaccine uptake. *AIDS Education and Prevention*, 17(3), 253-267.

- Salant, P., & Dillman, D. A. (1994). *How to conduct your own survey*. New York: John Wiley & Sons., Inc.
- Salazar, L. F., Holtgrave, D. R., Crosby, R. A., Peterman, J., & Frew, P. M. (2005). Issues related to gay and bisexual men's acceptance of a future AIDS vaccine. *Int J STDs & AIDS*, 16, 546-548.
- Schulz, A. J., Krieger, J., & Galea, S. (2002). Addressing social determinants of health: Community-based participatory approaches to research and practice. *Health Education and Behavior*, 29(3), 287-295.
- Seage, G. r., Holte, S., Metzger, D., Koblin, B., Gross, M., Celum, C., et al. (2001). Are US populations appropriate for trials of human immunodeficiency virus vaccine? - The HIVNET vaccine preparedness study. *American Journal of Epidemiology*, 153(7), 619-627.
- Sengupta, S., Strauss, R. P., DeVellis, R., Quinn, S. C., DeVellis, B., & Ware, W. B. (2000). Factors affecting African-American participation in AIDS research. *J Acquir Immune Defic Syndrome*, 24(3), 275-284.
- Sheppard, B. H., Hartwick, J., & Warshaw, P. R. (1988). The Theory of Reasoned Action: A meta-analysis of past research with recommendations for modifications and future research. *J. Consumer Research*, 15(3), 325-343.
- Shim, S., Morris, M. J., & Morgan, G. A. (1989). Attitudes toward imported and domestic apparel among college students: The Fishbein model and external variables. *Cloth Text Res*, 7(4), 8-18.
- Siminoff, L., Burant, C., & Ibrahim, S. (2006). Racial disparities in preferences and perceptions regarding organ donation. *J Gen Intern Med*, 21(9), 995-1000.
- Simon, B., Sturmer, S., & Steffans, K. (2000). Helping individuals or group members? The role of individual and collective identification in AIDS volunteerism. *Personality and Social Psychology Bulletin*, 26, 497-506.
- Smith, W. (2002). From prevention vaccines to community care: New ways to look at program success. In R. C. Hornik (Ed.), *Public Health Communication: Evidence for Behavior Change* (pp. 327-356). Mahwah, NJ: Lawrence Erlbaum Associates.

- Smith, Y. R., Johnson, A. M., Newman, L. A., Greene, A., Johnson, T. R. B., & Rogers, J. L. (2007). Perceptions of clinical research participation among African American women. *J. Women's Health, 16*(3), 423-505.
- Sneed, C. D., Morisky, D.E. (1998). Applying the theory of reasoned action to condom use among sex workers. *Social Behavior and Personality, 26*(4), 317-327.
- Snow, B. (2005). Working with communities. In P. Kahn (Ed.), *AIDS Vaccine Handbook: Global Perspectives* (2nd ed., pp. 275-280). New York: AVAC.
- Solomon, J. (2005, December 26, 2005). Waiting for an HIV vaccine: Companies lack incentive to make one, some say. *Detroit Free Press*.
- Stover, J., Bollinger, L., Hecht, R., Williams, C., & Roca, E. (2007). The Impact Of An AIDS Vaccine In Developing Countries: A New Model And Initial Results (Vol. 26, pp. 1147-1158).
- Strauss, R., Sengupta, S., Kegeles, S., McLellan, E., Metzger, D., & Eyre, S. (2001). Willingness to volunteer in future preventive HIV vaccine trials: Issues and perspectives from three US communities. *J Acquir Immune Def Syndr, 26*, 63-71.
- Swartz, L., & Kagee, A. (2006). Community participation in AIDS vaccine trials: Empowerment or science? *Social Science & Medicine, 63*, 1143-1146.
- Syrialala, A. H., Niskanen, M.C., & Knuuttila, M.L.E. (2002). The theory of reasoned action in describing tooth brushing, dental caries and diabetes adherence among diabetic patients. *Journal of Clinical Periodontology, 29*(5), 427-432.
- Tello, J., Soong, S. J., Hunter, B., Meriwether, R., Hook, E. W., & Mulligan, M. J. (1998). HIV vaccine acceptance among heterosexual clients of a sexually transmitted diseases clinic. *Am J Med Sci, 315*(1), 11-16.
- Thapinta, D., Jenkins, R., Morgan, P., Chiu, J., Boenim, W., Bussaratid, V., et al. (2002). Recruiting volunteers for a multisite phase I/II HIV preventive vaccine trial in Thailand. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 30*(5), 503-513.
- Thomas, P. (2001). *Big Shot: Passion, Politics, and the Struggle for an AIDS Vaccine* (1st ed.). New York, NY: Public Affairs.

- Tonks, A. (2007). The quest for an AIDS vaccine. *British Medical Journal*, 334, 1346-1348.
- Tramont, E., & Johnston, M. (2003). Progress in the development of an HIV vaccine. *Expert Opinion on Emerging Drugs*, 8, 37-45.
- Traylor, M. B., & Joseph, W. B. (1984). Measuring consumer involvement with products: Developing a general scale. *Psychology & Marketing*, 1, 65-77.
- U.S. Census Bureau. (2005, May 7, 2007). USA State and County QuickFacts. Retrieved July 23, 2007, from <http://quickfacts.census.gov/qfd/states/00000.html>
- UNAIDS/WHO. (2006). *AIDS Epidemic Update*. Geneva: UNAIDS/World Health Organization.
- UNAIDS/WHO. (2007). *AIDS Epidemic Update*. Geneva: UNAIDS/World Health Organization.
- van der Straten, A., King, R., & Grinstead, O. (1995). Couple communication, sexual coercion and HIV risk reduction in Kigali, Rwanda. *AIDS*, 9, 935-944.
- Verheggen, F. W. S. M., Nieman, F., & Jonkers, R. (1998). Determinants of patient participation in clinical studies requiring informed consent: Why patients enter a clinical trial. *Patient Education and Counseling*, 35, 111-125.
- Villarosa, L. (2003). Despite Need for HIV Vaccines, Fear Mutes Call for Volunteers. *The New York Times*, p. F.5.
- Vlahov, D., Astemborski, J., Solomon, L., Galai, N., Basarab, L., & Nelson, K. E. (1994). Interest in HIV vaccines among injection drug users in Baltimore, Maryland. *AIDS Res Hum Retroviruses*, 10(Suppl 2), S265-S268.
- Warner, R. A. (2008a). Preliminary Data Screening. In *Applied Statistics: From Bivariate through Multivariate Techniques* (pp. 125-180). Thousand Oaks: Sage.
- Warner, R. A. (2008b). Reliability, Validity, and Multiple-Item Scales. In *Applied Statistics: From Bivariate through Multivariate Techniques* (pp. 826-875). Thousand Oaks: Sage.
- Weiss, R. (1997). Recruiting Foot Soldiers in HIV Siege; Organizers Build Trust Before Clinical Trial Series: the new world of aids: the hunt for a vaccine. *The Washington Post*, p. A.09.

- Wendler, D., Kington, R., Madans, J., Wye, G. V., Christ-Schmidt, H., Pratt, L. A., et al. (2006). Are racial and ethnic minorities less willing to participate in health research? *PLoS Med*, 3(2), e19.
- Whetten, K., & Reif, S. (2006). Overview: HIV/AIDS in the deep south region of the United States. *AIDS Care*, 18 Suppl (1), S1-5.
- White, J. B., & Miles, M. P. (1996). The financial implications of advertising as an investment. *J. Adv Research*, 43-51.
- WHO. (2002). *Community participation in local health and sustainable development: Approaches and techniques*. Geneva: World Health Organization.
- Wingood, G., & DiClemente, R. (2002). The theory of gender and power: A social structural theory for guiding public health interventions. In R. DiClemente, R. Crosby & M. Kegler (Eds.), *Emerging theories in public health practice and research* (pp. 313-346). San Francisco, CA: Jossey-Bass Wiley.
- Wohlfeiler, D. (1998). *Community organizing and community building among gay and bisexual men: The STOP AIDS project*.
- Woodsong, C. (2004). Covert use of topical microbicides: Implications for acceptability and use. *Perspectives on Sexual and Reproductive Health*, 36(3), 127-131.
- Woody, G. E., Metzger, D., & Mulvaney, F. (1994). Preparation for AIDS vaccine trials. Recruitment and retention of in-and out-of-treatment injection drug users. *AIDS Res Hum Retroviruses*, 10(Suppl 2), S197-S199.
- Xu, Y., Summers, T. A., & Belleau, B. D. (2004). Who buys American alligator? Predicting purchase intention of a controversial product. *J. Business Research*, 57, 1189-1198.
- Zaichkowsky, J. L. (1985). Measuring the involvement construct. *J. Consumer Research*, 12, 341-352.
- Zimet, G. D., Blythe, M. J., & Fortenberry, J. D. (2000). Vaccine characteristics and acceptability of HIV immunization among adolescents. *Int J STDs & AIDS*, 11(3), 143-149.

Zimmerman, R. K., Tabbarah, M., Nowalk, M.P., Raymund, M., Jewell, H.K., Block, B., & Hall, D.G. (2005). Predictors of pneumococcal polysaccharide vaccination among patients at three inner-city neighborhood health centers. *The American Journal of Geriatric Pharmacotherapy*, 3(3), 149-159.

APPENDIX A
STUDY QUESTIONNAIRE

Attendee Survey

Thank you for taking the time to complete this survey. It should take no more than 15 minutes to complete this 101-item survey. Your participation in this survey is completely voluntary. You may choose not to participate or not to answer any specific question. You may skip any question you do not wish to answer.

Your response will provide valuable feedback on the effectiveness of Hope Clinic community education programs, community events, and communications. The information from this survey will be used to evaluate and make improvements in Hope Clinic-sponsored education and communication efforts. All answers are kept strictly confidential.

**Thank you for taking the time to complete this survey.
We appreciate your participation!**

This survey is being used to help the Hope Clinic better understand participant experiences at the Hope Clinic and reasons for joining a clinical research trial. The survey is being conducted by Paula Frew, MA, MPH and Carlos Del Rio, MD of the Hope Clinic of the Emory Vaccine Center, 603 Church St. Decatur, GA, 30030.

If you still have questions or concern about your rights as a participant in this survey, you may contact Dr. Colleen DiIorio, Chair of the Institutional Review Board of Emory University, who oversees the protection of human research participants. She can be reached at (404) 727-8741.

Please fill in the blank space or check the box next to the response that best expresses your assessment of the items below.

A. Demographics:

A1. What is your gender?

- ☐ Male
- ☐ Female
- ☐ Transgender
 - ☐ Male → Female
 - ☐ Female → Male

A2. What is your date of birth? ____/____/____
mm/ dd/ yyyy

A3. How old are you? ____ years old

A4. Are you currently in school?

- ☐ Yes
- ☐ No

A5. What is the highest level of school that you have completed?

- ☐ K-8 grade
- ☐ High school graduate/ GED
- ☐ Technical/ Vocational or Associates
- ☐ Bachelor degree
- ☐ Master's degree
- ☐ Doctorate

A6. How would you describe your race?

- ☐ White
- ☐ Non-white

A7. How would you describe your ethnic background?

- ☐ Asian/ Asian American/ Pacific Islander
- ☐ Hispanic/ Latino/ Chicano
- ☐ African American/ Black
- ☐ Caucasian/ White
- ☐ Native American/ American Indian/ Alaskan Native
- ☐ Multiracial/ multicultural

A8. Do you consider yourself:

- ☐ Straight (Heterosexual)
- ☐ Bisexual
- ☐ Gay (Homosexual)
- ☐ Don't Know

A9. What is your relationship status?

- ☐ Single
- ☐ Married/ Domestic Partner
- ☐ Divorced/ Separated
- ☐ Widowed

A10. Which of the following best describes your current employment status?

- ☐ Employed—full time
- ☐ Employed—Part-time
- ☐ Unemployed
- ☐ Other (specify) _____

A11. What is your annual household income?

- ☐ Less than \$20,000
- ☐ \$20,001-\$40,000
- ☐ \$40,001-\$60,000
- ☐ \$60,001-\$80,000
- ☐ \$80,001-\$100,000
- ☐ More than \$100,000

A12. Where do you primarily receive healthcare? (*select only one*)

- ☐ Healthcare provider office
- ☐ Community clinic or health center
- ☐ Hospital
- ☐ Prison clinic
- ☐ Other (specify) _____

A13. What is your home zip code? _____

B. Event Details/Site Perceptions:

B1. In your opinion, what is the primary focus of today's event? (*please check one*)

- ☐ To raise awareness about a health issue
- ☐ Education
- ☐ To conduct study recruitment
- ☐ Another reason (specify) _____

B2. What was your primary motivation to come to this activity/event?
(*please check one*)

- ☐ To get the latest scientific/medical information
- ☐ To learn about volunteer opportunities
- ☐ My sense of obligation to my community
- ☐ To meet others that share my concerns
- ☐ Other (specify) _____

B3. How far did you travel to this event/activity?

- ☐ Less than 5 miles
- ☐ 6-9 miles
- ☐ 10-20 miles
- ☐ More than 20 miles

B4. How easy was it to find this event/activity?

- ☐ Very easy
- ☐ Somewhat easy
- ☐ Difficult
- ☐ Very difficult

B5. How would you rate this event/activity?

- ☐ Excellent/Outstanding
- ☐ Good/Very Good
- ☐ Fair/Poor
- ☐ No opinion

B6. How likely are you to come to another event/activity of this type?

- ☐ Very likely
- ☐ Somewhat likely
- ☐ Not likely

B7. On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of future attendance: _____

B8. How would you rate your overall impression of the Hope Clinic?

☐ Excellent/Outstanding

☐ Good/Very Good

☐ Fair/Poor

☐ No opinion

B9. Before today, have you ever heard of the Hope Clinic of the Emory Vaccine Center?

☐ Yes

☐ No

If yes, where?

a. _____ Friends

b. _____ Family

c. _____ Healthcare provider

d. _____ Television

e. _____ Radio

f. _____ Internet

g. _____ Newspaper/Magazine

h. _____ Community event

i. _____ Flyer/poster

j. _____ Community organization

k. _____ Other (specify _____)

B10. What is the primary function of the Hope Clinic? (*select only one*)

☐ Prevention research/Clinical research studies

☐ Clinical care/medical treatment

☐ Health promotion/health education

☐ Other (specify _____)

☐ Don't Know

B11. Are you or were you ever enrolled in a Hope Clinic study?

☐ Yes *specify:* _____

☐ No

- B12. How likely are you to contact the Hope Clinic about study participation in the next 6 months?
- ☐ Very likely
☐ Somewhat likely
☐ Not likely
- B13. On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of contacting the Hope Clinic about study participation in the next 6 months: _____
- B14. How likely are you to enroll in a Hope Clinic study in the next 6 months?
- ☐ Very likely
☐ Somewhat likely
☐ Not likely
- B15. On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of future enrollment within the next 6 months: _____
- B16. In the past year, have you: *(select all that apply)*
- a. _____ Given blood
 - b. _____ Signed an organ donation card or donated an organ
 - c. _____ Given bone marrow
 - d. _____ Given sperm or eggs
 - e. _____ Donated your body to science
 - f. _____ Given money to a healthcare cause
 - g. _____ Participated in a health research study
 - h. _____ Other (*specify* _____)
 - i. _____ None of the above
- B17. I have attended a Hope Clinic-sponsored activity or event in the past year:
- a. _____ Yes (*specify*: _____)
 - b. _____ No
 - c. _____ Do not recall
- B18. I have attended a partner organization activity or event in the past year (e.g., SisterLove, AID Atlanta, NAESM, etc.)
- a. _____ Yes (*specify*: _____)
 - b. _____ No
 - c. _____ Do not recall

- B19. This event (or activity):
- a. ☐ Exceeds my expectations
 - b. ☐ Meets my expectations
 - c. ☐ Does not meet my expectations
- B20. I currently belong to a: *(select all that apply)*
- a. ☐ Church/synagogue/mosque/faith-based organization
 - b. ☐ Professional organization (e.g., Atlanta Young Professionals, AGLCC)
 - c. ☐ Volunteer organization (e.g., Hands On Atlanta, Habitat for Humanity)
 - d. ☐ Social organization (e.g., Book Club, Red Hat Society, Sorority/Fraternity)
 - e. ☐ Community organization (e.g., Center for Pan-Asian Community)
 - f. ☐ Activist organization (e.g., PETA)
- B21. I would like to learn more about HIV vaccines and new prevention research:
- a. ☐ Yes
 - b. ☐ No
 - c. ☐ Not sure
- B22. I would like to learn more about ethical issues in clinical research:
- a. ☐ Yes
 - b. ☐ No
 - c. ☐ Not sure
- B23. I would like my community to be more involved in HIV vaccine research:
- a. ☐ Yes
 - b. ☐ No
 - c. ☐ Not sure
- B24. After today, I will be actively promoting HIV vaccine research in my community:
- a. ☐ Very likely
 - b. ☐ Somewhat likely
 - c. ☐ Not likely
- B25. On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of promoting HIV vaccine research in your community: _____
- B26. I consider myself to be an active health information seeker:
- a. ☐ Yes
 - b. ☐ No
 - c. ☐ Not sure

B27. When it comes to health decision-making, I typically act on my intentions:

- a. _____ Yes
- b. _____ No
- c. _____ Not sure

B28. In the next 6 months, how likely is it that you will get others involved in HIV vaccine research?

- ☐ Very likely
- ☐ Somewhat likely
- ☐ Not likely

B29. On a scale from 0 (definitely not) to 10 (definitely so), rank your likelihood of getting others involved in HIV vaccine research in the next 6 months: _____

C. Attitudes about HIV Vaccine Research:

C1. Please place an x in the appropriate box for each question, to indicate how much you agree with each statement (1 = 'Strongly Agree,' 5 = 'Strongly Disagree')

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
My community would really benefit from an HIV vaccine.					
I like getting involved with HIV vaccine research.					
My actions can inspire other to act.					
My participation in an HIV vaccine study would be very good.					
I benefit from health science research.					
I like to do good for others.					
My involvement in this cause will result in more ethical research.					

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
My involvement in this cause will improve my community's trust in medical research.					
HIV testing is a benefit of an HIV vaccine study.					
I would benefit from the medical care associated with an HIV vaccine study.					
HIV is a serious concern in my immediate community.					
I would participate in an HIV vaccine research study because it would help to prevent AIDS.					
My participation an HIV vaccine research study would be more trouble than it's worth.					
Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.					
Participating in an HIV vaccine research study seems risky.					
I would participate in an HIV vaccine research study, but I don't like needles.					
I am concerned that an HIV vaccine will cause me to test positive for HIV.					

D. Community Perceptions of HIV Vaccine Research Involvement:

D1. Please place an x in the appropriate box for each question, to indicate how much you agree with each statement (1 = 'Strongly Agree,' 5 = 'Strongly Disagree')

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
People negatively judge those who participate in HIV vaccine research.					
I think my doctor would approve of my involvement in HIV vaccine research.					
I think some of my family members would be upset if I participated in an HIV vaccine research study.					
I think my work colleagues would approve of my involvement in this cause.					
I think my friends would negatively judge me if I joined an HIV vaccine research study.					
I tend to be concerned about what people think of me, even if I don't know them.					
I generally do what my family expects of me.					
I would not want to do something my friends disapproved of.					
My immediate family is supportive of my involvement in HIV vaccine research.					
If my superiors told me to do something I disagreed with, I would obey their wishes.					
Sometimes I do what my friends say to do, even though I know they are wrong.					
Most people important to me think my involvement in HIV vaccine research is good.					

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
Most people important to me usually support my interests.					
If my pastor supported HIV vaccine research, I would be inclined to get involved.					
Most people who are important to me think I should participate in the HIV vaccine effort.					
Most people who are important to me would approve of my involvement in this cause.					
Most people who are important to me would support my interest in this cause.					

E. Volunteer Affiliations:

E1. Please place an x in the appropriate box for each question, to indicate how much you agree with each statement (1 = 'Strongly Agree,' 5 = 'Strongly Disagree')

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
The Hope Clinic is very different from other organizations.					
It is extremely important to make the right choice in selecting a volunteer organization.					
I would be very concerned about the outcome of any organization of which I am affiliated.					
If people heard of my participation with the Hope Clinic, they would form an opinion of me.					
You can tell a lot about a person by their community affiliations.					
Being active with the Hope Clinic would help me to express who I am.					
Hearing that somebody else is involved with the Hope Clinic tells me a lot about that person.					
Others would view me favorably if I volunteered for a study at the Hope Clinic.					
Prior to joining any organization, I prefer to consult a friend that has experience with that group.					
When it comes to deciding whether to join a new organization, I rely on experienced friends or family members for advice.					
In general, I am among the last of my circle of friends to try new things.					

	1 Strongly Agree	2 Agree	3 Neutral/ No Opinion	4 Disagree	5 Strongly Disagree
If I heard of a new opportunity to participate in HIV vaccine research, I would be interested enough to join it.					
Compared to my friends, I participate in little volunteer work.					
In selecting my causes, I care a great deal about researching the organization before making a commitment.					
Being involved with the Hope Clinic helps me to feel empowered.					
I experience a sense of community in this cause.					
I feel a sense of belonging through my participation in this effort.					
My involvement is helping to protect the rights of others.					
I am advancing the public's health and well-being through my support of this cause.					
I am a source of HIV vaccine information in my community.					
Getting involved in the HIV vaccine effort is liberating.					
I feel a sense of purpose in this cause.					
It is fun to be involved with the Hope Clinic.					
HIV vaccine research is a social justice effort.					
A safe and effective HIV vaccine will reduce health disparities.					

THANK YOU
For your valuable feedback!

APPENDIX B

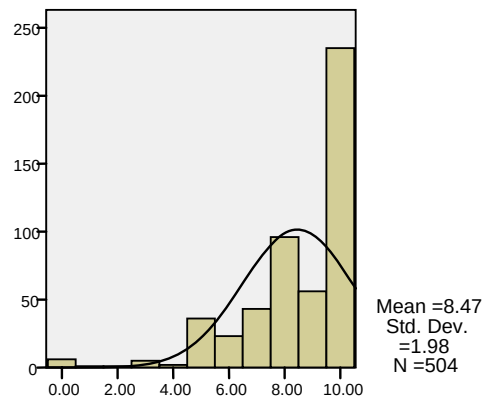
CONTINUOUS OUTCOME HISTOGRAMS AND CATEGORICAL TRANSFORMATIONS

ATTENDANCE:

1. RAW DATA (0-10 Continuous Intention Scale)

0 = Definitely Not

10 = Definitely



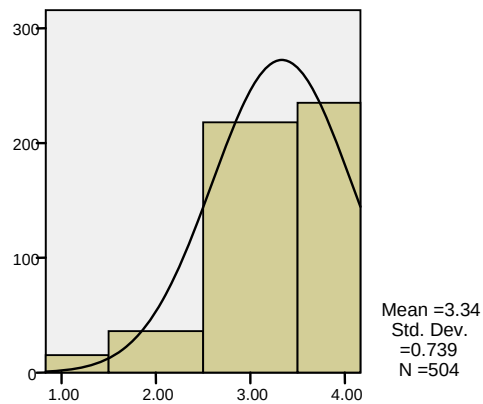
2. RECODED (CATEGORICAL)

1 = Definitely Not/Very Unlikely

2 = Neutral/No Opinion

3 = Likely/Very Likely

4 = Definitely

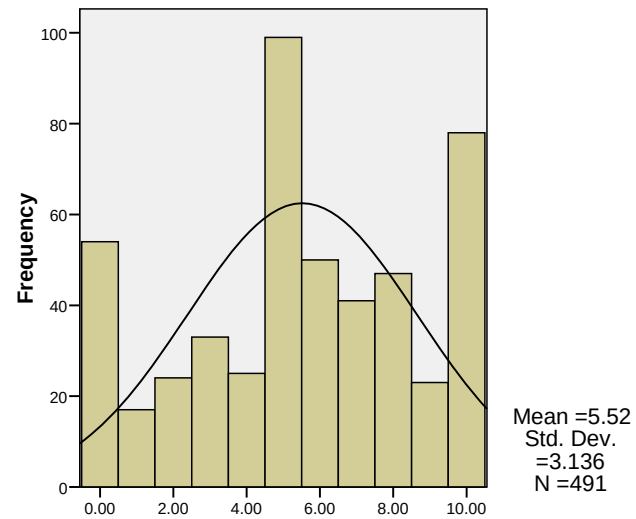


COMMUNITY MOBILIZATION:

1. RAW DATA (0-10 Continuous Intention Scale)

0 = Definitely Not

10 = Definitely



2. RECODED (CATEGORICAL)

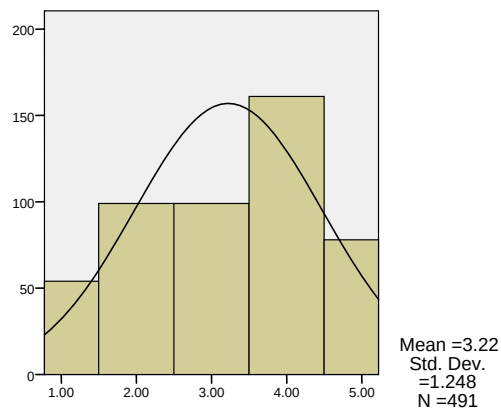
1 = Definitely not

2 = Unlikely/Very Unlikely

3 = Neutral/No Opinion

4 = Likely/Very Likely

5 = Definitely

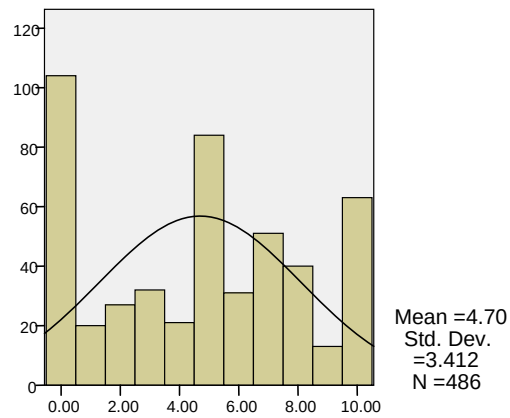


STUDY VOLUNTEERISM:

1. RAW DATA (0-10 Continuous Intention Scale)

0 = Definitely Not

10 = Definitely



2. RECODED (CATEGORICAL)

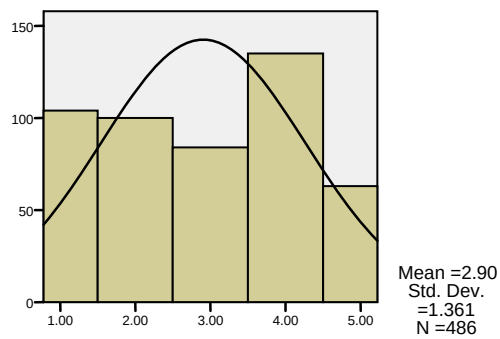
1 = Definitely not

2 = Unlikely/Very Unlikely

3 = Neutral/No Opinion

4 = Likely/Very Likely

5 = Definitely



APPENDIX C

FACTOR CORRELATION MATRIX

Outcome 1: Attendance (N = 504)

Correlations									
		behavbeliefs	attitudes	outcomeeval	normbeliefs	motivcomply	subjectnorms	orginvolve	persrelevance
behavbeliefs	Pearson Correlation	1	.823**	.096*	.547**	-.039	.499**	.397**	.586**
	Sig. (2-tailed)		.000	.032	.000	.378	.000	.000	.000
	Sum of Squares and Cross-products	503.000	413.865	48.174	275.084	-19.794	250.768	199.567	294.511
	Covariance	1.000	.823	.096	.547	-.039	.499	.397	.586
	N	504	504	504	504	504	504	504	504
attitudes	Pearson Correlation	.823**	1	.122**	.493**	.061	.427**	.334**	.531**
	Sig. (2-tailed)	.000		.006	.000	.171	.000	.000	.000
	Sum of Squares and Cross-products	413.865	503.000	61.395	248.148	30.688	214.663	167.852	267.145
	Covariance	.823	1.000	.122	.493	.061	.427	.334	.531
	N	504	504	504	504	504	504	504	504
outcomeeval	Pearson Correlation	.096*	.122**	1	.028	.491**	.164**	-.077	.026
	Sig. (2-tailed)	.032	.006		.528	.000	.000	.086	.562
	Sum of Squares and Cross-products	48.174	61.395	503.000	14.161	246.865	82.668	-38.524	13.026
	Covariance	.096	.122	1.000	.028	.491	.164	-.077	.026
	N	504	504	504	504	504	504	504	504
normbeliefs	Pearson Correlation	.547**	.493**	.028	1	-.180**	.770**	.484**	.588**
	Sig. (2-tailed)	.000	.000	.528		.000	.000	.000	.000
	Sum of Squares and Cross-products	275.084	248.148	14.161	503.000	-90.738	387.561	243.331	295.911
	Covariance	.547	.493	.028	1.000	-.180	.770	.484	.588
	N	504	504	504	504	504	504	504	504
motivcomply	Pearson Correlation	-.039	.061	.491**	-.180**	1	-.075	-.279**	-.123**
	Sig. (2-tailed)	.378	.171	.000	.000		.091	.000	.006
	Sum of Squares and Cross-products	-19.794	30.688	246.865	-90.738	503.000	-37.927	-140.484	-61.987
	Covariance	-.039	.061	.491	-.180	1.000	-.075	-.279	-.123
	N	504	504	504	504	504	504	504	504
subjectnorms	Pearson Correlation	.499**	.427**	.164**	.770**	-.075	1	.441**	.554**
	Sig. (2-tailed)	.000	.000	.000	.000	.091		.000	.000
	Sum of Squares and Cross-products	250.768	214.663	82.668	387.561	-37.927	503.000	221.737	278.418
	Covariance	.499	.427	.164	.770	-.075	1.000	.441	.554
	N	504	504	504	504	504	504	504	504
orginvolve	Pearson Correlation	.397**	.334**	-.077	.484**	-.279**	.441**	1	.572**
	Sig. (2-tailed)	.000	.000	.086	.000	.000	.000		.000
	Sum of Squares and Cross-products	199.567	167.852	-38.524	243.331	-140.484	221.737	503.000	287.882
	Covariance	.397	.334	-.077	.484	-.279	.441	1.000	.572
	N	504	504	504	504	504	504	504	504
persrelevance	Pearson Correlation	.586**	.531**	.026	.588**	-.123**	.554**	.572**	1
	Sig. (2-tailed)	.000	.000	.562	.000	.006	.000	.000	
	Sum of Squares and Cross-products	294.511	267.145	13.026	295.911	-61.987	278.418	287.882	503.000
	Covariance	.586	.531	.026	.588	-.123	.554	.572	1.000
	N	504	504	504	504	504	504	504	504

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Outcome 2: Community Mobilization (N = 491)

Correlations

		behavbeliefs	attitudes	outcomeeval	normbeliefs	motivcomply	subjnorms	orginvolv	persrelevance
behavbeliefs	Pearson Correlation	1	.821**	.083	.546**	-.066	.506**	.382**	.589**
	Sig. (2-tailed)		.000	.066	.000	.147	.000	.000	.000
	Sum of Squares and Cross-products	490.000	402.075	40.646	267.559	-32.136	248.001	187.170	288.584
	Covariance	1.000	.821	.083	.546	-.066	.506	.382	.589
	N	491	491	491	491	491	491	491	491
attitudes	Pearson Correlation	.821**	1	.114*	.508**	.036	.433**	.327**	.535**
	Sig. (2-tailed)	.000		.011	.000	.429	.000	.000	.000
	Sum of Squares and Cross-products	402.075	490.000	56.018	248.856	17.548	212.287	160.019	262.301
	Covariance	.821	1.000	.114	.508	.036	.433	.327	.535
	N	491	491	491	491	491	491	491	491
outcomeeval	Pearson Correlation	.083	.114*	1	.034	.499**	.156**	-.064	.021
	Sig. (2-tailed)	.066	.011		.455	.000	.001	.154	.648
	Sum of Squares and Cross-products	40.646	56.018	490.000	16.567	244.600	76.563	-31.556	10.132
	Covariance	.083	.114	1.000	.034	.499	.156	-.064	.021
	N	491	491	491	491	491	491	491	491
normbeliefs	Pearson Correlation	.546**	.508**	.034	1	-.202**	.772**	.509**	.604**
	Sig. (2-tailed)	.000	.000	.455		.000	.000	.000	.000
	Sum of Squares and Cross-products	267.559	248.856	16.567	490.000	-98.952	378.147	249.451	296.020
	Covariance	.546	.508	.034	1.000	-.202	.772	.509	.604
	N	491	491	491	491	491	491	491	491
motivcomply	Pearson Correlation	-.066	.036	.499**	-.202**	1	-.096*	-.303**	-.160**
	Sig. (2-tailed)	.147	.429	.000	.000		.033	.000	.000
	Sum of Squares and Cross-products	-32.136	17.548	244.600	-98.952	490.000	-47.197	-148.706	-78.418
	Covariance	-.066	.036	.499	-.202	1.000	-.096	-.303	-.160
	N	491	491	491	491	491	491	491	491
subjnorms	Pearson Correlation	.506**	.433**	.156**	.772**	-.096*	1	.457**	.564**
	Sig. (2-tailed)	.000	.000	.001	.000	.033		.000	.000
	Sum of Squares and Cross-products	248.001	212.287	76.563	378.147	-47.197	490.000	224.089	276.578
	Covariance	.506	.433	.156	.772	-.096	1.000	.457	.564
	N	491	491	491	491	491	491	491	491
orginvolv	Pearson Correlation	.382**	.327**	-.064	.509**	-.303**	.457**	1	.565**
	Sig. (2-tailed)	.000	.000	.154	.000	.000	.000		.000
	Sum of Squares and Cross-products	187.170	160.019	-31.556	249.451	-148.706	224.089	490.000	276.800
	Covariance	.382	.327	-.064	.509	-.303	.457	1.000	.565
	N	491	491	491	491	491	491	491	491
persrelevance	Pearson Correlation	.589**	.535**	.021	.604**	-.160**	.564**	.565**	1
	Sig. (2-tailed)	.000	.000	.648	.000	.000	.000	.000	
	Sum of Squares and Cross-products	288.584	262.301	10.132	296.020	-78.418	276.578	276.800	490.000
	Covariance	.589	.535	.021	.604	-.160	.564	.565	1.000
	N	491	491	491	491	491	491	491	491

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

Outcome 3: Study Volunteerism (N = 486)

Correlations

		behavbeliefs	attitudes	outcomeeval	normbeliefs	motivcomply	subjnorns	orginvolve	persrelevance
behavbeliefs	Pearson Correlation	1	.829**	.078	.552**	-.061	.496**	.399**	.582**
	Sig. (2-tailed)		.000	.086	.000	.179	.000	.000	.000
	Sum of Squares and Cross-products	485.000	402.193	37.786	267.839	-29.640	240.530	193.291	282.308
	Covariance	1.000	.829	.078	.552	-.061	.496	.399	.582
	N	486	486	486	486	486	486	486	486
attitudes	Pearson Correlation	.829**	1	.106*	.516**	.031	.433**	.355**	.540**
	Sig. (2-tailed)	.000		.019	.000	.491	.000	.000	.000
	Sum of Squares and Cross-products	402.193	485.000	51.598	250.092	15.183	209.840	171.981	261.727
	Covariance	.829	1.000	.106	.516	.031	.433	.355	.540
	N	486	486	486	486	486	486	486	486
outcomeeval	Pearson Correlation	.078	.106*	1	.025	.502**	.148**	-.111*	-.008
	Sig. (2-tailed)	.086	.019		.589	.000	.001	.014	.866
	Sum of Squares and Cross-products	37.786	51.598	485.000	11.920	243.259	71.970	-53.945	-3.733
	Covariance	.078	.106	1.000	.025	.502	.148	-.111	-.008
	N	486	486	486	486	486	486	486	486
normbeliefs	Pearson Correlation	.552**	.516**	.025	1	-.195**	.777**	.530**	.608**
	Sig. (2-tailed)	.000	.000	.589		.000	.000	.000	.000
	Sum of Squares and Cross-products	267.839	250.092	11.920	485.000	-94.536	376.775	257.267	294.928
	Covariance	.552	.516	.025	1.000	-.195	.777	.530	.608
	N	486	486	486	486	486	486	486	486
motivcomply	Pearson Correlation	-.061	.031	.502**	-.195**	1	-.104*	-.329**	-.162**
	Sig. (2-tailed)	.179	.491	.000	.000		.022	.000	.000
	Sum of Squares and Cross-products	-29.640	15.183	243.259	-94.536	485.000	-50.321	-159.474	-78.551
	Covariance	-.061	.031	.502	-.195	1.000	-.104	-.329	-.162
	N	486	486	486	486	486	486	486	486
subjnorns	Pearson Correlation	.496**	.433**	.148**	.777**	-.104*	1	.464**	.557**
	Sig. (2-tailed)	.000	.000	.001	.000	.022		.000	.000
	Sum of Squares and Cross-products	240.530	209.840	71.970	376.775	-50.321	485.000	224.975	270.001
	Covariance	.496	.433	.148	.777	-.104	1.000	.464	.557
	N	486	486	486	486	486	486	486	486
orginvolve	Pearson Correlation	.399**	.355**	-.111*	.530**	-.329**	.464**	1	.583**
	Sig. (2-tailed)	.000	.000	.014	.000	.000	.000		.000
	Sum of Squares and Cross-products	193.291	171.981	-53.945	257.267	-159.474	224.975	485.000	282.613
	Covariance	.399	.355	-.111	.530	-.329	.464	1.000	.583
	N	486	486	486	486	486	486	486	486
persrelevance	Pearson Correlation	.582**	.540**	-.008	.608**	-.162**	.557**	.583**	1
	Sig. (2-tailed)	.000	.000	.866	.000	.000	.000	.000	
	Sum of Squares and Cross-products	282.308	261.727	-3.733	294.928	-78.551	270.001	282.613	485.000
	Covariance	.582	.540	-.008	.608	-.162	.557	.583	1.000
	N	486	486	486	486	486	486	486	486

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

APPENDIX D

MULTIPLE IMPUTATION STATISTICS

(EXPECTATION MAXIMIZATION PROCEDURE)

Variable	n (%)	Mean	Est. Mean	SD	Est. SD
<i><u>Behavioral Beliefs scale</u></i> ($\alpha = 0.854$)					
BB1. My community would really benefit from an HIV vaccine.	526 (97.0)	1.525	1.528	0.801	0.805
BB2. My actions can inspire other to act.	522 (96.3)	1.801	1.809	0.778	0.781
BB3. My participation in an HIV vaccine study would be very good	522 (96.3)	2.067	2.071	0.886	0.886
BB4. I benefit from health science research	523 (96.5)	1.6960	1.698	0.798	0.798
BB5. My involvement in this cause will result in more ethical research.	523 (96.5)	2.0593	2.063	0.879	0.878
BB6. My involvement in this cause will improve my community's trust in medical research.	523 (96.5)	2.0899	2.093	0.911	0.909
BB7. I would participate in an HIV vaccine research study because it would help to prevent AIDS.	525 (96.9)	2.048	2.040	0.988	0.986
<i><u>Outcome Expectations</u></i> ($\alpha = 0.826$)					
OE1. My participation an HIV vaccine research study would be more trouble than it's worth.	533 (98.3)	2.516	2.517	1.155	1.153
OE2. Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.	533 (98.3)	2.880	2.882	1.137	1.137
OE3. Participating in an HIV vaccine research study seems risky.	527 (97.2)	2.934	2.938	1.223	1.220
OE4. I would participate in an HIV vaccine research study, but I don't like needles.	531 (98.0)	2.840	2.841	1.266	1.264
OE5. I am concerned that an HIV vaccine would cause me to test positive for HIV.	528 (97.4)	2.521	2.528	1.302	1.304
<i><u>Normative Beliefs</u></i> ($\alpha = 0.806$)					
NB1. I think my doctor would approve of my involvement in HIV vaccine research.	532 (98.2)	2.280	2.285	0.903	0.904
NB2. I think my work colleagues would approve of my involvement in this cause.	528 (97.4)	2.331	2.330	0.919	0.919
NB3. My immediate family is supportive of my involvement in HIV vaccine research.	526 (97.0)	2.608	2.605	0.863	0.865

Variable	n (%)	Mean	Est. Mean	SD	Est. SD
NB4. Most people important to me think my involvement in HIV vaccine research is good.	522 (96.3)	2.423	2.422	0.858	0.858
NB5. Most people important to me usually support my interests.	519 (95.8)	1.913	1.912	0.747	0.748
NB6. If my pastor supported HIV vaccine research, I would be inclined to get involved.	520 (95.9)	2.644	2.640	0.899	0.899
<i>Motivation to Comply</i> ($\alpha = 0.840$)					
MC1. I tend to be concerned about what people think of me, even if I don't know them.	519 (95.8)	2.432	2.441	1.247	1.256
MC2. I generally do what my family expects of me.	522 (96.3)	2.801	2.813	1.262	1.262
MC3. I would not want to do something my friends disapproved of.	521 (96.1)	2.472	2.480	1.172	1.174
MC4. If my superiors told me to do something I disagreed with, I would obey their wishes.	522 (96.3)	2.462	2.473	1.141	1.143
MC5. Sometimes I do what my friends say to do, even though I know they are wrong.	521 (96.1)	2.115	2.125	1.100	1.099
<i>Attitudes</i> ($\alpha = 0.732$)					
A1. I like to do good for others.	527 (97.2)	1.389	1.392	0.612	0.612
A3. I like getting involved with HIV vaccine research.	524 (96.7)	2.221	2.224	0.930	0.928
A4. HIV is a serious concern in my immediate community.	528 (97.4)	1.688	1.684	0.884	0.883
A5. HIV testing is a benefit of an HIV vaccine study.	524 (96.7)	1.664	1.669	0.769	0.769
A6. I would benefit from the medical care associated with an HIV vaccine study.	522 (96.3)	2.111	2.110	0.991	0.991
<i>Subjective Norms</i> ($\alpha = 0.843$)					
SN4. Most people who are important to me think I should participate in the HIV vaccine effort.	521 (96.1)	2.691	2.690	0.867	0.868
SN5. Most people who are important to me would approve of my involvement in this cause.	524 (96.7)	2.269	2.264	0.876	0.875
SN6. Most people who are important to me would support my interest in this cause.	525 (96.9)	2.147	2.146	0.871	0.871
<i>Organization Involvement</i> ($\alpha = 0.808$)					
BIS3. Being active with the Hope Clinic would help me to express who I am.	519 (95.8)	2.570	2.565	0.816	0.818
BIS4. Hearing that somebody else is involved with the Hope Clinic tells me a lot about that person.	522 (96.3)	2.462	2.461	0.831	0.833
BIS5. Others would view me favorably if I volunteered for a study at the Hope Clinic.	521 (96.1)	2.574	2.564	0.789	0.791

Variable	n (%)	Mean	Est. Mean	SD	Est. SD
<i>Personal Relevance</i> ($\alpha = 0.922$)					
CIP4. Being involved with the Hope Clinic helps me to feel empowered.	521 (96.1)	2.513	2.507	0.811	0.811
CIP5. I experience a sense of community in this cause.	523 (96.5)	2.228	2.221	0.785	0.785
CIP6. I feel a sense of belonging through my participation in this effort.	522 (96.3)	2.416	2.409	0.802	0.800
CIP7. My involvement is helping to protect the rights of others.	528 (97.4)	2.212	2.212	0.799	0.798
CIP8. I am advancing the public's health and well-being through my support of this cause.	528 (97.4)	2.085	2.084	0.768	0.768
CIP10. Getting involved in the HIV vaccine effort is liberating.	523 (96.5)	2.461	2.453	0.819	0.820
CIP11. I feel a sense of purpose in this cause.	526 (97.0)	2.146	2.145	0.788	0.785

APPENDIX E

INTERNAL CONSISTENCIES FOR OUTCOMES

(IMPUTED VALUES)

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	7	5	3	6	5	3	7
Cronbach's α	.737	.852	.820	.842	.794	.828	.807	.919
Cronbach's Standardized α	.742	.851	.823	.842	.795	.830	.807	.919
Item Mean	1.800	1.886	2.715	2.364	2.369	2.430	2.545	2.286
Item Range	.825	.573	.422	.551	.745	.676	.113	.437
Item Variance	.115	.051	.041	.083	.073	.057	.004	.029
Scale Mean	9.002	13.205	13.573	7.093	14.212	12.149	7.634	16.002
Scale Variance	8.457	18.597	21.032	5.002	12.934	19.845	4.147	20.224
Scale SD	2.908	4.312	4.586	2.236	3.596	4.455	2.036	4.497
Internal Consistency Measures- Future Attendance, (Imputed Data N=504, no missing values)								

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	7	5	3	6	5	3	7
Cronbach's α	.729	.849	.818	.845	.794	.828	.807	.919
Cronbach's Standardized α	.734	.848	.821	.845	.795	.830	.807	.919
Item Mean	1.800	1.889	2.698	2.362	2.364	2.422	2.552	2.299
Item Range	.837	.612	.420	.553	.757	.702	.136	.448
Item Variance	.121	.059	.040	.085	.073	.062	.005	.030
Scale Mean	8.999	13.222	13.488	7.087	14.187	12.111	7.656	16.093
Scale Variance	8.348	18.522	20.883	5.028	12.818	19.781	4.142	20.284
Scale SD	2.889	4.304	4.570	2.242	3.580	4.448	2.035	4.504
Internal Consistency Measures- Community Mobilization (Imputed data, N=491, no missing data)								

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	7	5	3	6	5	3	7
Cronbach's α	.736	.858	.820	.842	.795	.840	.812	.921
Cronbach's Standardized α	.741	.857	.823	.842	.797	.842	.811	.921
Item Mean	1.802	1.895	2.707	2.366	2.361	2.435	2.545	2.298
Item Range	.821	.596	.411	.558	.756	.683	.116	.442
Item Variance	.119	.055	.041	.085	.074	.059	.004	.030
Scale Mean	9.001	13.264	13.534	7.098	14.169	12.175	7.634	16.090
Scale Variance	8.501	19.281	21.324	5.024	12.977	20.692	4.259	20.492
Scale SD	2.916	4.391	4.618	2.241	3.602	4.549	2.064	4.527
Internal Consistency Measures- Study Volunteerism (Imputed data, N=486, no missing data)								

APPENDIX F

DESCRIPTIVE STATISTICS AND FACTOR LOADINGS

Outcome 1: Future Attendance

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
Dependent Measures						
1. Future Attendance: Likelihood of returning to activity or event	504 (93.0)	3.335	0.739	1.00	4.00	
Independent Measures						
<i>Behavioral Beliefs scale</i> ($\alpha = 0.852$)						
BB1. My community would really benefit from an HIV vaccine.		1.509	0.776	1.00	4.00	.531
BB2. My actions can inspire other to act.		1.800	0.761	1.00	4.00	.655
BB3. My participation in an HIV vaccine study would be very good		2.055	0.862	1.00	4.00	.771
BB4. I benefit from health science research		1.677	0.772	1.00	4.00	.548
BB5. My involvement in this cause will result in more ethical research.		2.049	0.862	1.00	4.00	.757
BB6. My involvement in this cause will improve my community's trust in medical research.		2.081	0.896	1.00	4.00	.754
BB7. I would participate in an HIV vaccine research study because it would help to prevent AIDS.		2.034	0.975	1.00	4.00	.710
<i>Outcome Expectations</i> ($\alpha = 0.820$)						
OE1. My participation an HIV vaccine research study would be more trouble than it's worth.		2.486	1.132	1.00	5.00	.749
OE2. Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.		2.857	1.123	1.00	5.00	.703
OE3. Participating in an HIV vaccine research study seems risky.		2.908	1.209	1.00	5.00	.773
OE4. I would participate in an HIV vaccine research study, but I don't like needles.		2.814	1.250	1.00	5.00	.583
OE5. I am concerned that an HIV vaccine would cause me to test positive for HIV.		2.509	1.290	1.00	5.00	.670

Variable	n (%)	Mean	Est. Mean	SD	Est. SD	Variable
<i>Normative Beliefs</i> ($\alpha = 0.794$)						
NB1. I think my doctor would approve of my involvement in HIV vaccine research.		2.284	0.894	1.00	4.00	.531
NB2. I think my work colleagues would approve of my involvement in this cause.		2.339	0.907	1.00	4.00	.605
NB3. My immediate family is supportive of my involvement in HIV vaccine research.		2.610	0.851	1.00	4.00	.710
NB4. Most people important to me think my involvement in HIV vaccine research is good.		2.425	0.844	1.00	4.00	.791
NB5. Most people important to me usually support my interests.		1.904	0.731	1.00	4.00	.572
NB6. If my pastor supported HIV vaccine research, I would be inclined to get involved.		2.650	0.886	1.00	4.00	.585
<i>Motivation to Comply</i> ($\alpha = 0.828$)						
MC1. I tend to be concerned about what people think of me, even if I don't know them.		2.401	1.225	1.00	5.00	.754
MC2. I generally do what my family expects of me.		2.769	1.247	1.00	5.00	.643
MC3. I would not want to do something my friends disapproved of.		2.444	1.138	1.00	5.00	.747
MC4. If my superiors told me to do something I disagreed with, I would obey their wishes.		2.442	1.111	1.00	5.00	.624
MC5. Sometimes I do what my friends say to do, even though I know they are wrong.		2.093	1.056	1.00	5.00	.743
<i>Attitudes</i> ($\alpha = 0.737$)						
A1. I like to do good for others.		1.378	0.591	1.00	4.00	.552
A2. I like getting involved with HIV vaccine research.		2.203	0.905	1.00	4.00	.695
A3. HIV is a serious concern in my immediate community.		1.680	0.880	1.00	4.00	.476
A4. HIV testing is a benefit of an HIV vaccine study.		1.655	0.757	1.00	4.00	.583
A5. I would benefit from the medical care associated with an HIV vaccine study.		2.087	0.976	1.00	4.00	.629

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
<i>Subjective Norms</i> ($\alpha = 0.842$)						
SN4. Most people who are important to me think I should participate in the HIV vaccine effort.		2.689	0.855	1.00	4.00	.703
SN5. Most people who are important to me would approve of my involvement in this cause.		2.266	0.859	1.00	4.00	.872
SN6. Most people who are important to me would support my interest in this cause.		2.138	0.851	1.00	4.00	.834
<i>Organization Involvement</i> ($\alpha = 0.807$)						
BIS3. Being active with the Hope Clinic would help me to express who I am.		2.580	0.799	1.00	4.00	.782
BIS4. Hearing that somebody else is involved with the Hope Clinic tells me a lot about that person.		2.470	0.819	1.00	4.00	.771
BIS5. Others would view me favorably if I volunteered for a study at the Hope Clinic.		2.583	0.778	1.00	4.00	.736
<i>Personal Relevance</i> ($\alpha = 0.919$)						
CIP4. Being involved with the Hope Clinic helps me to feel empowered.		2.516	0.795	1.00	4.00	.759
CIP5. I experience a sense of community in this cause.		2.206	0.773	1.00	4.00	.832
CIP6. I feel a sense of belonging through my participation in this effort.		2.410	0.791	1.00	4.00	.825
CIP7. My involvement is helping to protect the rights of others.		2.204	0.788	1.00	4.00	.773
CIP8. I am advancing the public's health and well-being through my support of this cause.		2.077	0.757	1.00	4.00	.754
CIP10. Getting involved in the HIV vaccine effort is liberating.		2.453	0.802	1.00	4.00	.771
CIP11. I feel a sense of purpose in this cause.		2.133	0.773	1.00	4.00	.797

Outcome 2: Community Mobilization

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
Dependent Measures						
2. Community Mobilization: Likelihood of involving others in the cause	491 (90.6)	3.224	1.248	1.00	5.00	
Independent Measures						
<i>Behavioral Beliefs scale</i> ($\alpha = 0.849$)						
BB1. My community would really benefit from an HIV vaccine.		1.492	0.771	1.00	4.00	.504
BB2. My actions can inspire other to act.		1.790	0.759	1.00	4.00	.645
BB3. My participation in an HIV vaccine study would be very good		2.076	0.877	1.00	4.00	.787
BB4. I benefit from health science research		1.663	0.767	1.00	4.00	.529
BB5. My involvement in this cause will result in more ethical research.		2.067	0.866	1.00	4.00	.756
BB6. My involvement in this cause will improve my community's trust in medical research.		2.104	0.899	1.00	4.00	.767
BB7. I would participate in an HIV vaccine research study because it would help to prevent AIDS.		2.031	0.977	1.00	4.00	.701
<i>Outcome Expectations</i> ($\alpha = 0.818$)						
OE1. My participation an HIV vaccine research study would be more trouble than it's worth.		2.469	1.121	1.00	5.00	.738
OE2. Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.		2.838	1.117	1.00	5.00	.687
OE3. Participating in an HIV vaccine research study seems risky.		2.890	1.207	1.00	5.00	.791
OE4. I would participate in an HIV vaccine research study, but I don't like needles.		2.796	1.257	1.00	5.00	.553
OE5. I am concerned that an HIV vaccine would cause me to test positive for HIV.		2.496	1.295	1.00	5.00	.696
<i>Normative Beliefs</i> ($\alpha = 0.794$)						
NB1. I think my doctor would approve of my involvement in HIV vaccine research.		2.292	0.893	1.00	4.00	.534
NB2. I think my work colleagues would approve of my involvement in this cause.		2.341	0.905	1.00	4.00	.595
NB3. My immediate family is supportive of my involvement in HIV vaccine research.		2.597	0.851	1.00	4.00	.717

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
NB4. Most people important to me think my involvement in HIV vaccine research is good.		2.416	0.844	1.00	4.00	.796
NB5. Most people important to me usually support my interests.		1.892	0.715	1.00	4.00	.554
NB6. If my pastor supported HIV vaccine research, I would be inclined to get involved.		2.649	0.876	1.00	4.00	.592
<i>Motivation to Comply</i> ($\alpha = 0.828$)						
MC1. I tend to be concerned about what people think of me, even if I don't know them.		2.393	1.215	1.00	5.00	.747
MC2. I generally do what my family expects of me.		2.781	1.248	1.00	5.00	.648
MC3. I would not want to do something my friends disapproved of.		2.436	1.131	1.00	5.00	.756
MC4. If my superiors told me to do something I disagreed with, I would obey their wishes.		2.443	1.120	1.00	5.00	.637
MC5. Sometimes I do what my friends say to do, even though I know they are wrong.		2.079	1.052	1.00	5.00	.725
<i>Attitudes</i> ($\alpha = 0.729$)						
A1. I like to do good for others.		1.370	0.587	1.00	4.00	.539
A2. I like getting involved with HIV vaccine research.		2.207	0.914	1.00	4.00	.709
A3. HIV is a serious concern in my immediate community.		1.669	0.878	1.00	4.00	.443
A4. HIV testing is a benefit of an HIV vaccine study.		1.648	0.755	1.00	4.00	.560
A5. I would benefit from the medical care associated with an HIV vaccine study.		2.105	0.981	1.00	4.00	.621

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
<i>Subjective Norms</i> ($\alpha = 0.845$)						
SN4. Most people who are important to me think I should participate in the HIV vaccine effort.		2.691	0.852	1.00	4.00	.699
SN5. Most people who are important to me would approve of my involvement in this cause.		2.258	0.861	1.00	4.00	.877
SN6. Most people who are important to me would support my interest in this cause.		2.138	0.853	1.00	4.00	.844
<i>Organization Involvement</i> ($\alpha = 0.807$)						
BIS3. Being active with the Hope Clinic would help me to express who I am.		2.606	0.793	1.00	4.00	.794
BIS4. Hearing that somebody else is involved with the Hope Clinic tells me a lot about that person.		2.470	2.580	1.00	4.00	.766
BIS5. Others would view me favorably if I volunteered for a study at the Hope Clinic.		2.579	0.781	1.00	4.00	.727
<i>Personal Relevance</i> ($\alpha = 0.919$)						
CIP4. Being involved with the Hope Clinic helps me to feel empowered.		2.526	0.798	1.00	4.00	.755
CIP5. I experience a sense of community in this cause.		2.233	0.774	1.00	4.00	.828
CIP6. I feel a sense of belonging through my participation in this effort.		2.432	0.792	1.00	4.00	.826
CIP7. My involvement is helping to protect the rights of others.		2.221	0.787	1.00	4.00	.774
CIP8. I am advancing the public's health and well-being through my support of this cause.		2.077	0.757	1.00	4.00	.755
CIP10. Getting involved in the HIV vaccine effort is liberating.		2.466	0.810	1.00	4.00	.769
CIP11. I feel a sense of purpose in this cause.		2.139	0.771	1.00	4.00	.800

Outcome 3: Study Volunteerism

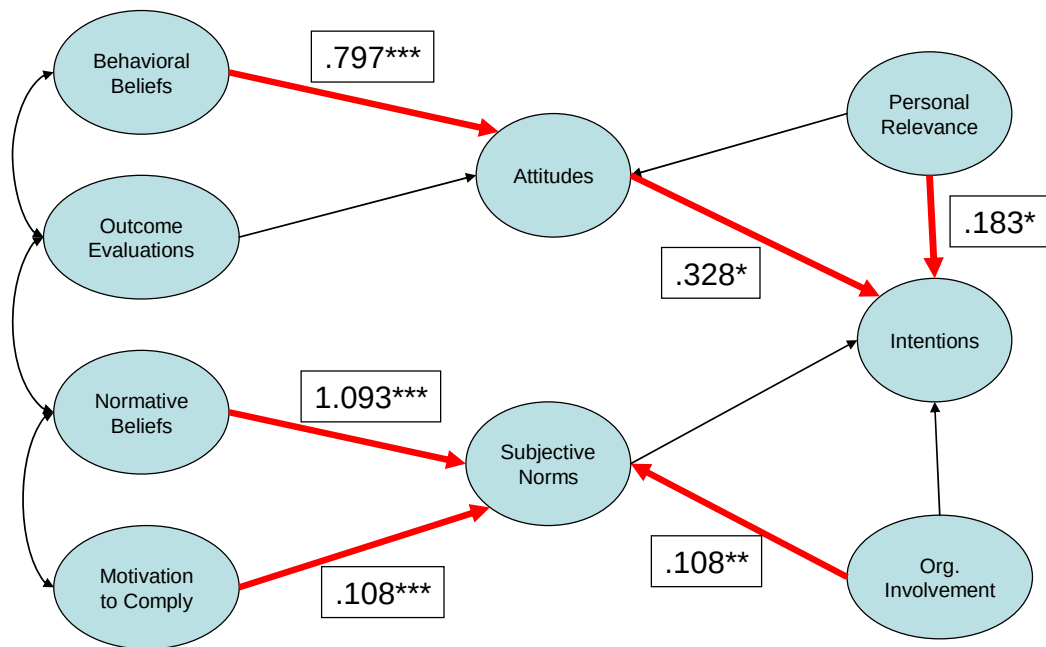
Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
Dependent Measures						
3. Study Volunteerism: Likelihood of contacting the site about study participation	486 (89.7)	2.903	1.361	1.00	5.00	
Independent Measures						
<i>Behavioral Beliefs scale</i> ($\alpha = 0.858$)						
BB1. My community would really benefit from an HIV vaccine.		1.505	0.775	1.00	4.00	.526
BB2. My actions can inspire other to act.		1.805	0.762	1.00	4.00	.666
BB3. My participation in an HIV vaccine study would be very good		2.079	0.884	1.00	4.00	.784
BB4. I benefit from health science research		1.677	0.772	1.00	4.00	.555
BB5. My involvement in this cause will result in more ethical research.		2.063	0.870	1.00	4.00	.763
BB6. My involvement in this cause will improve my community's trust in medical research.		2.100	0.905	1.00	4.00	.777
BB7. I would participate in an HIV vaccine research study because it would help to prevent AIDS.		2.036	0.988	1.00	4.00	.707
<i>Outcome Expectations</i> ($\alpha = 0.820$)						
OE1. My participation an HIV vaccine research study would be more trouble than it's worth.		2.482	1.136	1.00	5.00	.754
OE2. Even if I wanted to participate in an HIV vaccine research study, I just don't have the time.		2.857	1.124	1.00	5.00	.692
OE3. Participating in an HIV vaccine research study seems risky.		2.893	1.216	1.00	5.00	.774
OE4. I would participate in an HIV vaccine research study, but I don't like needles.		2.810	1.270	1.00	5.00	.575
OE5. I am concerned that an HIV vaccine would cause me to test positive for HIV.		2.492	1.301	1.00	5.00	.680
<i>Normative Beliefs</i> ($\alpha = 0.795$)						
NB1. I think my doctor would approve of my involvement in HIV vaccine research.		2.283	0.903	1.00	4.00	.540
NB2. I think my work colleagues would approve of my involvement in this cause.		2.338	0.905	1.00	4.00	.602
NB3. My immediate family is supportive of my involvement in HIV vaccine research.		2.595	0.851	1.00	4.00	.715

Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
NB4. Most people important to me think my involvement in HIV vaccine research is good.		2.431	0.843	1.00	4.00	.793
NB5. Most people important to me usually support my interests.		1.883	0.715	1.00	4.00	.563
NB6. If my pastor supported HIV vaccine research, I would be inclined to get involved.		2.640	0.893	1.00	4.00	.590
<i>Motivation to Comply</i> ($\alpha = 0.840$)						
MC1. I tend to be concerned about what people think of me, even if I don't know them.		2.381	1.214	1.00	5.00	.779
MC2. I generally do what my family expects of me.		2.787	1.249	1.00	5.00	.643
MC3. I would not want to do something my friends disapproved of.		2.455	1.150	1.00	5.00	.756
MC4. If my superiors told me to do something I disagreed with, I would obey their wishes.		2.448	1.125	1.00	5.00	.646
MC5. Sometimes I do what my friends say to do, even though I know they are wrong.		2.104	1.078	1.00	5.00	.760
<i>Attitudes</i> ($\alpha = 0.736$)						
A1. I like to do good for others.		1.373	0.591	1.00	4.00	.548
A2. I like getting involved with HIV vaccine research.		2.194	0.907	1.00	4.00	.691
A3. HIV is a serious concern in my immediate community.		1.673	0.877	1.00	4.00	.448
A4. HIV testing is a benefit of an HIV vaccine study.		1.661	0.762	1.00	4.00	.578
A5. I would benefit from the medical care associated with an HIV vaccine study.		2.107	0.988	1.00	4.00	.624

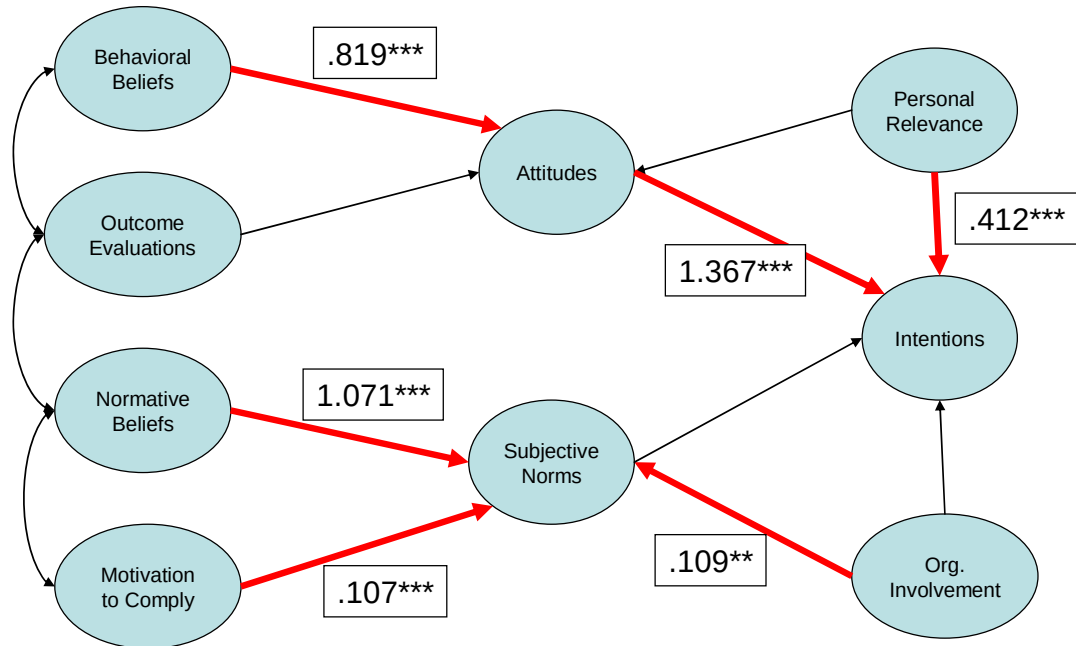
Variable	n (%)	Mean	SD	Min	Max	Factor Loadings ¹
<i>Subjective Norms</i> ($\alpha = 0.842$)						
SN4. Most people who are important to me think I should participate in the HIV vaccine effort.		2.693	0.857	1.00	4.00	.710
SN5. Most people who are important to me would approve of my involvement in this cause.		2.271	0.857	1.00	4.00	.867
SN6. Most people who are important to me would support my interest in this cause.		2.135	0.857	1.00	4.00	.833
<i>Organization Involvement</i> ($\alpha = 0.812$)						
BIS3. Being active with the Hope Clinic would help me to express who I am.		2.589	0.807	1.00	4.00	.801
BIS4. Hearing that somebody else is involved with the Hope Clinic tells me a lot about that person.		2.474	0.827	1.00	4.00	.773
BIS5. Others would view me favorably if I volunteered for a study at the Hope Clinic.		2.571	0.788	1.00	4.00	.726
<i>Personal Relevance</i> ($\alpha = 0.921$)						
CIP4. Being involved with the Hope Clinic helps me to feel empowered.		2.531	0.798	1.00	4.00	.758
CIP5. I experience a sense of community in this cause.		2.233	0.778	1.00	4.00	.845
CIP6. I feel a sense of belonging through my participation in this effort.		2.428	0.792	1.00	4.00	.829
CIP7. My involvement is helping to protect the rights of others.		2.218	0.794	1.00	4.00	.781
CIP8. I am advancing the public's health and well-being through my support of this cause.		2.089	0.758	1.00	4.00	.754
CIP10. Getting involved in the HIV vaccine effort is liberating.		2.461	0.807	1.00	4.00	.772
CIP11. I feel a sense of purpose in this cause.		2.131	0.766	1.00	4.00	.801

APPENDIX G
MODEL TEST RESULTS

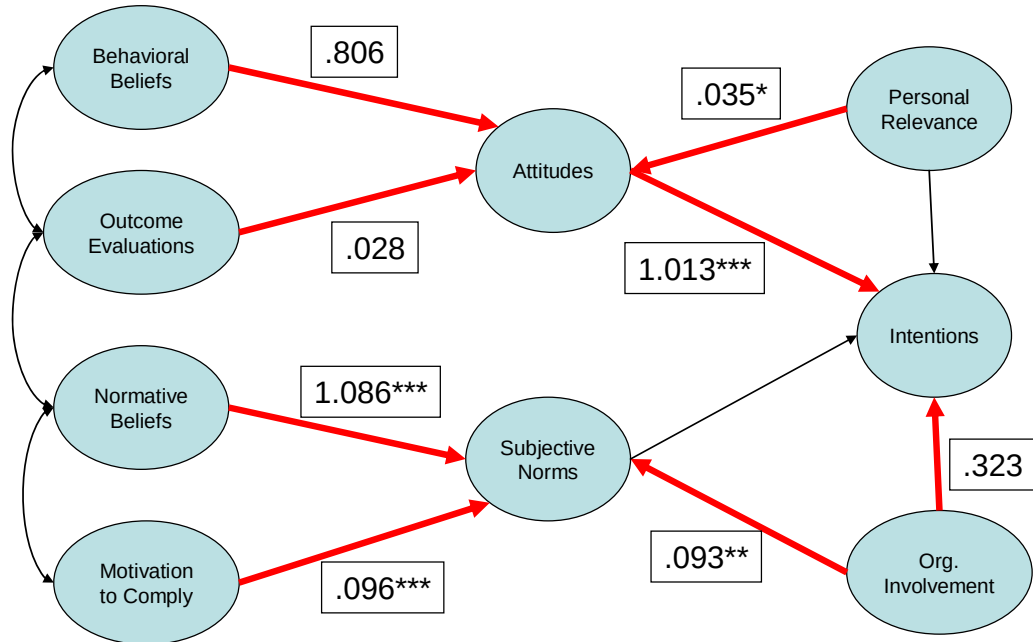
Future Attendance



Community Mobilization



Study Volunteerism



APPENDIX H

EMORY UNIVERSITY INSTITUTIONAL REVIEW BOARD

STUDY APPROVAL LETTER



EMORY
UNIVERSITY

Institutional Review Board

Carlos Del Rio, MD
SOM: Med: Infectious Diseases
69 Jesse Hill Jr. Dr
Atlanta, GA 30303

RE: **NOTIFICATION OF RENEWAL APPROVAL**
PI: Carlos Del Rio, MD
IRB ID: **566-2006**

TITLE: Evaluation of Hope Clinic Community Education and Communications Activities

DATE: May 09, 2007

Renewal Review Type: Expedited

The continuing approval request referenced above was reviewed and APPROVED by the IRB. This approval is valid from **5/8/2007** until **5/7/2008**. Thereafter, continued approval is contingent upon the submission of a renewal form that must be reviewed and approved by the IRB prior to the expiration date of this study.

Any serious adverse events or issues resulting from this study should be reported immediately to the IRB and to any sponsoring agency (if any). Amendments to protocols and/or revisions to informed consent forms/process must have approval of the IRB before being implemented.

All inquiries and correspondence concerning this protocol must include the IRB number and the name of the Principal Investigator. If you have any questions or concerns, please contact the IRB office at 404-712-0720 or at email address irb@emory.edu. Our web address is <http://www.emory.edu/IRB>. Thank you.

Sincerely,

Clifford J. Gunthel, MD
Vice Chair
Institutional Review Board

Cc: Lee N Miles
Subrina Parker

This approval is valid from 5/8/2007 until 5/7/2008.

PAGE 2 of RENEWAL APPROVAL

IRB ID: 566-2006

DATE: May 09, 2007

The above referenced protocol renewal was approved including the information below. Please review this information for accuracy. If there are any discrepancies, please notify your IRB coordinator immediately.

Informed Consents Associated with this protocol:

Version Date	Description	
3 /27/2007	Main consent	
Personnel		
Gallinot, Lauren	Other	Human Subjects Education Certification Information CITI - MED 1, 2, 3, 7, 12, 14, 17 (04-Sep-2005) SHB 1, 2, 3, 4, 5, 6 (04-Sep-2005)
Del Rio, Carlos	Main Investigator	CITI - MED 1, 2, 3, 7, 12, 14, 17 (22-May-2006) GCP Basic Modules (25-Mar-2007)
Frew, Paula	Co-Investigator	CITI - MED 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11(07-May-2006) SHB Refresher (13-May-2006) GCP Basic Modules
Parker, Subrina	Research Coordinator	CITI-MED (19-Mar-2006)
Miles, Lee N	Protocol Contact	CITI - MED 1, 2, 3, 7, 12, 14, 17 (15-Mar-2007) GCP Basic Modules (16-Mar-2007)
Gill, Priyanka	Other	CITI - MED 1, 2, 3, 7, 12, 14, 17 (14-Jun-2006) GCP Basic Modules (03-Apr-2007)
Shuster, Justin	Other	SHB 1, 2, 3, 4, 5, 6, 10, (25-Sep-2005) GCP Basic Modules (26-Mar-2007)
Harding, Ashley	Other	CITI - MED 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 SHB 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 (27-Sept-2005)
Batchelor, Cecilia	Other	CITI - MED 1, 2, 3, 4, 7, 12, 14, 17 (22-Jun-2006) SHB 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, (04-Jul-2006)
Hormes, Joseph	Other	CITI - MED 1, 2, 3, 7, 12, 14, 17 (05-Jul-2006)
Clifton, Sarah	Other	CITI - MED 1, 2, 3, 7, 12, 14, 17 (24-Oct-2006) SHB 1, 2, 3, 4, 5, 6, (23-Oct-2006) GCP Basic Modules (30-Mar-2007)

Number of Approved Emory Subjects 500 (This number indicates the number of subjects you can consent.)

Funding Agencies

NOT FUNDED

APPENDIX I

UNIVERSITY OF GEORGIA INSTITUTIONAL REVIEW BOARD

STUDY APPROVAL LETTER



Institutional Review Board
Human Subjects Office
612 Boyd GSR
Athens, Georgia 30602-741
(706) 542-319
Fax: (706) 542-336
www.ovpr.uga.edu/hs

APPROVAL FORM

Date Proposal Received: 2007-10-02

Project Number: 2008-10234-0

Name	Title	Dept/Phone	Address	Email
Ms. Paula Frew	PI	Health Promotion and Behavior Ramsey Center	3835 Colonial Trail, SW Lilburn, GA 30047 678-591-3494	pfrew@uga.edu
Dr. Su-I Hou	CO	Health Promotion & Behavior 309 Ramsey Center +6552 706-542-8206		shou@uga.edu

Title of Study: The Role of Culture-Centered Community Engagement in HIV Vaccine Research

45 CFR 46 Category: Administrative 4
Parameters:
None;

Change(s) Required for Approval:
None;

Approved : 2007-10-26 Begin date : 2007-10-26 Expiration date : 2012-10-25

NOTE: Any research conducted before the approval date or after the end date collection date shown above is not covered by IRB approval, and cannot be retroactively approved.

Number Assigned by Sponsored Programs:

Funding Agency:

Your human subjects study has been approved.

Please be aware that it is your responsibility to inform the IRB:

... of any adverse events or unanticipated risks to the subjects or others within 24 to 72 hours;
... of any significant changes or additions to your study and obtain approval of them before they are put into effect;
... that you need to extend the approval period beyond the expiration date shown above;
... that you have completed your data collection as approved, within the approval period shown above, so that your file may be closed.

For additional information regarding your responsibilities as an investigator refer to the IRB Guidelines.
Use the attached Researcher Request Form for requesting renewals, changes, or closures.
Keep this original approval form for your records.

Chairperson or Designee,
Institutional Review Board