

# Influences on adherence in African American women with HIV

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Boston College  
William F. Connell School of Nursing

INFLUENCES ON ADHERENCE IN AFRICAN AMERICAN WOMEN WITH HIV

a dissertation

by

SARA E. DOLAN LOOBY

submitted in partial fulfillment of the requirements

for the degree of

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# Influences on Adherence in African American Women with HIV

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## Abstract

Little is known about adherence among African American women with HIV. This cross-sectional study investigated the direct and indirect effects of subjective well-being (SWB), physical activity, depression, and spiritual beliefs on adherence to antiretroviral therapy, condom use, and appointment keeping in 86 participants. These variables formed a theoretical model proposed in response to findings in the literature and clinical observations.

Participants completed demographic and clinical questionnaires, the Center for Adherence Support Evaluation (CASE) Adherence Index (antiretroviral therapy adherence), Satisfaction with Life scale (SWB), Paffenbarger Physical Activity Questionnaire, CES-D (Depression), the *Faith* subscale of the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being scale (spiritual beliefs), and questions regarding condom use and appointment keeping. Descriptive statistics, ANOVA, t-tests, and Chi square analyses were used to analyze clinical and demographic variables, scale means, and effects on adherence variables. Linear and logistic regression analyses were used to test study hypotheses, and path analysis was used to confirm the relationships in the linear regression model.

The final model for medication adherence explained 31% of the variance. SWB had a direct effect ( $\beta = .30, p < .01$ ). Spiritual beliefs had direct (.21), and indirect effects

(.07) through SWB. Having a history of hospitalization for mental illness had direct (-.25), and indirect effects (-.06) through SWB. Physical activity had only a direct effect ( $\beta = -.19, p = .05$ ), and no effect on SWB ( $p = .26$ ). Findings failed to support relationships hypothesized in the model for condom and appointment adherence, though age was shown to have a positive effect ( $B = 0.06, p < .05$ ) on appointment adherence in the final model.

Further research is needed to replicate these findings in a larger cohort of African American women with HIV, and to identify factors that impact condom use and appointment keeping. Study findings argue for the need to assess spiritual beliefs, connect individuals with programs designed to enhance spiritual beliefs, and other resources that may positively influence well-being and medication adherence in this population.

## Acknowledgements

I would like to acknowledge all of the women who took time to meet with me and participate in this research study. On the hottest and coldest of days, you came out to meet with me and share your feelings, thoughts, and reflections for the benefit of other women living with HIV. What I have learned from your contributions, strength, and wisdom has forever changed my practice as a clinician and researcher.

I would like to acknowledge Dr. Anne Norris, my dissertation chair. Anne, you are an exemplary scientist, and mentor. I am truly grateful for your assistance, support, and encouragement during all phases of the dissertation process. I hope that I will be able to provide such exquisite mentorship to others in the future.

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Finally, I would like to acknowledge my husband Greg Looby, my parents Peter and Rosemary Dolan, my brother Robbie, my sister Amy, my grandmother Rita, and many other relatives and friends. Thank you for your love and support, laughter, and encouragement.

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## Chapter 1

### Introduction

HIV/AIDS is a growing health concern among women in the United States, particularly African American women (Centers for Disease Control and Prevention, June 2007). In 2005, African American women accounted for 64% of the approximate 126,964 female adults and adolescents living with HIV/AIDS in the United States, and the rate of AIDS diagnoses for African American women was approximately 23 times that of Caucasian women (Centers for Disease Control and Prevention). The disproportionate impact of HIV/AIDS on African American women in the United States highlights the need for research investigating social and culturally relevant influences on health promoting behaviors, including adherence to antiretroviral therapy, positive prevention, and medical appointments, among this population.

The definition of adherence in the context of HIV in the 21<sup>st</sup> century is complex, and should include a comprehensive collection of factors including antiretroviral medications, positive prevention, and medical appointments. This is evident for many reasons that have been previously discussed in the literature. It is well known that inadequate adherence to prescribed antiretroviral therapy may result in continued viral replication, emergence of drug-resistant strains of HIV, and treatment failure among individuals living with the virus (Bangsberg et al., 2000; Reynolds et al., 2004). In addition, the prevention of transmission of HIV and/or other sexually transmitted diseases among HIV positive individuals (described as “positive prevention”) has become a growing priority in prevention education and counseling among this population (Del Rio,

2003; Purcell, 2003). Adherence to routine medical appointments is necessary for reducing disease progression and AIDS-related mortality (Catz, McClure, Jones, & Brantley, 1999; Israelski, Gore-Felton, Power, Wood, & Koopman, 2001), as HIV is a complex illness that requires vigilant monitoring (Israelski, Gore-Felton, Power, Wood, & Koopman), and treatment is based on laboratory assessment of immune function, patient interviews, and physical examination. Thus, this investigation will evaluate an individual's ability to adhere to antiretroviral therapy, condom use as a positive prevention strategy, and scheduled medical appointments.

#### Limitations to the State of the Science Concerning Adherence

There are at least four limitations to the state of the science concerning adherence. This chapter will review these limitations, discuss what is known about adherence in women with HIV (particularly African American women), and present a direction for future research.

The first limitation is that the study of adherence has been guided by a narrow definition of the concept. In the majority of published research, adherence has been investigated in the context of antiretroviral medication use or non-use, or attendance to medical appointments exclusively. Only three published studies were found that investigated adherence to both antiretroviral therapy and medical appointments among men and women with HIV (Bakken et al., 2000; Holzemer et al., 1999; Sankar, Luborsky, Schuman, & Roberts, 2002). Though the studies by Bakken et al. (2000) and Holzemer et al.(1999) are valuable contributions to the literature, they have limited generalizability among the growing population of African American women with HIV, as

participants in these studies were predominately male and Caucasian. Sankar et al. (2002) measured clinic attendance adherence as a component of overall adherence (medication adherence was also part of this measurement) in their qualitative investigation, though reported only a percentage of overall adherence, and did not discuss clinic adherence as a separate construct.

Three studies have reported on adherence to appointment keeping among individuals with HIV (Catz, McClure, Jones, Brantley, 1999; Isrealiski, Gore-Felton, Power, Wood, Koopman, 2001; Bondenlos, Grothe, Whitehead, Konkle-Parker, Jones, & Brantley 2007). Although these investigations are significant contributions to the field, they are comprised of samples of mixed gender and ethnicity, and findings may not be applicable to women with HIV, African American women in particular.

The second limitation is that previously investigated factors influencing adherence may not be germane to those currently living with HIV, given the rapidly changing nature of HIV treatment. Several researchers have described multi-drug regimens, dose frequency, dietary requirements, and side effects of antiretroviral therapy as barriers to adherence (Ickovics & Meade, 2002; Gao, Nau, Rosenbluth, Scott, & Woodard, 2000). While these concerns were warranted at the time this literature was published, some of these barriers have disappeared due to advances in pharmaceutical and treatment research. For example, Scott (2005) described the successful impact of the use of one specific antiretroviral medication to “boost” or increase the potency of another antiretroviral medication so that the number of medications in a regimen, or the strength of the dose, can be reduced. Presently, a number of available HIV medications have been

combined into one pill. This change has resulted in a significant reduction in both dose frequency and the number of pills consumed daily. Though many antiretroviral regimens are still under investigation, some are approved for use as once-a-day agents (Piliero & Colagreco, 2003). Many researchers have also considered patient-reported adverse effects when developing new medications and dose concentrations to avoid toxicities and unpleasant symptoms, and these changes may reduce the number of medication related side effects. Finally, current HIV treatment guidelines do not recommend antiretroviral therapy use in otherwise healthy individuals with a CD4 count  $> 350$  cells/mm<sup>3</sup> and a HIV viral load  $< 100,000$  copies/ml (United States Department of Health and Human Services, 2005, p. 6). Therefore, some individuals living with HIV in the United States are not prescribed antiretroviral therapy. For this population, adherence to medical appointments is crucial.

The third limitation is that the majority of the interventions designed to improve adherence that were successful in research environments, may not translate to the clinical setting, or may lack relevance for all individuals living with HIV. These interventions include the use of pill boxes, electronic devices, self reported diaries, directly observed therapy, and provider initiated pill-counts (Fletcher et al., 2005; Fogarty et al., 2002; Liu et al., 2001; McPherson-Baker et al., 2000). Cost and unrealistic provider observation requirements can limit the possibility of these interventions (Stone, 2001; Wendel et al., 2001). Also, the amount of longitudinal data documenting the success of these interventions over time is limited. Other studies have investigated the use of behavior intervention programs with counseling and education, motivational interviewing, and

patient-tailored interventions (Holzemer, Henry, Portillo, & Miramontes, 2000; DiIorio et al., 2003; Smith, Rublein, Marcus, Brock & Chesney, 2003; Molassiotis, Lopez-Nahas, Chung, & Lam, 2003). These interventions often focus on behavior modification rather than building on strengths that are necessary to be able to engage and sustain behavior change. This limitation arises because the theoretical basis of many of these interventions focuses on fixing deficiencies and changing behaviors, instead of enhancing strengths and positive attributes that may be present. Moreover, these interventions have little relevance to those who are living with HIV and are not receiving antiretroviral therapy.

The fourth limitation is the majority of adherence research in HIV has been conducted among male or mixed gender study populations, and results may not be applicable to women with HIV. In addition, research that has focused on women has often investigated special populations of women with HIV infection. These populations include pregnant women (Wilson et al., 2001), incarcerated women (Mostashari, Riley, Selwyn, & Altice, 1998) and women with substance abuse and addiction concerns (Powell-Cope, White, Henkelman, & Turner, 2003). While these studies are of great value to women and to clinicians working with these special populations, the results cannot be generalized to the growing number of HIV-infected women who fall outside of them.

The surplus of male or mixed gender adherence literature is in part related to the lack of participation of women with HIV in clinical research trials. The recruitment and retention of women in clinical research has been a challenge for many investigators (Keyzer et al., 2005). In addition, African American women are under-represented in

HIV research trials despite their disproportional representation in HIV/AIDS cases in the United States (Cargill & Stone, 2005). Prior research has identified both gender-related barriers (Kelly & Cordell, 1996) and cultural barriers (Cargill & Stone) to research participation experienced by HIV-infected women. Researchers have suggested that lack of representation of African American men and women in research trials may be related to lack of trust in clinical research, or a history of a poor experience with the healthcare system (Cargill & Stone). Cargill and Stone (2005) believe that the improvement of participation in clinical trials by minorities is dependent on the development of research questions and interventions aimed at addressing issues that are of concern to minority communities.

Consequently, the understanding of adherence in women with HIV, particularly African American women, is limited. Demographic characteristics such as age, race/ethnicity, and socioeconomic status are frequently not associated with adherence in the literature (Cargill, Stone, & Robinson, 2004; Holzemer et al., 1999; Stone, 2001). However, the same cannot be said for gender. Women have been reported to be less likely to take antiretroviral therapy (ART; Hader, Smith, Moore, & Holmsberg, 2001), and are less adherent to ART than men (Powell-Cope, White, Henkelman, & Turner, 2003). Women may also experience different barriers to adherence. Roberts and Mann (2000) published one of the few investigations examining barriers to adherence experienced by women with HIV. The investigators discovered that in addition to medication-related challenges, women identified social relationships such as the stress associated with being a single parent and caretaker, and taking pills in public or in certain

social situations as barriers to adherence. Substance abuse has been reported as a predictor of poor adherence to antiretroviral medication among women (Powell-Cope et al., 2003). Depression also has been identified as a barrier to adherence in studies of women (Hader et al., 2001; Schuman et al., 2001) and combined samples of men and women (Holzemer et al., 1999; Stone, 2001). In addition, the patient-provider relationship has been described as a critical component for engaging HIV positive women with health care (Stone, 2001).

Researchers investigating adherence among combined samples of African American men and women have identified culturally specific barriers. African American men and women have higher AIDS mortality rates, suggesting potential delay in HIV/AIDS diagnosis, and/or poor or limited treatment access and exposure to treatment options (Cargill, Stone, & Robinson, 2004). Barriers to treatment experienced by this population often include a lack of trust in both the healthcare system, and in the safety and efficacy of antiretroviral therapy (Siegel, Kraus, & Schrimshaw, 2000; Cargill et al., 2004). African Americans also may experience many socio-cultural barriers resulting from racism, sexism, poverty, fear of disclosure, and stigma (Cargill et al.). Still other barriers have been described including depression and anxiety (Cargill et al.). Collectively, these barriers may be exacerbated by HIV diagnosis and subsequent healthcare needs (Cargill et al.).

A limited number of studies investigating influences of adherence among African American women exclusively were identified in the literature. Two studies found that African American women often do not adhere to antiretroviral therapy because taking

medication reminds them of being HIV positive (Sankar, Luborsky, Schuman, & Roberts, 2002; Gant & Welch, 2004). Edwards (2006) investigated the relationship between perceived social support and adherence and identified stigma, feeling “unloved,” relationship strain, and having a husband who was HIV positive as barriers. Sankar et al. (2002) found that African American women in their cohort practice “selective adherence” to protect “oneself and one’s children” related to fear of stigma (p. 215). In contrast, participants in the investigation by Gant and Welch (2004) reported that having a child helps to motivate medication adherence. Similarly, Edwards found that having young children facilitates adherence practices. All three studies identified support and encouragement from family members and healthcare providers as factors that strengthen adherence. In addition, Sankar et al. found that religiosity or support from a higher power (e.g., God) was suggested to be a strong influence on antiretroviral medication adherence and support among this population. Additional influences identified by Gant and Welch including substance abuse and sexual abuse are consistent with results previously reported among Caucasian and Latina women living with HIV.

The findings from these studies are important, though are limited by sample size and generalizability. Each study was qualitative in nature and utilized face to face interviewing, focus groups, and/or journaling for methodology. Two of the investigations interviewed participants from the clinic or community support agency in which they receive care or support, and therefore, there may be potential for over reporting of adherence or underreporting of barriers (Sankar, Luborsky, Schuman, & Roberts, 2002; Gant & Welch, 2004). In one of the studies, the use of journaling was not randomly



assigned, suggesting potential bias in findings (Edwards, 2006). The presence of these limitations warrants the need for further investigation and/or replication of these findings within this population.

Although the literature is limited, it suggests that African American women report unique barriers and challenges to adherence to their HIV treatment regimens. Stigma and depression pose a challenge to adherence for African American women. Spirituality or connection with a higher power is one resource that has been identified as a source of support for African American women during times of emotional crises, and has also been identified as a positive influence on adherence. Future research is needed to identify other strengths possessed by African American women living with HIV that may serve as a resource to help them overcome barriers to adherence. This may be possible through a research approach that differs from established interventions that focus on characteristics individuals may not possess including self efficacy and motivation, both of which require behavior modification to improve adherence. Research guided by a novel perspective offers a new direction for adherence research based on a broad definition of adherence and a strong focus on strengths and resources that these women bring to bear.

## Chapter 2

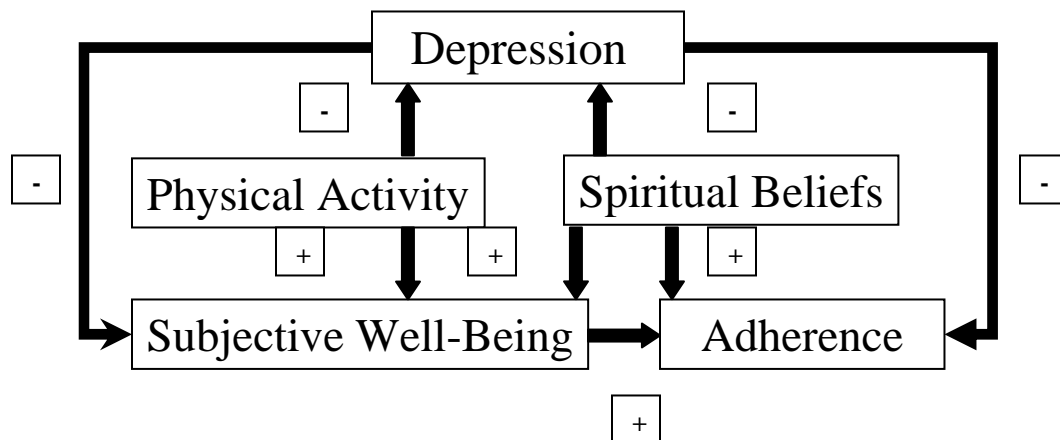
### Conceptual Model

Adherence to healthcare recommendations, including antiretroviral therapy, condom use, and scheduled medical appointments, is critical for viral suppression, prevention of transmission of resistant strains of HIV, symptom and disease management (Bangsberg et al., 2000; Purcell, 2003; Holzemer et al., 1999). Research on adherence in African American women is limited (Sankar, Luborsky, Schuman, & Roberts, 2002). However, available literature suggests that depression may play a role (Cargill, Stone, & Robinson, 2004), and qualitative research points to the use of personal resources, such as spiritual beliefs, to positively influence adherence among this population (Sankar et al., 2002). Unfortunately, the relationship of these unique and culturally relevant factors to adherence has not been well studied. In addition, Simoni, Frick and Huang (2006) contest that the area of adherence research is “relatively atheoretical” (p. 74), as there is no valid or established model or theory of adherence that explores the relationship of variables known to influence adherence and non-adherence among individuals with HIV.

This study investigates the direct and indirect influence of subjective well-being, physical activity, depression, and spiritual beliefs on adherence among African American women with HIV. Each of these factors captures a dimension of spirit, mind and body and has the potential to influence an individual’s ability to adhere to a prescribed treatment regimen. This study was guided by a novel theoretical model that examined the influence of these variables on adherence among African American women with HIV (Figure 1).

Figure 1.

Model of influences on adherence in African American women with HIV



#### Major Tenets of the Model and Rationale

##### *Adherence*

For the purpose of this study, adherence is defined as an individual's ability to participate in healthcare recommendations including antiretroviral therapy use, condom use as a positive prevention strategy, as well as scheduled medical appointments. Adherence to antiretroviral therapy is critical for viral suppression, and prevention of the development of resistance (Bangsberg et al., 2000). Adherence to medical appointments is of equal importance for symptom management and to reduce progression to AIDS (Catz, McClure, Jones, & Brantley, 1999; Israelski, Gore-Felton, Power, Wood, & Koopman), especially for those who are not receiving antiretroviral therapy. Adherence to positive prevention strategies including condom use is necessary to reduce transmission of HIV, and to limit exposure to other strains of the virus among individuals

who are positive (Del Rio, 2003; Purcell, 2003). This broad definition captures a comprehensive picture of adherence and has more applicability for clinical use among women living with HIV in the 21<sup>st</sup> century.

### *Subjective Well-Being*

Subjective well-being (SWB) is described as “happiness,” or the cognitive and affective evaluation of ones’ own life (Diener, 2000, p.34). SWB is measured by evaluating life satisfaction and positive and negative mood states. The majority of the HIV literature that has previously examined psychological reactions to disease has focused on distress, anxiety, and other negative psychological reactions to living with HIV (Goggin et al., 2001). This is likely a result of the profound impact that lack of treatment options and high mortality rates had on the psychological well-being of infected women at the beginning of the epidemic. Today, HIV is a less acute and more chronic illness for many in the United States, and researchers are beginning to investigate how women living with HIV can have a positive outlook on life despite a HIV diagnosis, and to identify factors that contribute to a positive or satisfying life among this population (Goggin et al., 2001; Dunbar, Mueller, Medina, & Wolf, 1998).

Research examining the relationship between subjective well-being and adherence is limited, particularly among women and African Americans with HIV. Gonzalez and colleagues (2004) found some support for the influence of SWB on adherence among individuals with HIV. The investigators specifically examined the relationship between adherence and social support, depression, and “positive state of mind (PSOM),” among men and women with HIV. Study results suggested that higher levels of PSOM were

significantly related to medication adherence and this relationship was independent of depression (Gonzalez et al., 2004). The investigators also found that PSOM was a mediator between social support and adherence among this cohort (Gonzalez et al., 2004). Thus, the results of this study indicate that positive state of mind influences adherence behaviors in this population. The researchers also comment on the need to investigate positive mood states as an influence on adherence to health practices in this population.

### *Physical Activity*

Physical activity consists of “any bodily movement produced by skeletal muscles that results in energy expenditure” (Caspersen, Powell, & Christenson, 1985, p. 126). Literature examining the physical and psychological benefits of physical activity among African American women living with HIV exclusively has not been published. However, physical activity in the form of progressive resistance training and/or aerobic activity has been associated with at least three benefits in the literature.

First, individuals with HIV experience many physiologic benefits from participation in physical activity. These physical benefits include improvement in cardiorespiratory fitness and waist circumference (Dolan et al., 2006), and reduced trunk fat (Roubenoff et al., 1999). Roubenoff and Wilson (2001) also found an association between participation in resistance training and improvement in physical functioning among HIV positive individuals with low weight.

Second, physical activity has been associated with improvement in subjective well-being. Lox and colleagues (1995) examined the role of a 12 week exercise program

as an intervention for enhancing subjective well-being (life satisfaction, positive and negative mood), and self efficacy among a cohort of HIV-infected men. The results showed that those who received the exercise intervention had enhanced positive mood, life satisfaction, and self-efficacy compared to the control group. These findings indicate that physical activity through aerobic or resistance training may enhance subjective well-being among individuals with HIV, and should be considered as an adjunct treatment for improving psychological symptoms associated with HIV (Lox, Tucker, & McAuley, 1995).

Third, participation in physical activity has been associated with improvement in depression among this population. Neidig and colleagues (2003) conducted a randomized trial to investigate the effects of 12 weeks of aerobic exercise on depression among men and women living with HIV. Upon completion of the study, participants randomized to the exercise component (control subjects did not receive any intervention) reported significantly lower depressive symptoms than the control subjects (Neidig, Smith, & Brashers, 2003). Results from this study suggest that participation in physical activity through aerobic exercise may result in a decreased incidence of depressed mood among men and women with HIV.

### *Depression*

Depression is a negative mood state associated with a cluster of symptoms including fatigue, poor appetite, weight loss, guilt, worthlessness, sleep disturbance, and trouble concentrating (Neidig, Smith, & Brashers, 2003; Radloff, 1977). It is estimated that one-third to one-half of men and women living with HIV experience symptoms of

depression (Eller et al., 2005). Depression has been described as a significant predictor of non-adherence among combined samples of men and women with HIV (Holzemer et al., 1999; Singh et al., 1996; Fogarty et al., 2002), and among women exclusively (Schuman et al., 2001).

Depression has been associated with poor health and treatment outcomes in African American women with HIV (Feist-Price & Wright, 2003; Cargill, Stone, & Robinson, 2004). African American women living with HIV have been reported to experience a higher incidence of depression and emotional distress compared to African American men with the virus (Feist-Price & Wright, 2003). Depression often translates into poor adherence practices among African Americans with HIV, though research investigating this relationship is limited (Cargill & Stone, 2005).

### *Spiritual Beliefs*

Spiritual beliefs are described by Holland and colleagues (1998) as “the degree to which individuals feel they derive meaning from an existential perspective” (p.462), or “a relationship to a superior being, or a perceived higher power” (p. 462). Spiritual beliefs are a source of meaning, expression, and a way to cope with illness among African American men and women (Johnson, Elbert-Avila, & Tulsy, 2005). Possession of spiritual beliefs has been associated with enhanced psychological well-being and coping among individuals living with cancer, and HIV (Reed, 1987; Coleman & Holzemer, 1999). Spiritual beliefs have also been shown to influence decision making and treatment preferences among African Americans with chronic illness, including HIV (Johnson et al., 2005; Polzer & Miles, 2005).

Spirituality expressed through spiritual beliefs has been found to influence adherence to health promoting behaviors among African American women. Sankar and colleagues (2002), as discussed in chapter one, reported “God” or support from a higher power as an influence of adherence to antiretroviral therapy among African American women with HIV. In their study of HIV-negative African American women, Holt and colleagues (2003) found that women who reported greater spiritual beliefs were more likely to utilize and have improved knowledge of mammography and cancer treatment than those with lower spiritual beliefs. Similarly, spirituality was identified as a source of emotional support that positively influenced health management and life satisfaction among African American women living with type-2 diabetes (Samuel-Hodge et al., 2000). Collectively, these results suggest a relationship exists between spiritual beliefs and adherence among African American women with chronic illness, including HIV.

Spiritual beliefs have also been shown to influence well-being and depression. Coleman and Holzemer (1999) investigated the influence of spiritual beliefs (defined as existential well-being or a spiritual source of meaning), socio-demographics, and HIV symptoms to psychological well-being (measured by depression, state-trait anxiety and hope) among African American men and women with HIV. Study results suggest that existential well-being was a strong predictor of psychological well-being among this cohort (Coleman & Holzemer, 1999). In a follow-up study, Coleman (2004) examined how spiritual beliefs, comprised of religious and existential well-being, influenced depression among a subgroup of heterosexual participants from his 1999 cohort. Study results indicated that participants with stronger spiritual beliefs (specifically higher



existential well-being and religious well-being scale scores) reported lower depression scores. Coleman's research suggests that spiritual beliefs can positively impact well-being and depression in this population.

### *Summary*

In summary, adherence to antiretroviral medication, medical appointments, and condom use is essential for positive health outcomes among individuals living with HIV. The number of African American women living with HIV in the United States is steadily increasing. However, little is known regarding the specific influences on adherence among this population. The literature review provided in this chapter identifies subjective well-being, physical activity, depression, and spiritual beliefs as potential direct or indirect influences on adherence among individuals, including African American women, living with HIV. Furthermore, spiritual beliefs and physical activity may positively influence depression and SWB among this population, suggesting that these variables have the potential to counter depression and its negative effects on adherence.

## Chapter 3

### Methods

#### *Specific Aims*

This study investigates the direct and indirect relationship of subjective well-being, physical activity, depression, and spiritual beliefs on adherence in African American women with HIV. Also of interest is the influence that physical activity and spiritual beliefs have on depression, a variable known to negatively impact adherence, and the influence these variables, including depression, have on subjective well being. This study utilizes a novel theoretical model to evaluate these relationships, and a multi-dimensional definition of adherence that captures medication use, condom use, and appointment keeping.

#### *Hypotheses*

With the use of the proposed theoretical model for guidance, this study will test the following hypotheses:

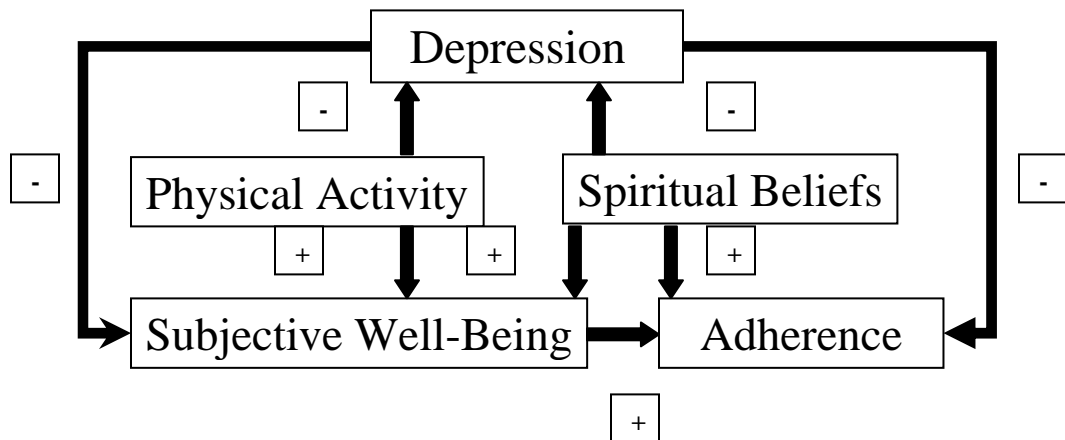
1. Adherence to antiretroviral medication, condom use, and health appointments is negatively influenced by depression, and positively influenced by subjective well-being, spiritual beliefs and physical activity in African American women with HIV. Physical activity is predicted to have only an indirect effect on adherence, and subjective well-being is predicted to have only a direct effect on adherence. Spiritual beliefs and depression are predicted to have both direct and indirect effects on adherence.

2. Subjective well-being is negatively influenced by depression, and positively influenced by spiritual beliefs, and physical activity among African American women with HIV.
3. Depression is negatively influenced (decreased) by physical activity and spiritual beliefs among African American women with HIV.

Also of interest is if any of the clinical, demographic, or open ended question data has a relationship with the major tenants of the model.

*Figure 1.*

Theoretical model of the influences on adherence in African American women with HIV



*Sample*

This study recruited African American women with HIV who reside in the state of Massachusetts.

*Inclusion Criteria*

1. Women age eighteen years or over
2. African American
3. HIV positive (self report)
4. English Speaking
5. Able to provide informed consent

The final study sample included 86 African American women with HIV who reside in Massachusetts. Eighty-seven women signed consent. One participant reported she was African American during the eligibility screening then checked only “White, not Hispanic” in the demographic questionnaire, and was excluded from study analyses.

Sample size varied in the regression analyses because of missing data. A sample size of 63 – 84 is able to detect effect sizes ranging from 0.15 - 0.21 assuming a power of 0.80 and using a one-tailed alpha level of 0.05 (Cohen & Cohen, 1983). This power analysis was performed for the linear regression analysis for medication adherence.

Participants were recruited through the distribution of research flyers and/or investigator-initiated communication with healthcare providers and leaders at AIDS Service Organizations (including housing, recovery, research fairs, support, and education centers), day and overnight shelters, local and statewide consumer advisory boards, and HIV clinics/health centers in community and hospital settings throughout the state of Massachusetts. The following Health Service Regions were targeted for community recruitment: Boston, Metrowest, Central, Northeast, Southeast, and Western Massachusetts (Commonwealth of Massachusetts, Department of Public Health,

Executive Office of Health and Human Services Regions 2000 Census Population, 2001). In addition, individuals who have participated in a clinical trial conducted in the Program in Nutritional Metabolism at the Massachusetts General Hospital, and gave permission to be contacted regarding other studies (and met the eligibility criteria) were contacted. A few of the participants reported learning about the study from a friend who had previously participated (e.g., “snowball sampling”).

The majority of the study participants were recruited from community settings/advertisement, and most participants were seen in the Boston Health Service Region (HSR; Table 1). The demographic pattern seen in recruitment and study visit location is representative of, and consistent with the statewide HIV/AIDS HSR surveillance data seen in Massachusetts. As of October 2007, women represented approximately 4,893 of the 17,057 reported individuals living with HIV/AIDS in Massachusetts, and African American women accounted for 40.4% (1,976) (Massachusetts Department of Public Health, 2007). Statewide, the majority of women infected with HIV, 23.3% (1,280), and the highest number of African American women and men with HIV 37.6% (2,069, reported as mixed gender) were reported in the Boston HSR, compared to the five other HSR in the state (Massachusetts Department of Public Health, 2007; Massachusetts Department of Public Health: HIV/AIDS Bureau, 2007).

Table 1

*Recruitment Demographics (N = 86)*


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Community recruitment	71% ( <i>n</i> = 61)
Prior study participation <sup>£</sup>	29% ( <i>n</i> = 25)
Boston <sup>§</sup>	58% ( <i>n</i> = 50)
Cambridge	16% ( <i>n</i> = 14)
Northeast	9% ( <i>n</i> = 8)
Central	8% ( <i>n</i> = 7)
Metrowest	5% ( <i>n</i> = 4)
Western	2% ( <i>n</i> = 2)
Southeast	1% ( <i>n</i> = 1)

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Note. <sup>£</sup> Reflects those who participated in other studies in the Program in Nutritional Metabolism at Massachusetts General Hospital and gave permission to be contacted regarding other studies.

<sup>§</sup> Includes Dorchester, Roxbury, Mattapan, and Roslindale. Based on Health Service Regions in the state of Massachusetts (Massachusetts Department of Public Health, Executive Office of Health and Human Services Regions 2000 Census Population)

Twenty-nine percent (*n* = 25) of the women enrolled have participated in a research study in the Program in Nutritional Metabolism at MGH. Approximately 76% (*n* = 19) of the women in this recruitment category have participated in a research study

with the current investigator. None of these subjects receive ongoing routine medical care, HIV-related infectious disease consultation, prescriptions for antiretroviral therapy (ART), or ART adherence assessment/management from the current investigator.

The demographic characteristics of the study participants are presented in Table 2. The median age of the sample was 48 years, and is consistent with the age of a majority of women living with HIV/AIDS in the state of Massachusetts. In November 2007, 19% of women with HIV/AIDS were age 45 to 49 years, and 25% were 50 years of age or older (Massachusetts Department of Public Health HIV/AIDS Surveillance Program, 2007). Subjects were asked to check all ethnic groups “that apply” on the demographic questionnaire. Ninety-eight percent ( $n = 84$ ) of the participants reported African American, and 2 participants checked both “Black Hispanic” and “Bi-racial including African American.” Nine participants (10%) reported “African American” in addition to other ethnic groups. Ninety-nine percent ( $n = 85$ ) of the participants were born in the United States. One participant was born outside of the United States, but was raised in the U. S. and reported “African American” ethnicity.

Most participants 36% ( $n = 31$ ) were high school graduates or had a GED, and 69% ( $n = 59$ ) were unemployed. Ninety-four percent ( $n = 81$ ) were recipients of the public health insurance plan for residents of Massachusetts known as “Mass Health” (Mass Resources, 2008; Table 2). Eighty-seven percent ( $n = 75$ ) reported practicing a religious faith by prayer or attending services, and close to half of the participants (43%;  $n = 37$ ) were Baptist.

Table 2

*Demographic Characteristics (N = 86)*


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Age (yrs)	
Median	48
Range	22 - 61
Race/Ethnic Group <sup>‡</sup>	
African American	98% (n = 84)
Black Hispanic	5% (n = 4)
Native American	6% (n = 5)
White, Non Hispanic	1% (n = 1)
Biracial including African American	4% (n = 3)
Born in the United States	99% (n = 85)
Education	
Less than High School Degree	29% (n = 25)
GED or High School Degree	36% (n = 31)
More than High School Degree	34% (n = 29)
Current Employment Status	
Not Working	69% (n = 59)
Work Full Time / Volunteer Full Time	13% (n = 11)
Work Part Time / Volunteer Part Time	19% (n = 16)
Current Partner Status	
Single	64% (n = 55)



Married/in a Relationship	36% ( <i>n</i> = 31)
Number of Children	
Participants with children	93% ( <i>n</i> = 80)
Median number of children	2
Range	1 - 7

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Note. <sup>£</sup> Participants were asked to check all ethnic groups that apply.

The majority (93%; *n* = 80) of the participants have children and 73% (58) of those with children have custody of their children (median number 2; range 1 - 6). Thirty-eight percent (*n* = 30) report their children live at home (median 2; range 1 - 4). Nine percent (8) of the participants either baby sit or care for other children routinely (median number of children 1; range 1 - 3).

The clinical characteristics of the study sample are presented in Table 3. Fifty-nine percent (*n* = 51) report having an undetectable HIV viral load, suggesting the sample has stable HIV infection. Data on current CD4 count was not obtained. However, 48% (*n* = 41) report a history of an AIDS diagnosis, and 44% (*n* = 38) report ever having had a CD4 count < 200, and the median duration of HIV (13 years) implies the sample represents women with chronic HIV infection. It is possible an AIDS diagnosis was given in the pre-HAART (high active antiretroviral therapy) era.

Table 3

*Clinical Characteristics (N = 86)*


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Duration of HIV (yrs)	
Median	13
Range <sup>‡</sup>	60 days – 30 years
AIDS Diagnosis	48% (n = 41)
Ever CD4 Count < 200	44% (n = 38)
Current Undetectable Viral Load	59% (n = 51)
Currently Receiving Antiretroviral Therapy	74% (n = 64)
Current Substance Abuse <sup>§</sup>	14% (n = 12)
History of Substance Abuse	79% (n = 68)
Most problematic substance	
Cocaine	41% (n = 26)
Crack	31% (n = 20)
Alcohol	30% (n = 19)
Heroin	23% (n = 15)
Marijuana	8% (n = 5)
Duration of Substance Abuse (yrs)	
Median	12
Range	1 - 36
Required Detoxification for Substance Abuse	69% (n = 59)
Current Smoker	59% (n = 51)

Number of cigarettes/day	4
Number of years	11
Range	1 – 46
Known Diagnosis of Depression	78% ( $n = 67$ )
Known Diagnosis of Anxiety	50% ( $n = 43$ )
Required Hospitalization for Mental Illness	41% ( $n = 35$ )
Currently Pregnant	0% ( $n = 0$ )

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Note. <sup>£</sup> Participant reports exposure in 1977 and confirmed testing in the early 1980s.

<sup>§</sup> Represents those who report substance abuse in the past 30 days.

Seventy-nine percent ( $n = 68$ ) of the participants report a history of substance abuse for a median duration of 12 years. Among those who reported a history of substance abuse, cocaine was the most problematic substance 41% ( $n = 26$ ), followed by crack 31% ( $n = 20$ ), and alcohol 30% ( $n = 19$ ). Participants often reported more than one substance as being problematic, and four subjects who reported a history of substance abuse did not identify a problematic substance.

### *Procedures*

Enrollment occurred between January 2007 and October 2007. Recruitment ceased when minimal calls were received after re-advertising at multiple locations across the state, and when a number of women who previously participated called again to inquire about the study. At this point, preliminary statistical analyses were performed to confirm that study outcomes could be measured with the current sample.

Study visits were typically scheduled within ten days of contact, and took place at a location that was mutually convenient for the investigator and the participant (e.g., public library). The study protocol and inclusion criteria were reviewed with each participant. Women who did not meet the eligibility criteria were not allowed to participate. The investigator reviewed the consent form and obtained written informed consent from all eligible participants at the time of the study visit. All participants received a copy of the signed consent form. Participants received identical anonymous survey packets that included demographic and clinical forms, and a collection of questionnaires. Eighty-one percent ( $n = 70$ ) of the participants completed the survey packets independently, and 19% ( $n = 16$ ) requested assistance from the investigator. Of note, there was no significant difference in adherence practices between those who completed the survey packets independently or with assistance ( $p = \geq .23$ ). Study visits took approximately 35 to 60 minutes to complete, and the investigator was present during the entire visit to answer questions and review completed survey packets for missing data. Participants placed the completed questionnaires in an individual envelope with an enrollment number listed on the outside, and returned the envelope to the investigator. Consent forms and eligibility check lists were placed in a separate binder. All completed questionnaires were reviewed in the presence of the study participants and preliminary CES-D scores were calculated. Participants who expressed emotional concerns related to study participation, had suicidal ideation, and/or a CES-D score greater than or equal to 18, were asked if they had current treatment and/or support for their symptoms, and were offered additional supportive services. Forty-one percent ( $n = 35$ ) of the participants had

a CES-D score greater than or equal to 18, and none of the participants requested or accepted any offers for additional supportive services. All study materials were stored in a secured area in the investigator's office. Participants who completed the study received a ten dollar gift card to a local pharmacy.

The investigator received approval from the Institutional Review Board (IRB) at both Partners Human Research Committee via Massachusetts General Hospital, and Boston College prior to the initiation of study procedures (Appendix A; for research consent form see Appendix B). In addition, a Certificate of Confidentiality was obtained from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) a division of the National Institutes of Health (NIH), to further protect the research participants (Appendix A).

## Definitions and Instruments

### *Adherence*

This investigation will evaluate an individual's ability to adhere antiretroviral therapy, condom use, and scheduled medical appointments. The questionnaires used to measure each dimension of adherence are described in the following paragraphs.

### *Medication Adherence*

Adherence to antiretroviral therapy (ART) was measured with the use of the Center for Adherence Support Evaluation (CASE) Adherence Index questionnaire (Appendix C; Mannheimer, et al., 2006). The CASE Adherence Index is a 3-item questionnaire designed to measure three dimensions of adherence to antiretroviral therapy. These dimensions include: frequency of "difficulty" taking medication (never,

rarely, most of the time, all of the time); average number of days per week at least one dose of ART was missed (everyday, 4 – 6 days/week, 2 -3 days/week, once a week, less than once a week, never); and the last time at least one dose was missed (within the past week, 1 – 2 weeks ago, 3 – 4 weeks ago, between 1 and 3 months ago, greater than 3 months ago, never; Mannheimer, et al., 2006). Total scores range from 3 – 16 with higher scores reflecting better adherence ( $> 10$  indicates good adherence,  $\leq 10$  indicates poor adherence; Mannheimer, et al., 2006). The CASE Adherence Index was developed and tested on a sample of 524 HIV positive individuals (34% female, 66% African American). To assess validity, the CASE Adherence Index was compared to a 3-day self-reported method of adherence (Chesney et al., 2000), and was found to perform significantly better in predicting changes in HIV RNA, and was similar to the three day self report measure for predicting CD4 count (Mannheimer, et al., 2006).

For the purpose of this investigation, Z scores were calculated from the raw scores for each individual CASE item. There were differences in the number of response items between questions 1, and 2 and 3, and Z scores provided a standardized item score which was then summed for the purpose of this analysis. The Cronbach's alpha coefficient for the total CASE Adherence Index using the Z scored items was 0.78 ( $n = 64$ ).

#### *Positive Prevention Adherence*

The concept of positive prevention was operationalized as adherence to condom use for the purpose of this investigation, and was measured using five questions derived from clinical experience, consultation from the dissertation committee, and the literature (Graham, Crosby, Sanders, & Yarber, 2005; Sheeran, Abraham, & Orbell, 1999). The

first three questions asked participants if they had a regular partner, if their partner was HIV positive, and partner gender. Question 4 measured frequency of condom use during sexual intercourse in the past three months, and response items included: “I am not having sex with my partner,” “Never,” “Some of the time,” “Most of the time,” and “All of the time.” Question five measured condom use at last intercourse, and response items included: “No I did not use a condom,” “Yes, but that was more than 3 months ago,” “Yes, and this was in the past 3 months,” and “This question does not apply to me.”

Question five, condom use at last intercourse, was used for study analyses. The response items for this variable were condensed into a dichotomized variable (No, I did not use a condom vs. Yes for any ever use of a condom reported) for study analyses.

#### *Appointment Adherence*

Participants were asked to answer three questions regarding appointment adherence. These questions were developed by the investigator and dissertation committee based on clinical experience. Question one asked about appointment frequency. Question two asked about missed/rescheduled appointments in the last 6 months (yes, no, or I had no scheduled appointments). The number of appointments that were missed, if applicable, was also collected. Question three inquired about missed appointments related to childcare.

Question two was used for study analyses, and was transformed into a dichotomized variable (yes or no). Response item three for question 2 was changed to “not applicable.” Adherence to appointment keeping was assessed overall and by frequency of appointment. Analyses were performed to see if a relationship existed

between frequency of appointments and appointment keeping behavior. Due to the small cell size, a series of Fishers exact analyses were computed and were not significant ( $p = .63$ ), suggesting that frequency of appointment did not effect appointment keeping behavior, therefore question 2 exclusively was used in the overall data analysis.

#### *Open Ended Question Data*

After completing each adherence questionnaire, participants were asked to list up to three reasons why they did not adhere to medications, condom use, and appointments. This question was in open ended format, and answered if it was applicable to the participant.

Participant responses were entered into the data base for each specific adherence variable (medication, condom use, and appointment adherence). The data was reviewed for emerging conceptual themes relative to each of the adherence variables (specific theme names are discussed in the Results section and Tables 8 - 10). Responses were assigned to each relevant theme by the investigator.

A subset of the responses and the list of the themes developed for each specific adherence question was shared with a rater and reviewed for inter-rater reliability. The rater was asked to assign each response to the most relevant theme. Theme assignments were reviewed for consistency upon completion. Agreement for theme assignment was reached for 38 of the 41 responses (93%) for medication adherence, 33 of the 38 responses (87%) for condom adherence, and 35 out of 39 of the responses (90%) for appointment adherence prior to discussion. Conflicting responses were then discussed resulting in 100% agreement for the final theme assignment used for data analysis



purposes. Of note, the title of one of the themes in the condom adherence question was modified from “Partner is also positive” to “Both partners aware of status,” after the rater discussions. Although calculated after rater discussion, and therefore only considered tentative estimates of reliability, Cohen’s Kappa values for each adherence theme were generally good ranging from 0.78 – 0.90 for the 3 themes for which agreement was not reached for medication adherence; 0.55 - 0.82 for the 5 themes for which agreement was not reached for condom adherence; and 0.76 - 0.87 for the 4 themes for which agreement was not reached for appointment adherence. Of note, the condom adherence theme with a Cohen’s Kappa of 0.55 was the theme that was modified to “Both partners aware of status,” as previously described.

#### *Demographic and Clinical Characteristics*

Demographic and clinical characteristics were reported on two separate forms (Appendix C). Demographic variables included: age (years), education (less than high school, high school graduate or GED, more than a high school degree), marital/ partner status, number of children (custody, are children living with research participant, other children who are cared for by the participant), employment status (full time, part time, retired, unemployed, volunteer), religion/practice or prayer, and type of health insurance.

Clinical variables consisted of duration of HIV in years, current undetectable viral load (yes - no), if ever a CD4 count < 200, and ever an AIDS diagnosis (yes - no).

Participants were also asked about current antiretroviral therapy use (yes or no), smoking history, substance abuse, history of anxiety, depression, hospitalization for mental illness, current pregnancy, and current physical impairment.

Responses for both demographic and clinical questionnaires were either multiple choice or open ended. Questions in this section were developed by the investigator with consultation from the dissertation committee.

### *Subjective Well-Being*

Subjective well-being (SWB) represents a cognitive and affective evaluation of an individual's own life, and is comprised of life satisfaction, and positive and negative affect/mood state (Diener, 2000). SWB was measured in this investigation with the use of the Satisfaction with Life Scale, and mood state was measured with the use of the Center for Epidemiologic Studies Depression Scale (described in subsequent paragraphs).

Life satisfaction is a “cognitive, judgmental process” or evaluation of global life domains (Diener, Emmons, Larsen, & Griffin, 1985, p. 71). Life satisfaction was measured by respondents' scores on the Satisfaction with Life Scale (SWLS; Appendix C). The SWLS is a valid and reliable measure of life satisfaction and SWB among a number of diverse cohorts (Diener, et al., 1985; Pavot, Diener, Colvin, & Sandvik, 1991). The SWLS is a 5 item scale, and participants are asked to indicate how true each statement is by selecting from response items ranging from 1 (strongly disagree) to 7 (Diener, 2006). Total scores are summed upon completion (range 5 – 35), and a higher score indicates greater life satisfaction. Categories associated with score ranges are as follows: 5 – 9 *extremely dissatisfied*, 10 – 14 *dissatisfied*, 15 – 19 *slightly below average in life satisfaction*, 20 - 24 *neutral (average score)*, 25 – 29 *high score*, 30 – 35 *extremely satisfied* (Diener, 2006).

Prior to study enrollment, the items on the SWLS were reviewed for clarity and comprehension by three women who were similar to the prospective study cohort. Based on their review, the wording was modified on items one and five. Item one was changed from “In most ways my life is *ideal*” to “In most ways my life is *perfect*.” Item 5 was changed from “If I could live my life over, I would change almost nothing” to “If I could live my life over *there is little I would change*.” In the initial reliability analysis, item 5 had a low item to total correlation ( $r = 0.21$ ) compared with the remaining four items which lowered Cronbach’s alpha to 0.76 ( $N = 86$ ), and this may reflect a problem with the wording of the item in relation to the response items. This item was dropped from data analyses for the purpose of this study, and the range for the total scale score changed to 4 – 28. In order to match the score range for assignment to a specific category for score interpretation purposes, the median scale score was multiplied by 1.25, per the advice of Dr. Diener (E. Diener, personal communication, January 12, 2008) a co-creator of the scale. The Cronbach’s alpha for the four item scale was 0.85 ( $N = 86$ ) in this study population.

### *Physical Activity*

Physical activity consists of “any bodily movement produced by skeletal muscles that results in energy expenditure” (Caspersen, Powell, & Christenson, 1985, p. 126). Engagement in physical activity was measured with the Paffenbarger Physical Activity Questionnaire (PPAQ; Paffenbarger, Wing, & Hyde, 1978; Lee, Paffenbarger, & Hsieh, 1992; Appendix C).

The PPAQ, also referred to as the *College Alumni Health Study*, is a self-report questionnaire that evaluates daily engagement in physical activity including stair climbing and walking, in addition to sports and recreation activities (Paffenbarger, Wing, & Hyde, 1978; Lee, Paffenbarger, & Hsieh, 1992). A number of reliability and validity analyses have been performed, as described by Pereira et al. (1997), and results have consistently supported the use of the PPAQ among individuals of diverse age, gender, and physical activity levels (Lee, Paffenbarger, & Hsieh, 1992). Items from the PPAQ have been described by Lee and colleagues in figure 1 of their publication (1992; excerpts from PPAQ items from 1962, 1966, 1977, & 1988), and Pereira and colleagues (1997) in their publication of physical activity questionnaires for health research. Items from the PPAQ presented in the publication by Pereira and colleagues (1997; p. S85-S86), were used for the purpose of this investigation.

The total gross number of weekly kilocalories per participant was calculated from the reported number of blocks walked and flights of stairs climbed per week. The sum of the number of reported blocks walked per day was multiplied by 56 kilocalories, and added to the total number of reported flights of stairs climbed per day multiplied by 14 kilocalories, to provide the total number of kilocalories per week per participant (Lee, Paffenbarger, & Hsieh, 1992; I. M. Lee, personal communication, January 24, 2008). Participants who reported engagement in an additional activity such as walking, jogging or bicycling, inconsistently reported frequency of participation in such an activity, and this made it difficult to calculate accurate kilocalorie scores for this item. Therefore, only the total and combined number of kilocalories expended from participation in stair

climbing and walking was used in the final study analyses. Item 8 of the questionnaire used in the current investigation is part of the Framingham Heart Study (Franco et al., 2005; I. M. Lee, personal communication, January 24, 2008), and requires a different scoring format. Therefore, item 8 was not used as part of the total score for the physical activity variable.

The total number of kilocalories of physical activity per week was rescaled into three kilocalorie segments (< 1,000; 1,000 – 2,500; and > 2,500 kilocalories as shown by Lee, Paffenbarger, and Hsieh, 1992), for the purpose of the logistic regression analyses for both appointment and condom use adherence. This rescaling was necessary to increase the size of the increment between intervals for estimation of the non-standardized coefficients in the logistic regression analyses. There was no significant difference between the continuous physical activity kilocalorie variable used in the linear regression analysis for medication adherence and the rescaled variable ( $r = 0.91$ ,  $p < .001$ ).

### *Depression*

Depression is a negative mood state associated with symptoms such as fatigue, poor appetite, weight loss, guilt, worthlessness, sleep disturbance, and trouble concentrating (Neidig, Smith, & Brashers, 2003; Radloff, 1977). Symptoms of depression were measured with the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff). The CES-D is a 20 item scale that asks participants to best describe how often they felt or behaved during the past week (Appendix C). Participants choose one of four response items ranging from rarely or none of the time (0), to most or all of the time (3).

Positive items (items 4, 8, 12, and 16) are reverse-coded prior to calculating total scale scores. Total scale scores range from 0 – 60, higher scores indicate higher levels of depressive symptoms. Participants were considered to have higher levels of depressive symptoms for data analysis purposes if their CES-D score was  $\geq 16$  as per Radloff. The reliability of this instrument in the general population is 0.85, and the reliability within a general patient sample is 0.90 (Radloff,). The Cronbach's alpha for the use of the 20 item CES-D in this study population was 0.84 ( $N= 85$ , as 1 participant was missing).

### *Spiritual Beliefs*

Spiritual beliefs are described by Holland and colleagues (1998) as “the degree to which individual's feel they derive meaning from an existential perspective” (p.462), or “a relationship to a superior being, or a perceived higher power” (p. 462). Spiritual beliefs were measured by respondents' scores on the *Faith* sub-scale of the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being Scale (FACIT-Sp Version 4; Peterman, Fitchett, Brady, Hernandez, & Cella, 2002). The FACIT-Sp is a twelve item scale originally intended to be part of the core functional assessment scale known as the Functional Assessment of Cancer Therapy-General (FACT-G; Cella, Tulsky, Gray, et al., 1993), though was later developed into its own spiritual well-being scale (FACIT-Sp; Peterman et al., 2002). The FACIT-Sp consists of 2 subscales; one that measures a sense of meaning and peace, and one that measures faith in the presence of illness (Peterman et al). The psychometric properties of both sub-scales, and the scale in its entirety were evaluated among two samples of individuals with cancer (Peterman et al.).

The *Faith* subscale of the FACIT-Sp consists of 4 items (*Faith* items include Sp9 – Sp12), that specifically inquire about faith/spiritual beliefs in the presence of illness. Participants are asked to indicate how true a specific statement is by selecting a response item that ranges from “not at all”(0) to “very much” (4), (Appendix C). Scores on the subscale range 0 – 16, and the Cronbach’s alpha of the *Faith* subscale among individuals with chronic illness is 0.88 (Peterman et al., 2002). The Cronbach’s alpha was 0.87 ( $N = 86$ ) in the current study of African American women with HIV.

#### *Data Analysis*

Data analyses were computed with the use of the SPSS statistical software program. Frequencies were run on all data to check for outliers, errors with data entry, skew, missing data, and to investigate any potential patterns existing in the missing data. Participants were generally missing from an analysis because a question was not applicable (e.g., missing on condom use because they did not have a sexual partner). One participant did not complete the CES-D as she was not feeling up to it. Therefore, the  $N$  for Tables 5 -7 vary where the CES-D is reported. Also, one participant did not answer the education question in the demographic data. Two model variables were fairly skewed, spiritual beliefs, as measured by the *Faith* subscale of the FACIT-sp (skewness = -2.035), and physical activity (skewness = 2.659).

Descriptive statistics (mean, median, mode, and standard deviation) were used to analyze the total scale scores, demographic and clinical data, and the data from the open-ended questions for the adherence variables. The effect of categorical demographic and clinical variables and responses from the open ended question data on adherence was

analyzed using Student's t-test and analysis of variance (ANOVA) for continuous measures, and Chi-square analysis for categorical measures of adherence. The effect of continuous variables on continuous measures of adherence was assessed with correlation and t-test for categorical measures of adherence. Mann Whitney U and Kruskal Wallis tests were also used as a supplement analysis for mean comparisons in response to concerns about the robustness of t-test and ANOVA related to heterogeneous group variances and/or large differences in sub-group sizes.

If a significant relationship existed between a demographic/clinical variable or data from the open ended questions and an adherence variable, and the subgroups for the variable were comparable in size or consisted of  $\geq 20$  participants, they were included in the regression analyses. Variables that were significant but had subgroups of less than 20 participants and were not comparable in size were excluded from subsequent regression analyses, as the effects associated with these variables would be unstable.

In the original study proposal, the Affectometer 2 (Kammann & Flett, 1983) was approved for use to measure both positive and negative affect. However, the net Affectometer score was highly correlated ( $r(82) = -0.68; p \leq .001$ ) with the CES-D arguing for potential problems with multicollinearity should both variables be included in the same regression analysis as originally proposed. The net Affectometer score had no significant relationship or associations with any of the measures of adherence. Hence this variable was not included in any of the model testing.

#### *Tests of Study Hypotheses*



A series of linear and logistic regression analyses were conducted in three phases. First, linear and logistic regression analysis were used to test hypotheses derived from the proposed theoretical model, and to identify variables that should be retained in the original theoretical model. All hypotheses were evaluated using a one-tailed significance test. One outlier caused skewing in the residual of the medication adherence regression analysis. This outlier represented less than 2% of the sample and was removed as per Cohen and Cohen's (1983) recommendations.

Second, regression analyses were conducted including the only the variables that were significant in the initial regression analyses. The results from these analyses were used to establish the path coefficients for the revised model for each adherence variable.

Finally, regression analyses were conducted incorporating the theoretical variables that remained significant from the second phase, and the demographic and clinical variables found to be significant in univariate analyses. These results were used to specify the path coefficients for a best-fitting and final model for each of the adherence variables.

Wright's (1934) method for calculating direct and indirect effects was used to complete the path analysis in the linear regression model for medication adherence. However, this method could not be applied to the path model constructed for appointment adherence. Tests of this adherence model required logistic regression analyses and there is no method for standardizing the coefficients produced in this analysis.

## Chapter 4

### Results

#### Descriptive Analyses

Median scale scores, ranges, and percentages are reported in Table 4. Sixty-four of the 86 participants were receiving antiretroviral therapy. The median CASE index score prior to converting items to *Z* scores was 13 ( $M = 12$ ,  $SD = 3.32$ ). Sixty-nine percent ( $n = 44$ ) of the participants had a total medication adherence score greater than 10, suggesting that the majority of the participants who are receiving medications are taking them as directed.

Forty-two percent ( $n = 28$ ) of the 66 participants who responded to the condom adherence item reported they did not use a condom at last intercourse (Table 4). Fifty-nine percent ( $n = 51$ ) of the total cohort ( $N = 86$ ) reported having a “regular partner”, and 37% ( $n = 19$ ) of the 52 participants who responded to positive prevention item 2 (partner’s HIV status) reported that their partner was HIV positive. Forty-six participants responded to both positive prevention item 2 (partner’s HIV status) and condom use at last intercourse, and within this subgroup, 61% ( $n = 28$ ) of the participants reported having a HIV negative partner, and 39% ( $n = 18$ ) reported having a HIV positive partner. Forty-four percent ( $n = 8$ ) of those with a HIV positive partner reported not using a condom at last intercourse, and 56% ( $n = 10$ ) reported using a condom with their HIV positive partner. Forty-six percent ( $n = 13$ ) of those with a HIV negative partner reported they did not use a condom at last intercourse, compared with 54% ( $n = 15$ ) who reported using a condom with their HIV negative partner.

Table 4

*Scale Scores*


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CASE medication adherence index ( <i>n</i> = 64)	
Median Z score	.45
Range	-7 to 3
% Adherent	69% ( <i>n</i> = 44)
Condom use at last intercourse ( <i>n</i> = 66)	
No	42% ( <i>n</i> = 28)
Yes	58% ( <i>n</i> = 38)
Missed an appointment in last 6 months ( <i>n</i> = 85)	
No	59% ( <i>n</i> = 50)
Yes	41% ( <i>n</i> = 35)
Satisfaction with life scale ( <i>N</i> = 86)	
Median	18
Range	4 to 28
Total kilocalories of PA per week ( <i>N</i> = 86)	
Median	273
Range	0 to 3,500
CES-D ( <i>n</i> = 85)	
Median	15
Range	0 to 49
Score $\geq$ 16	47% ( <i>n</i> = 40)

Faith subscale of the FACIT-sp ( $N = 86$ )

Median	14
Range	0 to 16

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Forty-one percent ( $n = 35$ ) of the participants reported they missed an appointment with their HIV provider in the last 6 months (Table 4). The mean number of appointments missed was 1 ( $SD = 1.44$ , range 0 – 6). Fifty percent ( $n = 43$ ) of the participants had appointments scheduled every three months. Eleven percent ( $n = 8$ ) of the 74 participants who responded to appointment adherence item 3 reported having missed an appointment related to a childcare issue.

The median score for the SWLS was 18 (Table 4), indicating a “Neutral/Average” life satisfaction score. This median score, when multiplied by 1.25 ( $Mdn = 22$ ;  $N = 86$ ) suggests that individuals are satisfied with most areas of their lives, but have some areas that need improvement (Diener, 2006).

The median number of kilocalories per week for total blocks and stairs was 273 (Table 4). The majority of participants (86%;  $n = 74$ ) expended < 1,000 kilocalories per week. Forty-one percent ( $n = 35$ ) reported walking one to five blocks per day and 69% ( $n = 59$ ) reported climbing up and down one to five flights of stairs per day.

#### *Demographic and Clinical Variables*

Only two demographic and clinical variables appeared to have any influence on medication and appointment adherence, a history of hospitalization for mental illness and

age. No demographic or clinical variable appeared to have an influence on condom adherence.

Those who were not hospitalized for mental illness in the past had a higher medication adherence score ( $M = 0.54$ ,  $SD = 2.35$ ;  $n = 41$ ) than those who had been hospitalized ( $M = -0.96$ ,  $SD = 2.52$ ;  $n = 23$ ,  $t(62) = 2.40$ ,  $p \leq .05$ ). Meanwhile, those who kept all of their appointments were older ( $M = 48$ ,  $SD = 7.77$ ;  $n = 50$ ) than those who did not ( $M = 45$ ,  $SD = 6.21$ ;  $n = 35$ ,  $t(83) = 2.22$ ,  $p < .05$ ).

#### *Associations between Adherence Variables*

No significant association was seen between appointment keeping and taking antiretroviral therapy ( $p = .98$ ). Also, no significant association was seen between medication adherence and appointment adherence; appointment adherence and condom use adherence; or medication adherence and condom use adherence ( $p \geq .62$ ).

#### *Initial Test of the Theoretical Model*

The results of the linear and logistic regression analyses for each adherence variable are shown in Tables 5 – 7. Results confirmed some but not all of the relationships that were predicted in the proposed model with respect to adherence (Figure 1).

#### *Medication Adherence*

In the initial regression analysis for medication adherence ( $n = 62$ ), subjective well-being (as measured by the SWLS) positively influenced adherence ( $\beta = .37$ ,  $p < .01$ ; Table 5). A smaller positive relationship between spiritual beliefs and medication adherence was also shown ( $\beta = .21$ ,  $p < .05$ ), and both relationships were consistent with

those predicted in the model. Physical activity had a direct and negative effect on medication adherence ( $\beta = -.21, p < .05$ ), though was hypothesized to have only an indirect effect on adherence. Of interest, no relationship was seen between depression and medication adherence ( $\beta = .08, p = .28$ ).

Table 5

*Results of Initial Linear Regression Model for Medication Adherence (n = 62)*

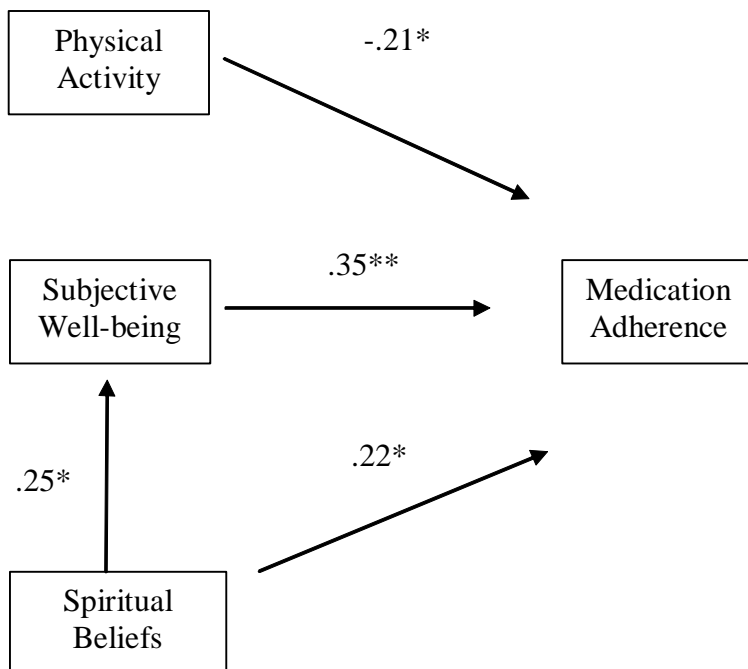
Variables	B	SE	Beta	p
SWL	0.143	0.051	.373	.003**
CES-D	0.021	0.036	.076	.279
FACIT-Sp <sup>‡</sup>	0.124	0.069	.213	.039*
Physical Activity	-0.001	0.001	-.212	.036*
R <sup>2</sup> = .24	----	----	----	.003**

Note. \*  $p < .05$ , \*\*  $p < .01$ ; <sup>‡</sup> Faith subscale of the FACIT-Sp

Figure 2 presents the path coefficients for the revised model for medication adherence. A significant effect was not seen between medication adherence and depression. Therefore this variable was not included in the revised model. The coefficients in Figure 2 were estimated using only those variables for which significant effects were observed. No significant effect was seen between physical activity and spiritual beliefs or subjective well-being ( $p \geq .34$ ).

Figure 2.

Revised path model for medication adherence ( $n = 63$ )



$$R^2 = .25^{***}$$

\*  $p < .05$ , \*\*  $p < .01$ , \*\*\*  $p = .001$

### *Positive Prevention Adherence*

No significant effects on condom adherence were observed for any of the model variables and the direction of many of the effects contradicted model predictions (Table 6,  $n = 65$ ). A negative relationship between depression and condom use was seen which is consistent with the model but this effect was not significant (OR = 0.96,  $p = .08$ ). The logistic regression analysis was also run with the non-scaled physical activity variable,

and the results did not differ when the non-scaled variable was substituted for the rescaled physical activity variable. The rescaled physical activity variable was used in the final analysis as the non-standardized coefficient for the non-rescaled variable could not be interpreted because the size of the co-efficient was too small ( $B < 0.001$ ).

Table 6

*Results of Initial and Final Logistic Regression Model for Positive Prevention*

*Adherence (Condom Use; n = 65)*

Variables	B	SE	OR	<i>p</i>
SWL	-0.011	0.054	0.989	.418
CESD	-0.046	0.033	0.955	.081
Physical Activity	-0.406	0.622	0.666	.257
FACIT-Sp <sup>£</sup>	-0.036	0.081	0.965	.329
Cox & Snell $R^2 = 0.042$				
Nagelkerke $R^2 = 0.057$				

Note. <sup>£</sup> Faith subscale of the FACIT-Sp

*Appointment Adherence*

No significant effects on appointment adherence were observed for any of the relationships predicted in the model. Contrary to study hypotheses, physical activity had a direct, negative effect on appointment adherence (OR = 0.40,  $p = .05$ ; Table 7).



Table 7

*Results of Logistic Regression Model for Appointment Adherence (n = 84)*

Variables	B	SE	OR	<i>p</i>
SWL	0.012	0.046	1.012	.398
CESD	0.019	0.030	1.019	.259
Physical Activity	-0.918	0.546	0.399	.047*
FACIT-Sp <sup>‡</sup>	0.065	0.065	1.067	.158
Cox & Snell R <sup>2</sup> = 0.052				
Nagelkerke R <sup>2</sup> = 0.071				

Note. \* *p* = .05; <sup>‡</sup> Faith subscale of the FACIT-Sp

#### *Best Fitting Final Models and Path Analysis*

Results from the univariate analyses examining the effect of the clinical and demographic variables on the three types of adherence were incorporated into the revised path models to identify the best fitting final model for each adherence variable. The best fitting final model for both medication adherence and appointment adherence are described. No further testing was indicated for the condom use adherence variable, as no effects were seen for the demographic and clinical variables on condom adherence.

Figure 3 presents the best fitting final model for medication adherence. The model explained 31% of the variance for medication adherence. Subjective well-being was found to have only a direct effect on medication adherence ( $\beta = .30, p < .01$ ). Spiritual beliefs had both direct (.21), and indirect effects (.07) through subjective well-

being with a combined effect of .28 to medication adherence. Having a history of hospitalization for mental illness had a direct (-.25), and indirect effect (-.06) through subjective well-being with a combined effect of -.31. Physical activity had only a direct effect on medication adherence ( $\beta = -.19, p = .05$ ), and did not have an effect on subjective well-being ( $p = .26$ ). Having a history of hospitalization for mental illness did not have an effect on either spiritual beliefs or physical activity ( $p = \geq .19$ ).

Figure 3.

Best fitting final model for medication adherence ( $n = 63$ )

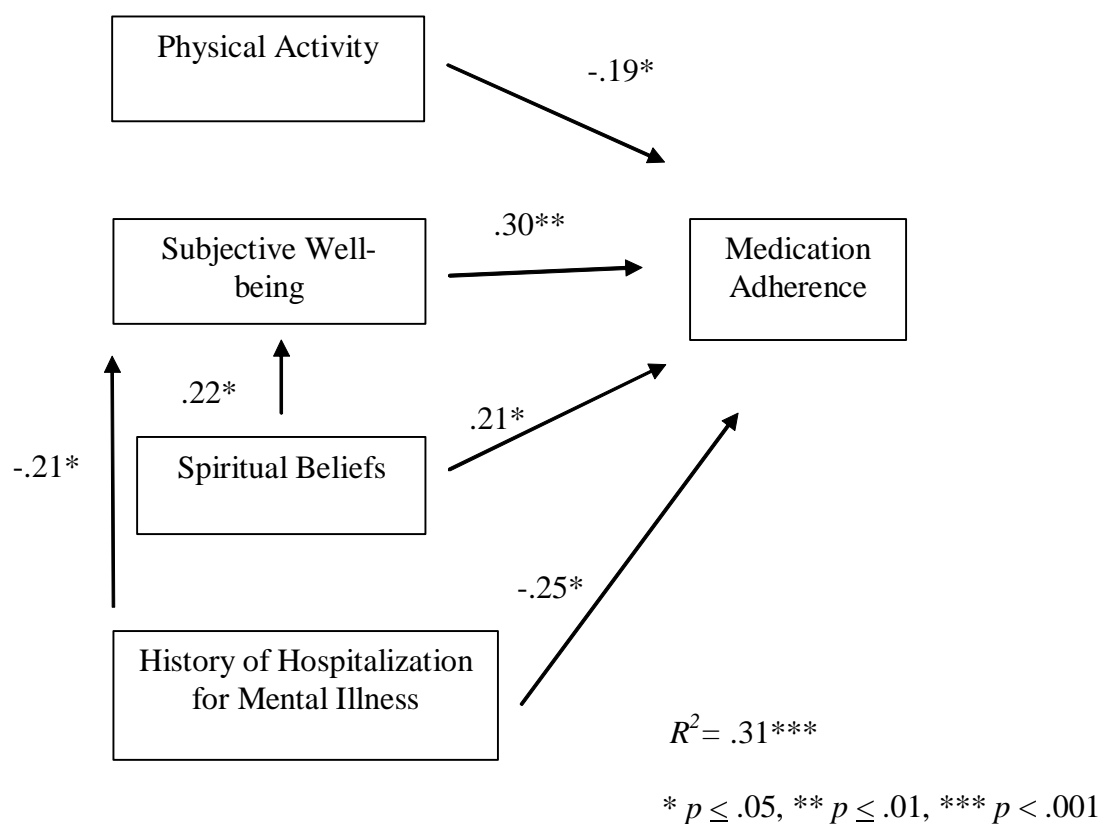
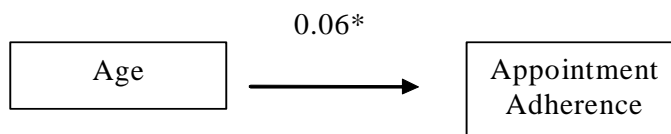


Figure 4 presents the revised and final model for appointment adherence. Age was shown to have a significant negative effect on appointment adherence. However, physical activity no longer had an effect ( $B = -0.60, p = .14$ ) on appointment adherence. The small to moderate correlation ( $r = -0.26, p < .01$ ) between age and physical activity argues against multicollinearity and suggests that age mediates the association between physical activity and appointment adherence. These results did not substantively differ when the non-rescaled physical activity variable was substituted for the rescaled variable. However, the non-standardized coefficient could not be interpreted because the size of the increment was too small ( $B < 0.001$ ), therefore the rescaled variable was used in the analysis. A direct effect was not computed for age because the standardized coefficient was not produced in the logistic regression analysis.

*Figure 4.*

Revised and final model for appointment adherence ( $n = 85$ )



\*  $p < .05$ ; non-standardized co-efficient

### *Open Ended Question Data*

Various themes were identified in participants' reasons for missing a dose of medication, an appointment, or not using a condom. Each theme was then converted to a dichotomous variable (Present = 1; Absent = 0) so that its relationship to adherence could be assessed in subsequent univariate analyses. However, no significant relationships were observed between the themes identified from the open ended questions and adherence in these univariate analyses. Hence, only the themes in the open ended question data are summarized here, and the variables reflecting these themes are not included in any of the regression models previously discussed.

### *Medication Adherence*

A total of 8 themes describing participant's reasons for missing medication emerged from the data (Table 8). Most participants reported missing a dose of medication because of forgetfulness, hence the theme *Forgot* emerged. Some examples of responses assigned to this theme include "forgot to bring with me," and "couldn't remember if I took it or not." The second theme, *Away from home/change in environment*, emerged from statements such as "didn't have medications with me," "overnight at my partners and ran out," "working late," and "hospitalized." The theme entitled *Slept through medication dose*, included participant responses such as "fell asleep early and woke up in the morning," or "overslept." The fourth theme, *Illness related symptoms*, included responses such as "tired" or "too tired," and other symptoms such as "depression," and "vomiting." Eight participants reported "medication burnout," "don't

like taking medications,” or “tired of taking meds,” and these responses were assigned to the theme entitled *Don’t like taking medications/tired of medications*.

The theme *Busy lifestyle* emerged from statements such as “busy life,” “in a hurry and forgot meds,” and “in a rush to leave.” The theme entitled *Side effects related to medications* consisted of responses such as “messes with my nervous system,” “choking my throat,” and “makes me feel sick.” The theme *Unable to fill prescription* emerged from the responses “unable to get it from the pharmacy,” and “forgot to get prescription filled.”

Table 8

*Open Ended Question Data for Medication Adherence by Theme (n = 44)*

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Forgot	32% (n = 14)
Away from home/change in environment	27% (n = 12)
Slept through medication dose	25% (n = 11)
Illness-related symptoms	21% (n = 9)
Don’t like taking medications/tired of medications	18% (n = 8)
Busy lifestyle	14% (n = 6)
Side effects related to medications	11% (n = 5)
Unable to fill prescription	7% (n = 3)

---

*Positive Prevention Adherence*

A total of 10 themes emerged from participant’s responses related to reasons for not using condoms (Table 9). The most common theme for lack of condom use was

*Partner did not want to use one*, and responses in this category included “he doesn’t believe in using them,” “he did not feel it was necessary,” “partner refuses to.” In contrast, seven participants reported *I don’t want to use one* and responses for this theme included “I didn’t feel I needed to,” “sometimes I don’t ask him to put it on,” and “I didn’t want to wait.” Responses such as “he pulls out,” “one partner only,” and “not wearing one gives me the perception that I am low risk,” were assigned to the *Perception of low risk* theme. The theme *Both partners aware of status* consisted of responses such as “both HIV positive” and “partner positive too.”

Multiple responses related to condoms specifically (e.g., feeling, side effects, and product-related issues) emerged and were assigned to 3 separate themes: *I don’t like the feeling of condoms*, *Condom related issues*, and *Cause irritation or symptoms*. Responses such as “doesn’t feel good,” “I don’t like the feel,” and “it takes away the feeling” were assigned to the theme *I don’t like the feeling of condoms*. Responses such as “they break,” “too small” and “not enough lubricant” were assigned to *Condom related issues*. Responses for the theme entitled *Cause irritation or symptoms* included “make me itch,” “condoms cause me dryness,” and “allergic.” The theme *Condoms not available/under the influence* emerged from responses such as “didn’t have one,” “heat of the moment,” and “under the influence of drugs and alcohol.” Two participants reported lack of condom use related to being in a same sex relationship, and one participant reported condom use “reminds me of having the virus.”

Table 9

*Open Ended Question Data for Condom Use Adherence by Theme (n = 42)*


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Partner did not want to use one <sup>£</sup>	44% (n = 17)
I don't like the feeling of condoms	17% (n = 7)
I didn't want to use one	17% (n = 7)
Condom not available/Under the influence	17% (n = 7)
Perception of low risk	14% (n = 6)
Both partners aware of status	10% (n = 4)
Condom-related issues	10% (n = 4)
Cause irritation or symptoms	7% (n = 3)
Same sex relationship (female)	5% (n = 2)
Reminds me of having the virus	2% (n = 1)

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Note. <sup>£</sup> n = 39 for this theme.

*Appointment Adherence*

A total of 9 themes reflecting participant's reasons for missing appointments emerged from the data (Table 10). Fifteen participants reported missing an appointment due to "depression," "sugars too high," "tired" and "no energy," and these responses were assigned to the theme *Symptoms related to illness*. Thirteen participants reported they "forgot" about their appointment. The theme *Unexpected circumstances/other*

*commitments* emerged from responses including “death in the family,” “MD rescheduled,” “away at a training for work,” and “school.” Responses such as “overslept,” “didn’t feel like it,” and “didn’t want to go” were assigned to the theme *Overslept/Not Up for It*.

Two participants reported not attending appointments related to fear or “denial” of HIV status, and comments such as “afraid they will find something wrong” and “afraid I will have to start meds” were included in this theme (entitled *Fear or denial*). The remaining themes that emerged included *Transportation/financial concerns*, *More than one appointment that day*, *Childcare/family related issue*, and *Weather* and consisted of responses that were identical to each respective title.

Table 10

*Open Ended Question Data for Appointment Adherence by Theme (n = 46)*

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Symptoms related to illness	33% (n = 15)
Forgot	28% (n = 13)
Unexpected circumstances/other commitments	26% (n = 12)
Overslept/not up for it	24% (n = 11)
Transportation/financial concerns	15% (n = 7)
More than 1 appointment that day	11% (n = 5)
Childcare/family related issue	11% (n = 5)
Fear or denial	4% (n = 2)
Weather	7% (n = 3)

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## Chapter 5

### Discussion

#### *Introduction*

This investigation explored the direct and indirect effects of subjective well-being, physical activity, depression, and spiritual beliefs on three separate adherence variables among a cohort of 86 African American women with HIV. These variables formed a theoretical model proposed in response to findings in the literature and observations derived from clinical experience. Study findings provided some support for the relationships that were hypothesized with respect to medication adherence, but failed to provide support for relationships hypothesized for condom adherence and appointment adherence. Although clinical and demographic variables were not included in the original theoretical model, having a history of hospitalization for mental illness had an effect on medication adherence, and age had an effect on appointment adherence. Hence, both variables were added as predictors of these adherence behaviors. Study findings also confirm that adherence to medication, positive prevention (condom use), and appointments are three very different behaviors and should be evaluated as such. The specific findings for each adherence variable are discussed in the following paragraphs.

#### *Medication Adherence*

Study findings supported a role for both subjective well-being and spiritual beliefs in the model for medication adherence. Subjective well-being, as measured by life satisfaction, had a direct and positive effect on medication adherence. These findings are consistent with prior research involving HIV positive men and women in which a

positive state of mind (Gonzalez et al., 2004), or having a meaningful life (Holzemer et al., 1999) had a positive effect on medication adherence.

Spiritual beliefs had both positive direct and indirect effects on medication adherence in this investigation. The direct effect is consistent with other findings in studies of African American women who are HIV negative, suggesting that spirituality plays a key role in coping, healing, and clinical decision making among African American women with and without chronic illness (Samuel-Hodge et al., 2000; Holt, Lukwago, & Kreuter, 2003; Harvey, 2006). Study results also confirm the qualitative findings of Sankar and colleagues (2002) who identified having a connection with God or a higher power positively influenced medication adherence among African American women with HIV.

Additionally, spiritual beliefs and subjective well-being were related in this study. This relationship is consistent with Coleman and Holzemer (1999), finding that spiritual beliefs, defined as “existential well-being” was a significant predictor of psychological well-being among African Americans with HIV.

Physical activity had a direct and negative effect on medication adherence, but no effect on subjective well-being. The latter finding is at odds with Lox, Tucker, and McAuley’s (1995) observation of a positive relationship between physical activity and subjective well-being in their sample of thirty-three individuals with HIV. The lack of support for study hypotheses with respect to physical activity and medication adherence may reflect differences in the measurement of physical activity, or differences in the study samples. For example, Lox et al. (1995) measured active participation in physical

activity via random assignment in their intervention study, whereas a self-report survey measure of physical activity was used in the current investigation.

Contrary to the findings from past research, (Holzemer et al., 1999; Singh et al., 1996; Fogarty et al., 2002; Schuman et al., 2001; Stone, 2001), depression did not have an effect on medication adherence within this cohort. Having a history of hospitalization for mental illness did have a negative effect on medication adherence, and greater than half of the study cohort reported a known history of depression. However, the median CES-D score for the study cohort did not show evidence of clinical symptoms of depression, suggesting that any symptoms of depression may be well managed, and thus less likely to interfere with medication adherence behaviors. Individuals who are more symptomatic may be less likely to adhere to medication. A few participants did report “depression” as a reason for missing medication in the open-ended question data, implying that depression may have a negative impact on medication adherence. Unfortunately, the low level of depressive symptomatology in the study cohort may have prevented detection of an effect for depression on medication adherence.

No effect was seen between the demographic variables and medication adherence, which is consistent with previous research (Cargill, Stone, & Robinson, 2004; Holzemer et al., 1999; Stone, 2001). There was no relationship between current substance abuse and medication adherence in these data, but this is likely due to the small number of women who reported current substance abuse. A positive relationship between clinical variables such as CD4 count less than 200 or presence of an undetectable viral load was not

seen, but these clinical variables were based on self report, and not actual measurement of serum markers.

No relationship was seen between the themes that emerged from the open-ended question data and medication adherence. However, the themes in this study were similar to those reported previously. For example, Barfod, Sorensen, Nielsen, Rodkjaer, and Obel (2006) identified the following themes as most frequent for their sample of predominately male, Caucasian individuals with HIV who reported low adherence: *Forgot, Were away from home, Had a change in daily routine, Were busy with other things, and Fell asleep, slept through dose time*. This suggests that reasons for missing medications may be consistent among individuals with HIV, and not directly influenced by gender or race/ethnicity. However, the lack of relationship between these reasons and medication adherence in the present study highlights the difficulty in relating reasons to behavior. It is possible that reasons are caused by the need to explain one's adherence behavior and do not reflect actual causes of non-adherence.

Other themes reported such as *Illness related symptoms* and *Tired of taking medications* hint at medication "burn out" and the advancement of disease, or the development of co-morbidities that may cause additional symptoms. It is also worth noting that the theme *Medication side effects* was only reported among a small number of participants in the current study. *Medication side effects* has been more frequently reported as a reason for non-adherence in prior studies (Roeger et al., 2004). It is possible that the lower frequency observed here may reflect the development of newer simplified regimens with reduced dose frequency, and side effects (Piliero & Colagreco, 2003).

### *Adherence to Condom Use*

Although 42% of women with a sexual partner reported not using condoms, none of the hypothesized relationships were supported with respect to adherence to condom use, and no effects were observed for any of the demographic or clinical variables and condom adherence. Depression did not have an effect on condom use in this investigation, and this finding differs from that of prior investigations on condom use among women with HIV (Lambert, Keegan, & Petrak, 2005). Again, the median CES-D score for this cohort was not indicative of clinically significant depressive symptoms, and this may have contributed to the non-significant effect of depression on condom use.

Limited data exists on the relationship between spiritual beliefs and condom use among women with HIV, African American women in particular. A recent study reported an association between higher levels of spiritual well-being (in the religion subscale) and lower perceived barriers to condom use among African American men with HIV (Coleman & Ball, 2007). A large number of the women in the present cohort reported practice of a religious faith by prayer or attending services, and had a high median score on the faith/spiritual beliefs subscale. However, neither of these variables had an effect on condom use. It is possible that possession of spiritual beliefs alone may not be enough to help women address some of the social influences on condom use previously identified among African American women with HIV such as partner communication, negotiation, and self efficacy (Raiford, Wingood, & DiClemente, 2007).

No effect was seen between condom use adherence and the themes identified from the open ended question data. The most common theme that emerged in response to

reasons for non-adherence to condom use was *Partner did not want to use one*. This finding is consistent with the findings of Bedimo, Bennett, Kissinger, and Clark (1998) who investigated barriers to condom use among African American women with HIV. Women in the investigation by Bedimo et al. (1998) reported male partner refusal and lack of trust in condoms as barriers to condom use. Similarly, women in the current investigation reported “condoms break” and “they’re not safe.” These findings suggest a need for the development of interventions to support and empower communication and negotiation skills, and provide education on the safety and efficacy of condoms in preventing the transmission of HIV and other sexually transmitted diseases among African American women with HIV.

Another theme that emerged in the open-ended question data as a reason for non-adherence to condoms was *Both partners aware of status*. Eighteen participants in the current investigation reported having a HIV positive partner, and eight (44%) of these participants did not use a condom at last intercourse with their positive partner. However, twenty-eight participants reported having a HIV negative partner, and thirteen (45%) of these participants did not use a condom at last intercourse. These findings highlight the need for ongoing prevention, education and counseling sessions on condom adherence among HIV positive couples and sero-discordant couples, to help reduce the risk for re-infection with another strain of HIV, and to reduce transmission of HIV and other sexually transmitted diseases within this population (Purcell, 2003).

#### *Appointment Adherence*

Of all the variables in the theoretical model, only physical activity had an effect on adherence to appointment keeping. However, this effect did not remain significant once age was included in the analyses despite the small relationship between these two variables, suggesting that age may mediate the relationship between physical activity and appointment adherence. This finding implies that participation in physical activity may play a role in appointment keeping in this population, particularly as women advance in age.

Being older increased the likelihood of appointment keeping in this study. This finding is consistent with previous research involving men and women with HIV (Israelski, Gore-Felton, Power, Wood, Koopman, 2001; Catz, McClure, Jones, & Brantley, 1999). Both Israelski and colleagues (2001), and Catz et al. (1999) found an association between older age and appointment adherence. The relationship between older age and appointment adherence may be related to factors such as acceptance of living with a chronic illness over time, or perhaps older women with HIV find that attending appointments counters loneliness or isolation. Study findings, in addition to the findings in the literature, argue for the development of interventions to enhance appointment adherence among African American individuals with HIV, particularly those of younger age.

Lack of association between spiritual beliefs and appointment keeping is consistent with Catz, McClure, Jones, & Brantley (1999), who found no effect for religious coping and appointment keeping. It is possible that spiritual beliefs may have an effect on variables such as life satisfaction and values, but not on behaviors such as

appointment adherence or condom adherence, where other social variables and circumstances may have a greater impact.

Depression did not have an effect on appointment adherence in this cohort, and this finding is similar to that of Bodenlos et al. (2007) who investigated the relationship between attitudes towards healthcare providers, social support, and depression among a sample of predominately African American males with HIV. Similarly, Catz and colleagues (1999) found no association between hopelessness, a symptom of depression, and appointment keeping. Perhaps attending appointments serves as a source of social contact and healthcare provider support among this population. This notion is consistent with prior publications who report that appointment adherence has been associated with positive attitudes towards health care providers (Bodenlos et al.), whereas non-adherence has been associated with lower perceptions of engagement with health care providers (Bakken et al., 2000).

Duration of HIV was not related to appointment adherence in this sample. Due to the chronic nature of the virus, and the use of measurements such as CD4 count and viral load to determine treatment status and outcomes during all stages of illness, it is not surprising that duration of HIV does not have an effect on appointment keeping in this population.

In contrast to previous research, no effect for clinical variables such as serum CD4 count, or a history of an AIDS diagnosis was seen. However, baseline serum levels of CD4 and viral load were not collected in the present study. Instead, participants reported whether they had a current CD4 count less than 200, or an undetectable HIV viral



load, and presence of an AIDS diagnosis was based on recall and self-report. This may have created some inaccuracy in the measurement of these variables, making it difficult to detect their effect on appointment adherence.

No effect was seen between appointment adherence and the themes that emerged from the open ended question data. The most common theme for missing an appointment was *Symptoms related to illness*. The remaining themes such as *Forgot*, and *Family related issues*, were relatively common and consistent with previous research (e.g., Neal, Hussain-Gambles, Allgar, Lawlor, & Dempsy, 2005).

#### *Conclusion and Relevance of Findings to African American Women*

A strength of this study is its focus on African American women exclusively. African American women are infected with HIV at a disproportional rate and accounted for 64% of the 126,964 women living with HIV/AIDS in the United States in 2005 (Centers for Disease Control and Prevention, June 2007). An understanding of culturally sensitive and gender-specific attitudes, beliefs, and behaviors is critical for the development of programs that provide culturally competent HIV prevention education (Scott, Gilliam, & Braxton, 2005), and for delivering optimal care to African Americans with HIV (Smith et al., 2003). It is possible that resources such as spiritual beliefs, and themes identified by the data from the open ended questions in this investigation will assist in the development of culturally competent interventions to enhance adherence practices in African American women with HIV.

The positive relationship between subjective well-being and medication adherence among African American women with HIV is a relatively novel finding.

Research investigating the relationship between positive psychological variables, such as subjective well-being, and HIV-related health behaviors is limited, and this finding is of value clinically as individuals are living longer lives with the virus. Additionally, in populations where depression is fairly well managed, subjective well-being may be a more useful predictor of medication adherence.

Meanwhile, the relationship between spiritual beliefs and subjective well-being argues for ongoing assessment of spiritual beliefs and interventions that support and enhance this resource. Braxton and Colleagues (2007) believe that spirituality is an integral part of survival among African American women that promotes psychological well-being, and helps to reduce social and illness-related stressors.

The lack of support for the hypotheses related to condom adherence and the large population of women reporting non-use of condoms highlight the need for further research of this phenomenon in African American women with HIV. Raiford, Wingood, & DiClemente (2007) contest that there is paucity in the literature with respect to investigations that report on factors that contribute to high risk sexual behaviors and condom use among women with HIV exclusively, as most of the research in this area is among men with HIV.

Findings from this study also highlight the need for the development of strategies to improve appointment adherence among African American women with HIV, particularly those of lower age. Though the relationship between lower age and appointment adherence has been reported in prior investigations of mixed gender samples of individuals with HIV, the current study supports the need for further assessment of

appointment adherence among African American women in particular. This is important as African American women are becoming infected with HIV at a higher rate compared with women of other ethnic backgrounds (Centers for Disease Control and Prevention, 2007), and appointment adherence is necessary to reduce the development of AIDS defining illness, and to assess symptom management and adherence practices (Catz, McClure, Jones, & Brantley, 1999; Israelski, Gore-Felton, Power, Wood, Koopman, 2001).

#### Limitations

There were at least five limitations in this study. First, the study design was cross-sectional not longitudinal. Hence, longitudinal data are needed to verify causal directions implicit in the path model. Nevertheless, the proposed relationships in this study were guided and supported by prior research in populations of African American women, and men and women with HIV of other ethnicities.

Second, study data were obtained by self-report. Hence, these data may be influenced by problems with recall and social desirability. Self-report of current CD4 count and viral load is not the most precise way to measure the relationships between illness factors and adherence behaviors. Variables such as duration of HIV, duration of smoking use, and/or duration of substance use did not have a relationship with the adherence variables, and this may be related to an individual's inability to accurately recall the exact length of time in participation in such activities.

Although the current investigator does not provide primary HIV care to the women in this study, it is possible that some participants over or under reported

adherence practices. However, problems with social desirability were minimized by use of self administered surveys, and the surveys did not contain any identifying information.

Third, the sample size and low frequency of some of the variables (e.g., themes in the open-ended question data) limited the data analysis. For example, I was only able to study condom ever use, not use at last intercourse, and there was little diversity with respect to appointment frequency, and participants who reported appointment non-adherence. A larger sample size would have yielded greater power, but recruitment of large samples of women can pose a challenge, despite the use of diverse methods of community advertisement that were implemented in this study. Nevertheless, I was able to test all relationships proposed in the theoretical model, and the study sample was large enough to detect small to medium effects among the study variables.

The use of a purposeful and non-random sample is a fourth limitation to this investigation, particularly given that the women in this sample were more likely to be adherent to their HIV medications, condom use, and appointments. It is unclear whether this reflects unique characteristics of women living with HIV in the Greater Boston area, specifically with respect to: (a) increased access and/or availability of care due to the surplus of hospitals, community health centers, and AIDS service organizations in the area, or (b) a bias in the sampling process, or (c) problems with social desirability. However, as stated previously, study methods were designed to minimize social desirability. Also, the sampling process occurred at diverse community locations across the state of Massachusetts, and recruitment sites ranged from shelters and AIDS service organizations, to clinics and community health centers. Thus it is most likely that the

participants in this study were somewhat unique. It is possible that suboptimal adherence practices are seen among those with lower levels of immune response or with poor access to HIV-related health services or education. Therefore, these study findings may be limited in their generalizability to populations with similar access to care. Replication of these findings is needed in an investigation of a larger, random sample of African American women with HIV, and access to care should also be examined.

A fifth limitation is reflected in the difficulty of measuring medication adherence and physical activity. Presently, there is no “gold standard” for the assessment of adherence to antiretroviral therapy (Chesney, 2006). The CASE adherence index, used here, is a relatively new instrument and limited reliability analyses have been reported in the literature. Total medication adherence Z scores were used for data analyses, and Z score transformation was not included in the original scoring methodology recommended by those who developed the scale. However, Z score transformations were necessary to ensure scalar equivalency of the items, and improved reliability of the measure. Hence, to not use the transformations would have violated measurement principles and also would have created a less reliable measure of medication adherence. Nevertheless, the lack of a “gold standard” raises the possibility that the results obtained here could be influenced more by the measure than by the phenomenon being measured.

Physical activity is also a variable that poses measurement challenges. Although a well established measure was used (Paffenbarger, Wing, & Hyde, 1978; Lee, Paffenbarger, & Hsieh, 1992), it is possible that the participants in the present study may have over or under-reported the actual number of blocks walked and/or flights climbed

per day. Accurately estimating the number of blocks and/or mileage walked can be challenging. In addition, the scoring procedure assumes that individuals participate in these activities seven days a week and does not allow for daily variability in participation. Moreover, the standard deviations for the total kilocalorie scores were large, due to the individual variability with respect to individual participation in physical activity, and the total kilocalorie score was skewed. Also, data on participation in other forms of physical activity, such as sports related activity, were not specific with respect to frequency/duration of participation in an activity. Therefore, the total number of kilocalories expended from participation in other activities could not be added to the total kilocalorie score that was calculated for blocks and stairs. This problem arises because the total physical activity score used in the study analyses does not include kilocalorie measurement for sports related activities, and this could have affected the use of the variable in the study analyses. Finally, there was no correlation between physical activity and subjective well-being, suggesting there may be conceptual concerns with the physical activity measure. In sum, even this commonly used measure appeared to have several concerns raising the possibility that the effect of physical activity on adherence might have been stronger, and effects on depression and subjective well-being might have been present in this cohort, though were unable to be detected with the use of this measure.

#### Implications for Future Research

The results from this cross-sectional investigation provide some support for the proposed theoretical model of adherence. However, most importantly, study results suggest that different models may be needed for different types of adherence. The model

proposed here appeared to fit the question of medication adherence better than it did secondary prevention as measured by condom use and appointment adherence.

The findings from the current study identify at least five other important implications for future research. First, research among a sample of African American women with more diverse sociodemographic and clinical backgrounds is needed to increase the generalizability of study findings, and also to evaluate the relationships between study variables among a potentially less adherent study population. It is possible that those who participated in this investigation were more likely to seek, access, and receive HIV-related health and supportive services that are available and accessible in the Greater Boston area, resulting in a stable and adherent study sample. The availability and accessibility of such services may have contributed to the lower levels of depressive symptoms and the moderate level of life satisfaction seen in this cohort. Future investigations should seek alternative methods of recruitment, including strategies aimed at identifying individuals with less stable HIV, who may have a greater need for social support. Replicating this investigation among a sample that is more clinically diverse may provide further support for the findings in the current investigation, or offer a different perspective on adherence practices. Findings may also have implications for the evaluation of interventions aimed at improving adherence practices among African American women with suboptimal adherence.

Second, further evaluation of positive psychological states, such as subjective well-being, is needed among women with HIV. Although the current sample may be limited by clinical and demographic diversity, study findings argue for the evaluation of

positive psychological states, the resources that may influence them, and the effect they may have on clinical decision making, such as adherence, among women with stable HIV.

Third, study findings argue for further investigation of faith/spiritual beliefs and factors that foster the development of spiritual beliefs in this population. In this investigation, spiritual beliefs had a positive effect on medication adherence and subjective well-being. However, it is not clear whether this effect is related to social support associated with regular church attendance, or the relationship between spiritual beliefs and/or a personal connection with a higher power and hope. Regardless, findings from this investigation support including measures of spiritual beliefs in studies of adherence among individuals with HIV. Future investigators may consider using the entire version of the FACIT-sp to capture both dimensions of the scale, and to allow for a more comprehensive interpretation of overall scale scores. Study findings also argue for the inclusion and evaluation of support and education programs in faith-based organizations and/or centers that promote and enhance spiritual beliefs among individuals with HIV.

Fourth, study findings support the need for further investigation of condom use among African American women with HIV. Women in this cohort reported engaging in unprotected intercourse with both HIV positive and negative partners. Clearly new interventions as well as better understanding of this phenomenon are needed.

Fifth, these findings argue for continued research on the measurement of adherence. Methods such as obtaining serum markers of immune response, or pill counts



are alternatives to the CASE Adherence Index, but may not lend themselves to large sample studies. Meanwhile, it is unclear whether methods such as chart review may be a more effective method of accurately measuring appointment adherence, and future research is needed to assess the correspondence between chart review and self report measures of appointment adherence in this population.

#### Implications for Clinical Practice

The current investigation provides novel, culturally relevant research findings among a cohort of African American women with HIV living in Massachusetts. Despite study limitations discussed earlier, practice implications arise with respect to psychosocial needs and adherence.

#### *Psychosocial Needs*

Although these women tended to keep their HIV-related appointments, use condoms, and exhibit fairly good medication adherence, they reported several psychosocial needs that clinicians should address or consider when caring for this population. These needs may not only impact adherence, but also have implications on the quality of life of these women. For example, half of the sample had a known diagnosis of anxiety, greater than half of the sample has a known diagnosis of depression, and greater than half of the participants report having a past history of substance abuse. These findings argue for ongoing assessment and/or treatment of mental health issues in this population. Nurses should also be aware of the benefits and services offered by community AIDS service organizations, and refer individuals when appropriate for additional support services.

It is worth noting that the majority of the women in the current sample were single, have children, and greater than half were unemployed. These findings suggest the need for nurses to assess the social needs of this population and their families, and to provide case management services for social needs including income, benefits, and support for children and families.

#### *Adherence Practices*

Spiritual beliefs had direct and positive effects on medication adherence and subjective well-being in this population. These findings support the need for nurses to conduct baseline and ongoing assessment of spiritual beliefs, or mechanisms through which an individual has a connection with a higher power, as well as quality of life. Based on this assessment, nurses can help support and enhance spiritual practices by referring and/or educating women on available resources that are designed to enhance spirituality, and also refer to local faith-based organizations, or centers designed to enhance spirituality if appropriate. Nurses can encourage other resources or activities for individuals that positively influence subjective well-being or life satisfaction such as becoming peer advocate or educator, or joining a local consumer advisory board.

Study findings argued for the ongoing assessment of condom use, and barriers to condom use experienced by this population. Nurses should assess an individual's understanding of the need to use condoms with both HIV positive and negative partners, and provide education and support.

Study findings also argued for an effect of age on appointment adherence. This suggests that new or different strategies may be needed to increase appointment keeping

in individuals who are younger. Until such strategies are identified, it is important to monitor appointment adherence carefully in this population. The failure to keep an appointment should be followed up immediately, and interventions such as reminder calls, or more flexible office hours can be implemented.

Finally, the themes generated from the open ended question data provide reasons for missing medications, lack of condom use, and missing appointments identified by this cohort. These themes may be helpful for the development of education and supportive strategies for African American women with HIV, and in the development of clinic-based interventions to improve and enhance adherence practices within this population. However, prior evaluation of the effectiveness of these strategies and interventions would be essential given the limited ability of this study to fully test the effects of the reasons reflected in these themes on adherence.

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## Appendix A

*Institutional Review Board & NIAAA Approvals*

## 1). Partners Human Research Committee, Massachusetts General Hospital

Original Approval: October 2, 2006

Continuing Review Approval: August 13, 2007

## 2). Boston College Institutional Review Board

Original Approval: November 8, 2006

Continuing Review Approval: October 3, 2007

## 3). National Institutes of Health, National Institute on Alcohol Abuse &amp; Alcoholism

## Confidentiality Certificate

Issued on: January 12, 2007




Partners Human Research Committee  
Partners Human Research Office  
116 Huntington Avenue, Suite 1002  
Boston, MA 02116  
(617) 424-4100

## Application: Notification of IRB Approval/Activation

**Protocol #: 2006-P-001835/3; MGH**

Date: 10/03/2006

To: Sara Looby, RN  
Medical Services  
Longfellow 7

From: LaNeia Thomas   
PHS Research Management  
HN-116 10-1024L

Title of Protocol: Influences on Adherence in African American Women with HIV  
Version Date: 10/02/2006  
Sponsor: Nurses' Educational Funds, Inc.  
IRB Review Type: Expedited  
Minimal Risk: 45 CFR46.110 and 21 CFR56.110  
Expedited Category/ies: (7) Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or QA methodologies.  
IRB Approval Date: 10/03/2006  
Approval Effective Date: 10/03/2006  
IRB Expiration Date: 10/03/2007

This Project has been reviewed and approved by the MGH IRB, Assurance # FWA00003136. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

**NOTES: The following documents were reviewed and approved by the IRB: Protocol, Protocol Summary (version date 10/02/2006), Script, Phone Screen, Inclusion Criteria List, Advertisement, Letter, Questionnaires (10) and a Consent Form.**

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.



Partners Human Research Committee  
Partners Human Research Office  
116 Huntington Avenue, Suite 1002  
Boston, MA 02116  
(617) 424-4100

4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to LaNeia Thomas, 617-424-4120.




Partners Human Research Committee  
Partners Human Research Office  
116 Huntington Avenue, Suite 1002  
Boston, MA 02116  
(617) 424-4100

## Continuing Review: Notification of IRB Approval/Activation

**Protocol #: 2006-P-001835/3; MGH**

Date: 08/14/2007

To: Sara Looby, RN  
Medical Services  
Longfellow 7

From: LaNeia Thomas   
PHS Research Management  
HN-116 10-1024L

Title of Protocol: Influences on Adherence in African American Women with HIV  
Version Date: 08/01/2007  
Sponsor: Nurses' Educational Funds, Inc.  
IRB Continuing Review #: 1  
IRB Review Type: Expedited  
Minimal Risk: 45 CFR46.110 and 21 CFR56.110  
Expedited Category/ies: (7) Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or QA methodologies.  
IRB Approval Date: 08/13/2007  
Approval Effective Date: 08/14/2007  
IRB Expiration Date: 08/13/2008

This Project has been reviewed and approved by the MGH IRB, Assurance # FWA00003136. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

**NOTES: The following documents were reviewed and approved by the IRB: Protocol (dated 08/01/2007), Protocol Summary (dated 08/01/2007), Study Information Sheet, Script, Phone Screen, Inclusion Criteria List, Advertisement, Letter, Questionnaires (9), and a Consent Form.**

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.



Partners Human Research Committee  
Partners Human Research Office  
116 Huntington Avenue, Suite 1002  
Boston, MA 02116  
(617) 424-4100

5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to LaNeia Thomas, 617-424-4120.



**BOSTON COLLEGE**  
**Institutional Review Board**  
Office for Human Research Participant Protection  
Carney 116  
Phone: (617) 552-4778, fax: (617) 552-0948

**IRB Protocol Number: 06.319.01**

DATE: November 8, 2006

TO: Sara Dolan Looby

CC: Anne Norris

FROM: Institutional Review Board – Office for Human Research Participant Protection

RE: Influences on Adherence in African American Women with HIV

**Notice of IRB Review and Approval**  
**Expedited Review as per Title 45 CFR Part 46.110, FR 60366, FR, # 7**

---

The project identified above has been reviewed by the Boston College Institutional Review Board (IRB) for the Protection of Human Subjects in Research using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted;
3. You will immediately inform the Office for Human Research Participant Protection (OHRPP) of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the informed consent documents that have been approved by the IRB;
6. You will give each research subject a copy of the informed consent document;
7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the**

**IRB approval expiration date. Without continuing approval the Protocol will automatically expire on November 7, 2007.**



**Additional Conditions:** *Any research personnel that have not completed NIH certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Revision and Amendment Form to add their names to the protocol, along with a copy of their NIH certificates.*

Approval Period: November 7, 2006 – November 6, 2007.

Boston College and the Office for Human Research Participant Protection appreciate your efforts to conduct research in compliance with Boston College Policy and the federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation and patience with the IRB process.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ch Booth Steele'.

Christina Booth Steele, MS, CIPP  
IRB Designee  
Administrative Director





**BOSTON COLLEGE**  
**Institutional Review Board**  
Office for Human Research Participant Protection  
Waul House, 2<sup>nd</sup> Floor  
Phone: (617) 552-4778, fax: (617) 552-0948

**IRB Protocol Number: 06.319.02**

DATE: October 3, 2007

TO: Sara E. Dolan Looby

FROM: Institutional Review Board – Office for Human Research Participant Protection

RE: Influences of Adherence in African American Women with HIV

**Notice of IRB Review and Approval-Continuing Review**  
**Expedited Review as per Title 45 CFR Part 46.110, FR 60366, FR, # 7**

---

The project identified above has been reviewed by the Boston College Institutional Review Board (IRB) for the Protection of Human Subjects in Research using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform the Office for Human Research Participant Protection (OHRPP) of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the informed consent documents that have the IRB approval dates stamped on them (approved copies enclosed);
6. You will give each research subject a copy of the informed consent document;
7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the**



**IRB approval expiration date. Without continuing approval the Protocol will automatically expire on October 3, 2008**

*Additional Conditions: Any research personnel that have not completed NIH certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Revision and Amendment Form to add their names to the protocol, along with a copy of their NIH certificates.*

Approval Period: **October 3, 2007 - October 2, 2008**

Boston College and the Office for Human Research Participant Protection appreciate your efforts to conduct research in compliance with Boston College Policy and the federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation and patience with the IRB process.

Sincerely,

Christina Booth Steele, MS, CIPP  
IRB Designee  
Administrative Director

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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National Institutes of Health  
National Institute on Alcohol Abuse & Alcoholism  
5635 Fishers Lane, Room 3108, MSC 9304  
Bethesda, Maryland 20892-9304

Anne E. Norris, Ph.D., R.N.C.S., F.A.A.N.  
Boston College Psychiatric Mental Health Nursing Program  
Cushing Hall 3361  
140 Commonwealth Avenue  
Chestnut Hill, MA 02467

Dear Dr. Norris:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Influences on Adherence in African American Women with HIV." Please note that the Certificate expires on January 1, 2009. We have provided one more year of Certificate coverage than you requested since many studies take longer to complete than initially projected. Providing an extra year ensures coverage for subjects and may spare you the need to formally submit a request for an extension.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, January 1, 2009, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the

Measures to be taken to protect confidentiality include confidentiality training for research staff, restricted access to study records, use of codes instead of recognizable names, publication only of grouped data, and other steps to protect privacy.

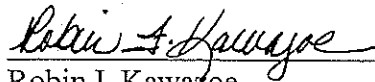
This research begins on October 3, 2006, and is expected to end on January 1, 2009.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on January 1, 2009. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.



Robin I. Kawazoe  
Acting Deputy Director  
National Institute on Alcohol Abuse and Alcoholism

1/12/07

Date

## CONFIDENTIALITY CERTIFICATE

Number: AA-30-2007

Issued to

**Boston College Psychiatric Mental Health Nursing Program**

**conducting research known as**

**Influences on Adherence in African American Women with HIV**

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Anne E. Norris, Ph.D, R.N.C.S., F.A.A.N., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Norris is primarily responsible for the conduct of this research, which is supported by the Nurses Educational Funds, Inc.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the Boston College Psychiatric Mental Health Nursing Program and its contractors or cooperating agencies and
2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as "Influences on Adherence in African American Women with HIV,"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

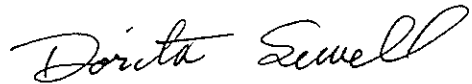
The purpose of this project is to investigate the influence of a number of factors on adherence to antiretroviral therapy, prevention practices, and action on medical appointments among African American women with HIV. Surveys will provide data. About 200 women are expected to participate.

A Certificate of Confidentiality is needed because potentially illegal or sensitive use of addictive substances or other sensitive information will be collected during the course of the study. The Certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to Dorita Sewell, Ph.D., Confidentiality Certificate Coordinator, Office of Science Policy and Communications, National Institute on Alcohol Abuse and Alcoholism/NIH, 5635 Fishers Lane, Room 3108, Rockville, MD 20852; 301-443-2890, Fax 301-480-1726; [dsewell@mail.nih.gov](mailto:dsewell@mail.nih.gov).

Sincerely,

A handwritten signature in cursive script that reads "Dorita Sewell". The signature is written in black ink and is positioned above the printed name and title.

Dorita Sewell, Ph.D.  
Confidentiality Certificate Coordinator

Enclosure  
cc: Mr. John Carfora  
Sponsored Programs

Appendix B

*Research Consent Form*

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Version 5.1: April 2003

Subject Identification
------------------------

**Protocol Title:** Influences on Adherence in African American Women with HIV

**Principal Investigator:** Sara E. Dolan Looby, RN, PhD(c)

**Site Principal Investigator:** \_\_\_\_\_

**Description of Subject Population:** African American Women with HIV age 18 and older

## PURPOSE

We would like permission to enroll you as a participant in a research study. This study is being done to learn more about adherence (following a prescribed plan) to HIV-related healthcare practices in adult African American women. Adherence to HIV-related healthcare practice is your ability to:

1. Take the correct number of HIV pills every day
2. Keep scheduled appointments with your HIV doctor or nurse
3. Practice ways to prevent the spread of HIV to others.

This study focuses on adherence in African American women because African American women are becoming infected with HIV at a higher rate than other ethnic groups (such as Hispanic/Latina, Asian, or Caucasian/white women) in the United States. There is not much information on what may influence adherence in this population.

Adherence to HIV-related healthcare practices can be hard. Yet, poor adherence may cause HIV to become worse and difficult to treat. This study will look at some of the factors that may affect adherence. These factors are:

- mood and feelings
- physical activity
- depression or depressed mood
- faith/spiritual beliefs:

The researcher will find out the relationship between these factors and adherence by asking you to complete surveys (a series of questions to be answered with a pen or a pencil). This study does not involve any medicine or treatment.

**Subject Population:** African American Women with HIV age 18 and older

**IRB Protocol No.:** 2006P-001835

**Sponsor Protocol No.:** N/A

**Consent Form Valid Date:** 08/14/2007

**IRB Amendment No.:** N/A

**Sponsor Amendment No.:** N/A

**IRB Expiration Date:** 08/13/2008

**IRB Amendment Approval Date:** N/A



# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification
------------------------

Version 5.1: April 2003

We are asking you to take part in this study because you are an adult African American woman with HIV. About 200 women will take part in this study. We will schedule the study visit at a time and place that works best for you and the researcher.

## STUDY CONTACTS

Sara E. Dolan Looby, RN, PhD(c) is the person in charge of this research study. You can call her at any time at 617-726-1423 or 617-726-2000 Pager 38009, 24 hours a day, with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Sara E. Dolan Looby, RN, PhD(c) at 617-716-1423.

## PROCEDURES

This study is only one visit. Please take your time and read the survey questions carefully. The researcher will be available to answer any questions. You will need to complete the questionnaires during the study visit. You may not take them home to complete and return at a later date. There is no time limit, though the entire visit should last about 90 minutes (one and a half hours).

After your questions are answered, you will sign the consent form. A copy of the signed consent form will be given to you to keep.

Next, you will fill out a packet of surveys. The surveys will be about:

- Your background (such as your age and job)
- Your HIV and treatment
- Taking your medications, keeping appointments, and what you do to prevent spreading HIV to others
- Your mood and feelings
- Your faith and beliefs
- Your physical activity

If you are not taking medications for your HIV, you can still take part in the study. Although we hope you will answer all the questions, you may skip over any questions you don't wish to answer.

<b>Subject Population:</b> <u>African American Women with HIV age 18 and older</u>		
<b>IRB Protocol No.:</b> <u>2006P-001835</u>	<b>Sponsor Protocol No.:</b> <u>N/A</u>	
<b>Consent Form Valid Date:</b> <u>08/14/2007</u>	<b>IRB Amendment No.:</b> <u>N/A</u>	<b>Sponsor Amendment No.:</b> <u>N/A</u>
<b>IRB Expiration Date:</b> <u>08/13/2008</u>	<b>IRB Amendment Approval Date:</b> <u>N/A</u>	

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification
------------------------

Version 5.1: April 2003

The researcher will review how to fill out the surveys and will give you a sealable envelope to put them in when you are done. You will fill out the surveys in a quiet area by yourself. If you need help reading some or all of the questions, please ask the researcher to help you. The researcher will be there to answer any questions you may have. When you are finished, the researcher will review the packet to make sure that the surveys are completed, seal the envelope, and give you a gift certificate.

You will receive a \$10 gift certificate to a local pharmacy when you complete the study. The researcher will give you the gift certificate at the end of the study visit, after she has reviewed the surveys and confirmed you have completed them. If you sign the consent form and then decide you do not want to complete the surveys, you will not receive a gift certificate.

## COSTS

You will need to pay for parking and transportation to the meeting place where you will sign the consent form and complete the surveys.

## RISKS AND DISCOMFORTS

Because the surveys are about your health, health practices, feelings and emotions, you may feel sad when answering certain questions. The investigator would like to know if you find anything upsetting about these questions and will be available to talk with you about your feelings. If you feel that you need more help, with your approval, the investigator will contact the social services department at the Massachusetts General Hospital, or a counselor if you are completing the study at a community clinic or AIDS service organization.

Also, no names will be used on the survey and any information linking your name to the survey (such as the consent form) will be kept locked and only the researcher has access to this. We have a Confidentiality Certificate (CC) from the US government that adds special protection for the research information that identifies you. It says we do not have to identify you, even under a court order or subpoena. Still, we may report medical information (if you need medical help), probable harm to yourself or others, or probable child abuse or neglect, the government may see your information if it audits us, in addition to the institutional review boards at the Massachusetts General Hospital, Boston College, and the researcher's dissertation committee made up of three PhD prepared nurses. This does not imply government approval or disapproval.

**Subject Population:** African American Women with HIV age 18 and older

**IRB Protocol No.:** 2006P-001835

**Sponsor Protocol No.:** N/A

**Consent Form Valid Date:** 08/14/2007

**IRB Amendment No.:** N/A      **Sponsor Amendment No.:** N/A

**IRB Expiration Date:** 08/13/2008

**IRB Amendment Approval Date:** N/A

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification
------------------------

Version 5.1: April 2003

## BENEFITS

There is no direct benefit if you decide to take part in this study. Other adult African American women with HIV may benefit from the information learned in this study.

## ALTERNATIVES

Your decision to take part in this research study won't change the medical care you get within Partner's now or in the future. There is no penalty and you will not lose any benefits. Taking part in this study is up to you. You can decide not to take part. If you take part in this study and want to drop out you should tell us. We can make sure you stop the study safely and can direct you to follow-up care if needed.

## PRIVACY AND CONFIDENTIALITY

Federal law requires Partners HealthCare System, Inc. and its affiliated hospitals, researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). If you enroll in the research described in this consent form, your "protected health information" will be used and shared with others as explained below.

### 1. What protected health information about me will be used or shared with others during this research?

- Existing medical records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires. Because this research involves potentially sensitive protected health information, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the investigators cannot be forced by court order (for example by court subpoena) to disclose research information that may identify you in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. Disclosures may be necessary, however, upon request of NIH, DHHS, or the IRB for audit or program evaluation purposes. A Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

### 2. Why will protected health information about me be used or shared with others?

- The main reasons include:

<b>Subject Population:</b> African American Women with HIV age 18 and older		
<b>IRB Protocol No.:</b> 2006P-001835	<b>Sponsor Protocol No.:</b> N/A	
<b>Consent Form Valid Date:</b> 08/14/2007	<b>IRB Amendment No.:</b> N/A	<b>Sponsor Amendment No.:</b> N/A
<b>IRB Expiration Date:</b> 08/13/2008	<b>IRB Amendment Approval Date:</b> N/A	

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification
------------------------

Version 5.1: April 2003

- to conduct and oversee the research described earlier in this form;
  - to ensure the research meets legal, institutional, and accreditation requirements; and
  - to conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm).
- Other reasons for sharing protected health information may include for treatment, payment, or health care operations. For example, some medical information produced by this study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given the Partners' Notice for Use and Sharing of Protected Health Information which provides more information about how Partners and its affiliates use and share protected health information.)
  - Note that the Certificate of Confidentiality may protect against disclosure of identifying information for some of these purposes, with exceptions noted below.

### 3. Who will use or share protected health information about me?

- Partners and its affiliated researchers and entities participating in the research will use and share your protected health information. In addition, the Partners review board that oversees the research at Partners and its affiliated staff who have a need to access this information to carry out their responsibilities (for example, oversight, quality improvement, and billing) will be able to use and share your protected health information. The Certificate of Confidentiality, however, will protect against required disclosure of identifying information in the types of proceedings noted above in #1.

### 4. With whom outside of Partners Healthcare System may my protected health information be shared?

All reasonable efforts will be made to protect the confidentiality of your protected health information, which may be shared with the following others for the reasons noted above:

- Outside individuals or entities that have a need to access this information to perform functions on behalf of Partners and its affiliates (for example, data storage companies, Partners' insurers, or legal advisors when necessary).
- Limited government agencies: The Certificate does not protect against disclosure of identifiable information to the Department of Health and Human Services upon request for an audit, program evaluation, or investigation. Such disclosure also may be made if required by the Federal Food, Drug, and Cosmetic Act or its regulations. When state law would generally require the researchers to disclose information (such as in a child abuse situation), the study will voluntarily provide that information to state authorities. However, in making these disclosures, the study will take all available efforts to protect your privacy.
- Third parties in rare cases: Under a Certificate, a researcher may voluntarily disclose identifiable information, such as in compelling circumstances where you or a third party is at risk.
- The sponsor(s) of the study, its subcontractors, and its agents: \_\_\_\_\_
- Other researchers and medical centers participating in this research, if applicable.

<b>Subject Population:</b> African American Women with HIV age 18 and older		
<b>IRB Protocol No.:</b> 2006P-001835	<b>Sponsor Protocol No.:</b> N/A	
<b>Consent Form Valid Date:</b> 08/14/2007	<b>IRB Amendment No.:</b> N/A	<b>Sponsor Amendment No.:</b> N/A
<b>IRB Expiration Date:</b> 08/13/2008	<b>IRB Amendment Approval Date:</b> N/A	

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification

Version 5.1: April 2003

- Hospital accrediting agencies.
- A data and safety monitoring board organized to oversee this research, if applicable.
- Other, specify: Boston College Institutional Review Board, and Dissertation Committee members including: Anne Norris, PhD, RNCS, FAAN, Barbara Wolfe, PhD, RN, CS, FAAN, and Carol Bova, PhD, RN, ANP

We recognize that some of those who receive protected health information may not have to satisfy the privacy requirements that we do and may redisclose it, so we share your information only if necessary and we use all reasonable efforts to request that those who receive it take steps to protect your privacy.

**5. For how long will protected health information about me be used or shared with others?**

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process. Research information may be analyzed and re-analyzed in light of scientific and medical advances, or reviewed for quality assurance, oversight, or other purposes.

**6. Statement of privacy rights:**

- You have the right to withdraw your permission for the researchers and participating Partners entities to use or share your protected health information. We will not be able to withdraw all of the information that already has been used or shared with others to carry out the research or any information that has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure the quality of the study. If you withdraw your permission, you cannot participate further in the research. If you want to withdraw your permission, you must do so in writing by contacting the researcher listed as the Study Contact.
- You have the right to choose not to sign this form. If you decide not to sign, you cannot participate in this research study. However, refusing to sign will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.
- You have the right to request access to your protected health information that is used or shared during this research and that relates to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed under Study Contacts.

**PUBLICATION OF RESULTS OR USE FOR TEACHING PURPOSES**

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission.

**REQUEST FOR MORE INFORMATION**

You may ask more questions about the study at any time. The investigator(s) will provide their telephone number so that they are available to answer your questions or concerns about the study. You will be

<b>Subject Population:</b> <u>African American Women with HIV age 18 and older</u>		
<b>IRB Protocol No.:</b> <u>2006P-001835</u>	<b>Sponsor Protocol No.:</b> <u>N/A</u>	
<b>Consent Form Valid Date:</b> <u>08/14/2007</u>	<b>IRB Amendment No.:</b> <u>N/A</u>	<b>Sponsor Amendment No.:</b> <u>N/A</u>
<b>IRB Expiration Date:</b> <u>08/13/2008</u>	<b>IRB Amendment Approval Date:</b> <u>N/A</u>	

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
Spaulding Rehabilitation Hospital  
Partners Community HealthCare, Inc.

Subject Identification
------------------------

Version 5.1: April 2003

informed of any significant new findings discovered during the course of this study that might influence your continued participation. A copy of this consent form will be given to you to keep.

If you want to speak with someone not directly involved in the study about your rights as a research subject, your participation in the study, any concerns you may have about the study, or a research-related injury, contact a representative of the Human Research Committee at (617) 424-4100. You can also contact them if you feel under any pressure to enroll or continue to participate in this study.

### REFUSAL OR WITHDRAWAL OF PARTICIPATION

Participation in this study is voluntary. Refusal to participate or dropping out of the study at any time will involve no penalty or loss of benefits to which you are otherwise entitled or affect your present or future care by the doctors or the participating hospitals. In addition, the doctor in charge of this study may decide to end your participation in this study at any time after he/she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed. Please also see the statement of privacy rights above if you wish to withdraw permission for your health information to be used and shared for study purposes.

### INJURY STATEMENT

If you are injured during the course of the study and as a direct result of this study, you should contact the investigator at the number provided under the Study Contacts section in this form. You will be offered the necessary care to treat that injury. This care does not imply any fault or wrong-doing on the part of the Partners institutions participating in this study or the doctor(s) involved. Where applicable, the appropriate Partners institution participating in this study reserves the right to bill third party payers for services you receive for the injury and to make other decisions concerning payment in such instances. The Hospitals will not provide you with any additional compensation for such injuries.

### CONSENT TO PARTICIPATE IN RESEARCH AND AUTHORIZATION TO USE OR RELEASE INDIVIDUAL HEALTH INFORMATION FOR RESEARCH

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts and potential benefits that I may experience have been explained to me. Alternatives to my participation in this research study also have been discussed. All my questions have been answered. I have read this consent form. My signature below indicates my willingness to participate in this research study and my authorization to use and share with others my "protected health information" as described in the preceding paragraphs.

### **SIGNATURES:**

\_\_\_\_\_  
Subject or Parent(s), if minor child

\_\_\_\_\_  
Date/Time

**Subject Population:** African American Women with HIV age 18 and older

**IRB Protocol No.:** 2006P-001835

**Sponsor Protocol No.:** N/A

**Consent Form Valid Date:** 08/14/2007

**IRB Amendment No.:** N/A

**Sponsor Amendment No.:** N/A

**IRB Expiration Date:** 08/13/2008

**IRB Amendment Approval Date:** N/A

# Research Consent Form

Brigham and Women's Hospital  
Massachusetts General Hospital  
Newton-Wellesley Hospital  
North Shore Medical Center  
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Partners Community HealthCare, Inc.

Version 5.1: April 2003

Subject Identification
------------------------

OR, if applicable, individual authorized by subject to make health care decisions

\_\_\_\_\_  
Court-appointed Guardian/Health Care Proxy Date/Time

OR

\_\_\_\_\_  
Family Member/Next-of-Kin Date/Time

Identify relationship to subject: \_\_\_\_\_

Subject's preferred contact information during course of study: \_\_\_\_\_

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts and potential benefits. I have answered any questions regarding the research study to the best of my ability.

\_\_\_\_\_  
Investigator/Individual Obtaining Consent Date/Time

In certain situations, the Human Research Committee will require the use of a subject advocate in the consent process. The subject advocate is an individual who has no vested interest in the research and who agrees to act as an impartial third party in the consent process.

\_\_\_\_\_  
Subject Advocate (if required by the HRC for this study) Date/Time

<b>Subject Population:</b> <u>African American Women with HIV age 18 and older</u>	
<b>IRB Protocol No.:</b> <u>2006P-001835</u>	<b>Sponsor Protocol No.:</b> <u>N/A</u>
<b>Consent Form Valid Date:</b> <u>08/14/2007</u>	<b>IRB Amendment No.:</b> <u>N/A</u> <b>Sponsor Amendment No.:</b> <u>N/A</u>
<b>IRB Expiration Date:</b> <u>08/13/2008</u>	<b>IRB Amendment Approval Date:</b> <u>N/A</u>

## Appendix C

*Study Questionnaires*

Demographic Information.....1– 2

Clinical Information.....3 – 4

For information on the following instruments, please refer to the citations listed below:

Satisfaction with Life Scale:..... <http://s.psych.uiuc.edu/~ediener/>

CASE Adherence Index:

Mannheimer, S. B., Mukherjee, R., Hirschhorn, L. R., Dougherty, J., Cleano, S. A.,  
Ciccarone, D., et al. (2006). The CASE adherence index, a novel method for  
measuring adherence to antiretroviral therapy. *AIDS Care*, 18(7), 853-61

Paffenbarger Physical Activity Questionnaire:

Lee, I. M., Paffenbarger, R. S., Hsieh, C. C. (1992). Time trends in physical activity  
among college alumni. *American Journal of Epidemiology*, 135(8), 915 – 925.

Pereira, M. A., FitzGerald, S. J., Gregg, E. W., Joswiak, M. L., Ryan, W. J., & Suminski,  
R. R. et al. (1997). A collection of physical activity questionnaires for health-  
related research. *Medicine & Science in Sports & Exercise*, 29(6 Supplement), S1  
- 205.

CES-D:..... <http://www.nimh.nih.gov>

*Faith* subscale of the FACIT-sp:.....<http://www.facit.org/> &

See reference for Peterman, et al. (2002).



## DEMOGRAPHIC INFORMATION

1. **How old were you on your last birthday?** \_\_\_\_\_
  
2. **What ethnic or racial groups do you consider yourself a member of?**  
(Please **Check** all that apply)
 

<input type="checkbox"/> Black or African American	<input type="checkbox"/> Native American
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander	<input type="checkbox"/> White Hispanic or Latino
<input type="checkbox"/> Caribbean Black	<input type="checkbox"/> White, not - Hispanic
<input type="checkbox"/> Black Hispanic	<input type="checkbox"/> Biracial, including African American
<input type="checkbox"/> African	
  
3. **Where you born in the United States?**     YES     NO
  
4. **What is your highest level of education?** (Please **Check** all that apply)
 

<input type="checkbox"/> Grade school	<input type="checkbox"/> 2 Year College graduate
<input type="checkbox"/> Some High School	<input type="checkbox"/> 4 Year College graduate
<input type="checkbox"/> High School Graduate or GED	<input type="checkbox"/> Graduate school
<input type="checkbox"/> Vocational or Technical School Graduate	
  
5. **What is your current partner or marital status?**  
(Please **Check** the one that best fits you)
 

<input type="checkbox"/> Single living with a partner	<input type="checkbox"/> Divorced
<input type="checkbox"/> Single never married	<input type="checkbox"/> Separated
<input type="checkbox"/> In a steady relationship	<input type="checkbox"/> Widowed
<input type="checkbox"/> Married	
  
6. **How many children do you have?** \_\_\_\_\_

7. **Do you have custody of your children?**

YES **how many?** \_\_\_\_\_  NO

a. **How old are your children?** \_\_\_\_\_

8. **Do your children live with you?**

YES  NO

a. **If yes, how many live at home with you?** \_\_\_\_\_

b. **How old are the children that live with you?** \_\_\_\_\_

10. **Do any other children live with you (i.e. grandchildren, nieces/nephews, etc.)?**

YES  NO

a. **If yes, how many live at home with you?** \_\_\_\_\_

b. **How old are these children?** \_\_\_\_\_

c. **Do you baby-sit/care for these children regularly?**  YES  NO

11. **What is your work status?** (Please Check the one that best fits you)

Not working  Retired

Work Full time  Volunteer full time

Work Part time  Volunteer part time

12. **Do you practice a religious faith by prayer or by attending services?**

YES  NO

**If yes, what religion are you?** \_\_\_\_\_

13. **What type of health insurance do you have?** \_\_\_\_\_

**CLINICAL INFORMATION**

1. **How many years have you had HIV?** \_\_\_\_\_
  
2. **Have you ever been given an AIDS diagnosis?**  
 YES     NO     DON'T KNOW
  
3. **Are you CURRENTLY taking medication for your HIV?**  
 YES     NO
  
4. **Have you ever had a CD4 count less than 200?**  
 YES     NO     DON'T KNOW
  
5. **Do you currently have an UNDETECTABLE Viral Load?**  
 YES     NO     DON'T KNOW
  
6. **Do you smoke?**     YES     NO
  - a. How many cigarettes a day? \_\_\_\_\_
  - b. How many years? \_\_\_\_\_
  
7. **If you don't smoke now, did you ever smoke?**  
 YES     NO
  - a. How many years \_\_\_\_\_
  
8. **When was the last time you used a substance (alcohol or drugs)?**  
\_\_\_\_\_
  - a. **What substance:** \_\_\_\_\_
  - b. **How much of the substance were you using at a time?** \_\_\_\_\_  
\_\_\_\_\_

9. Do you have a history of substance abuse?  YES  NO

If **YES**:

a. What was/were your most problematic substance(s)? \_\_\_\_\_

\_\_\_\_\_

b. How much of the substance were you using at a time? \_\_\_\_\_

\_\_\_\_\_

10. How long did you abuse substance(s) for? (in YEARS) \_\_\_\_\_

11. Did you ever require detox and or rehabilitation for substance abuse?  YES  NO

12. Have you ever been told by a doctor or a nurse that you have depression?  YES  NO

13. Were you told by a doctor or nurse that you had depression before or after you found out you had HIV?  Before  After

14. Have you ever been told by a doctor or a nurse that you have anxiety?  YES  NO

15. Were you ever hospitalized for mental illness?  YES  NO

16. Are you pregnant right now?  YES  NO

17. Do you have a physical impairment (i.e. use a cane or unable to do an activity because of an injury)  YES  NO

## Appendix D

### *Permission for use of Instruments in the Current Investigation*

Satisfaction with Life Scale (letter from E. Diener)

CASE Adherence Index (email from S. Mannheimer)

Paffenbarger Physical Activity Questionnaire (email from I. M. Lee)

Affectometer 2 (email from Ross Flett – this scale was not used in final analyses)

CES-D (email from NIMH Info)

FACIT-sp (email confirming registration from [information@facit.org](mailto:information@facit.org))

SWLS

---

*Ed Diener, Ph.D.  
Psychology Department  
University of Illinois  
603 E. Daniel St.  
Champaign, IL 61820  
217-333-4804 [ediener@s.psych.uiuc.edu](mailto:ediener@s.psych.uiuc.edu)*

Dear Requester:

Thank you for requesting the Satisfaction with Life Scale. As you may know, there is an article in the 1985, Volume 45, issue of Journal of Personality Assessment, which reports on the validity and reliability of the scale. In addition, we currently have another article titled, "Review of the Satisfaction With Life Scale" in Psychological Assessment\*. The results reported in this second article are extremely encouraging. The SWLS correlates substantially with reports by family and friends of the target person's life satisfaction, with number of memories of satisfying experiences, and with other life satisfaction scales. The SWLS was examined in both a college student and elderly population. In both populations the scale was valid and reliable (internally consistent and stable).

The SWLS is in the public domain (not copyrighted) and therefore you are free to use it without permission or charge. You will, however, have to type or reproduce your own copies.

Best wishes,

Ed Diener, Ph.D.  
Professor

\*Pavot, W., & Diener, E. (1993). Review of the Satisfaction with Life Scale. *Psychological Assessment*, 5, 164-172.

---

Looby, Sara Elizabeth Dolan,N.P.

Case Adherence

From: sbm20@columbia.edu  
Sent: Wednesday, September 06, 2006 1:34 PM  
: Looby, Sara Elizabeth Dolan,N.P.  
Subject: Re: Adherence index

Follow Up Flag: Follow up  
Flag Status: Flagged



CASE ADHERENCE abstract O-115 .  
ndex QUESTIONN...Case Adherence ...

Thanks for your interest.

i don't think it has been published yet- still in press at AIDS Care. i'll attach the instrument and a presentation describing it. Let me know if you have any questions.  
Sharon Mannheimer

Quoting "Looby, Sara Elizabeth Dolan,N.P." <SLOOBY@PARTNERS.ORG>:

> Hello Dr. Mannheimer, my name is Sara Dolan Looby and I work with  
> Steven  
> Grinspoon at MGH. I am also a PhD candidate at Boston College.  
> My research  
> interest is examining the influences of adherence in African  
> American women with  
> HIV. Back in the spring, I spoke with Lisa Hirschhorn and she  
> informed me about  
> the CASE Adherence Index. I was wondering if your article  
> regarding this  
> instrument has been published yet, or if it was possible for me  
> to potentially  
> use the CASE Adherence Index as an adherence instrument in my  
> study? I look  
> forward to hearing from you,  
>  
> Sincerely,  
>  
> Sara Dolan Looby

**Looby, Sara Elizabeth Dolan,N.P.**

---

**From:** I-Min Lee [ilee@rics.bwh.harvard.edu]  
**Sent:** Thursday, January 24, 2008 4:16 PM  
**To:** Looby, Sara Elizabeth Dolan,N.P.  
**Subject:** Re: FW: Paffenbarger Physical Activity Questionnaire

Yes, you can use the qx free of charge; but please credit the qx as the College Alumni Health Study qx and reference it appropriately.

Looby, Sara Elizabeth Dolan,N.P. wrote:

> Dear I-Min, thank you for your swift response! I truly appreciate it. I tried  
> contacting Dr. Paffenbarger in the past re: permission to use the scale or at  
> least questions from the scale (in my dissertation) citing his reference, even  
> though it is published formally in Medicine & Science in Sports & Exercise. Is  
> it free for public use? Thank you, Sara

>

>

>



**Looby, Sara Elizabeth Dolan, N.P.**

*Affectometer 2*

**From:** Ross Flett [r.a.flett@massey.ac.nz]  
**Sent:** Wednesday, April 19, 2006 5:50 PM  
**Subject:** Doian, Sara, R.N.  
Re: Affectometer 2

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi Sara - happy to give permission to use the scale and send you the relevant material - will put it in the mail soon

best of luck with your studies

rf

At 05:14 a.m. 20/04/2006, you wrote:

>Hello Dr. Flett, my name is Sara Dolan and I am a doctoral student at Boston  
>College in Massachusetts, USA. I am interested in using the Affectometer 2 as  
>an instrument in my dissertation research. I am measuring influences of  
>adherence behaviors among HIV-positive African American women, and subjective  
>well-being is one of the influences I am measuring. I would like to use the  
>Affectometer 2 to measure affect, and Diener's Satisfaction with Life  
>scale for  
>life satisfaction. I understand Dr. Kammann has passed away and I would like I  
>to receive permission for the use of this scale and to obtain a copy of the  
>scale with scoring instructions. Can you provide this information for me, or  
>put me in touch with someone who can? Thank you in advance for your  
>assistance.

truly appreciate your help!

>Sincerely,

>

>Sara Dolan

>

>

>Sara E. Dolan, MSN, ANP

>Program in Nutritional Metabolism

>Massachusetts General Hospital

>55 Fruit Street, LON 207

>Boston, Ma 02114

>

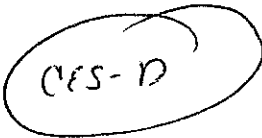
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Ross Flett PhD

Senior Lecturer, School of Psychology, Massey University, PN, New Zealand.

Phone: +64 6 350 5799 ext 2051, Fax: +64 6 350 5673

email: R.A.Flett@massey.ac.nz


 CES-D

**Looby, Sara Elizabeth Dolan, N.P.**

---

**From:** NIMH Info [nimhinfo@nih.gov]  
**Sent:** Wednesday, November 08, 2006 10:11 AM  
**To:** Looby, Sara Elizabeth Dolan, N.P.  
**Subject:** RE: Center for Epidemiologic Studies Depression Scale  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear Sara:

Thank you for your e-mail to the National Institute of Mental Health (NIMH), part of the National Institutes of Health (NIH).

We are sending the Center for Epidemiologic Studies Depression (CES-D) Scale as an attachment to this e-mail. This scale is in the public domain and can be copied, revised, or reproduced as needed. Citation of the NIMH as the source is appreciated.

If you need information about scoring and interpretation of data, we suggest you search the literature through PubMed, the National Library of Medicine's searchable database of 15 million scientific research abstracts and citations at: <http://www.ncbi.nlm.nih.gov/pubmed>.

We hope this information is helpful. The NIMH conducts and supports medical research to improve people's mental health. We provide a wide range of information based on that research. If you have additional questions, please contact us again.

Information Center  
 National Institute of Mental Health  
 E-mail: [nimhinfo@nih.gov](mailto:nimhinfo@nih.gov)  
 Web site: <http://www.nimh.nih.gov>

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Department of Health and Human Services

National Institutes of Health

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-----Original Message-----

From: Looby, Sara Elizabeth Dolan, N.P. [mailto:SLOOBY@PARTNERS.ORG]  
 Sent: Tuesday, November 07, 2006 4:54 PM  
 To: NIMH Info  
 Subject: RE: Center for Epidemiologic Studies Depression Scale

Hello, just following up re: the message below, thanks!

> -----Original Message-----

11/8/2006

**Looby, Sara Elizabeth Dolan,N.P.**

---

**From:** information@facit.org  
**Sent:** Wednesday, September 20, 2006 9:16 PM  
**To:** Looby, Sara Elizabeth Dolan,N.P.  
**Subject:** your facit.org registration  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Rn, PhD(c) Sara Dolan Looby, Thank you for registering with facit.org. When visiting the site in the future, please take the time to log in so that you will have access to restricted information and features of our site.

Thank you,  
The staff at facit.org

# Functional Assessment of Chronic Illness Therapy

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