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THE RELATIONSHIP BETWEEN TREAMENT SELF-EFFICACY AND HIV/AIDS TREATMENT ADHERENCE IN PEOPLE LIVING WITH HIV/AIDS: A PILOT STUDY

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Presented to the faculty of the School of Nursing

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by

Marc Rensis Labrador Fontanares

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Abstract

of

THE RELATIONSHIP BETWEEN TREATMENT SELF-EFFICACY AND TREATMENT ADHERENCE IN PEOPLE LIVING WITH HIV/AIDS

by

Marc Rensis Labrador Fontanares

Statement of Problem

The advent of anti-retroviral therapies (ART) to manage HIV/AIDS disease sequalae has provided improved health outcomes, longevity, decrease in HIV/AIDS related mortality and morbidity, and optimization of quality of life. For ART to be effective, optimum adherence to treatment must be achieved. However, there continues to be poor viral suppression among HIV/AIDS populations and thus warrants exploration of correlates such as Treatment Self-Efficacy on ART adherence among adults living with HIV/AIDS.

Sources of Data

Data is to be collected from a convenience sample of adults as clients in a local San Diego County HIV/AIDS resource care center, who completed a survey during routine center visits, that included demographic data, HIV Adherence Self-Efficacy Scale (HIV-ASES) (Johnson, et al., 2007), 30-day Visual Analog Scale (VAS) (Walsh, Mandalia, & Gazzard, 2002), and 30-day 3-Item Adherence Scale (Wilson et al., 2013).

ACKNOWLEDGEMENTS

I would like to acknowledge my family, extended family for believing in me and motivating me to be the best that I can be.

To my best of friends, I thank you for your support in life and in academia, I hope to have served as an inspiration to you all and to always believe in the passion that is of our profession.

I express my sincere appreciation to Dr. Denise Boren and Dr. Linnea Axman and the faculty of the California State University, San Marcos School of Nursing for the wisdom, guidance and commitment in preparation of this project. I am forever inspired by your contributions to the elegant art and science that is within our profession of *nursing*.

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CHAPTER ONE: INTRODUCTION

It is well known that effective management of individuals with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) is affected by optimum treatment adherence. The advent of highly active retroviral treatments (HAART), and the development of varying pharmacological classes of treatments that allow for reduction in pill burden and simplicity of treatments, and effective management with improved clinical outcomes are now more feasible and accessible. For effective viral suppression and improved health outcomes, treatment adherence must be achieved and maintained to suppress viral load. However, literature indicates that there is persistent decline in treatment adherence in the general population, resulting in treatment failure and poor health outcomes.

Epidemiological data from national surveillance initiatives in the United States such as The National HIV Surveillance System (The Centers for Disease Control and Prevention, 2015), provides an exemplar of the magnitude of HIV prevalence and sub-optimal medication adherence rates as evidenced by sustained viral loads, and thus warrants consideration in interventions to improve care management of HIV/AIDS populations. Research has considered diverse avenues of approaching treatment adherence, providing insight and perspectives on developing interventions to facilitate improving treatment adherence.

Guiding this exploration of treatment adherence is the theoretical framework of *Self-Efficacy*, developed by Albert Bandura, with foundations in Social Cognitive Theory (SCT). Self-efficacy theory links proposed factors that dynamically affect human behavior, specifically when applied to health care behaviors. The theoretical framework posits that an individual's perception of *efficacy* is based on four constructs: (1) *mastery experience,* (2) *vicarious*

experience, (3), *verbal persuasion*, and (4) *somatic and emotional state*, all of which interact respectively resulting in a change in behavior (Bandura, 1977). Further exploration of this theory and relevance to this research will be discussed in Chapter 2.

Literature review elucidates that there are contributing factors that affect treatment adherence specifically with HAART among HIV/AIDS populations. Constructs as such in Social Cognitive Theory and Self-Efficacy Theory have been examined for associated significance in treatment adherence and thus warrants further study for validation and generalizability.

Background and Significance

In order to optimize health outcomes, HIV/AIDS must be managed with appropriate modalities (conventionally with use of HAART) requiring consistent adherence to achieve and maximize the intended viral suppressive benefits. Similar to other disease processes, HIV infection is approached as a chronic illness, that must be managed with daily treatments to suppress the infection sequelae and improve health outcomes (Nokes et al., 2012). To delay the progression of the illness, and reduce morbidity and mortality from HIV infection, optimum adherence of >95% must be met to suppress viral load and minimize associated disease pathology (Cohen, Meyers, & Davis, 2013). Antiretroviral therapies can take form as single dose regimens to multi-dose combination therapies, but nonetheless for optimum efficacy of treatment, prescribed doses must be followed. Nachega et al. (2011), determined that a patient may not miss more than one dose per month for maximum treatment efficacy (p. 108). Non-adherence, frequent interruption in scheduled drug doses, ineffective or sub-optimal drug selection, and low serum drug concentrations can result in drug resistance, treatment failure and poor health outcomes with increased health care burden and costs (p.109-110).

A published Morbidity and Mortality Report provided by The Centers for Disease Control and Prevention, estimates that in 2012, there is approximately 1.2 million cases of HIV infections in the United States among people ages 13 years and older. Of those cases, 12.8% or approximately 156,000 individuals are un-diagnosed (as cited in Hall et al., 2015). Sub-populations with the highest incidence of HIV diagnosis in 2010 include *White men who have sex with men* (MSM), with significant increase in incidence among young African-American MSM. It is estimated that the rate of new HIV infections among African-Americans are 7.9 times more likely than Whites (Karon et al., 2008). Though HIV incidence rates remained stable across subpopulations in 2010. Furthermore, as viral suppression is essential for optimum health outcomes, medication adherence rates must be considered in this issue. The Centers for Disease Control and Prevention estimates that in the United States, 89% HIV infected individuals are on prescribed anti-retroviral treatments (ART), of those, 77% had viral suppression; only an estimated 28% of all HIV-infected person in the United had viral load suppression (Cohen at al., 2011).

There exist numerous research inquiries that explore the concept of medication adherence related to HIV/AID anti-retroviral treatments (ART). Studies have explored specific determinants of medication adherence, across varying populations (demographics) among HIV/AIDS populations and have provided insight into possible correlates; evidence to reinforce necessity for interventions, healthcare and public health implications and approaches to health promotion and education (Nachega et al., 2011).

The Problem

Despite interventions and initiatives for HIV prevention, rates of infection have remained stable in the United States. The inception of antiretroviral therapies has provided improved

quality health outcomes, prolonging life and decrease mortality related to HIV/AIDS (Brown et al., 2013). However, for treatment to successfully suppress viral loads, strict adherence to ART must be achieved and maintained, and literature reinforces the paucity of improving medication adherence through specific and effective interventions. The necessity for high levels of medication adherence are required to prevent adverse disease sequelae and premature death, however, epidemiological surveys are finding sustained and increasing number of patients that are sub-optimal in treatment adherence and do not achieve nor maintain appropriate levels of ART adherence resulting in poor health outcomes (Langebeek et al., 2014).

Purpose of the Research

The purpose of this research study is to explore the relationship of *self-efficacy* on the rates of treatment adherence among adults living with HIV/AIDS that are currently prescribed anti-retroviral treatments (ART), as clients in a local San Diego County HIV/AIDS resource center. Furthermore, this pilot study will identify the level of self-efficacy in the greater San Diego area supporting the development of a client education program to increase self-efficacy and improve treatment adherence rates. A larger study will follow exploring the differences in self-efficacy of participants prior to and following an educational intervention.

Research Question

The research question is, “For adults living with HIV/AIDS (PLWHA) as clients in a local San Diego County HIV/AIDS resource clinic, is there a relationship between self-efficacy and individuals’ self-reported anti-retroviral treatment (ART) adherence?”

Research Variables

The independent variable in this study is the self-reported anti-retroviral adherence self-efficacy as measured by the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES)

(Johnson et al., 2007). The dependent variable in this study self-reported ART adherence instruments specifically the 30-day Visual Analog Scale (VAS) (Walsh, Mandalia & Gazzard, 2002; Nokes et al., 2012), and the 30-day 3-Item Adherence Scale (Wilson et al., 2013). Baseline demographic factors will also be included in data collection, including participants' age, gender, ethnic background, education level, occupation status, and presence of health insurance coverage.

CHAPTER TWO: LITERATURE REVIEW

Literature, research studies and other supplemental information were derived from online research databases including Cumulative Index to Nursing and Allied Health Literature (CINAHL), Pubmed, and Google Scholar. A total of 150 abstracts and articles were reviewed for consideration in this literature review, 60 were utilized for in depth-review and analysis, and a total of 37 were included in this thesis. Specific keywords (terminologies) were utilized in database research including: *HIV/AIDS, treatment, adherence, self-efficacy, antiretroviral.* Characteristics of the literature are English written articles published dating from 1970 to present. The research focused on general epidemiological data of HIV/AIDS prevalence and incidence rates, medication adherence rates, pathophysiology of the disease process/sequalae, treatment guidelines, theoretical framework and correlates/predictors (variables) related to ART adherence.

Nokes et al., (2012) conducted a cross-sectional, descriptive national study of HIV/AIDS participants (n=1,414), currently on active antiretroviral treatments, to explore the role of *treatment adherence self-efficacy* and potential relationships with self-reported ART adherence, and constructs as defined in Social Cognitive Theory. The study findings indicated a *moderately strong relationship* of adherence self-efficacy with adherence to ART, and emphasized the mediating role of *self-efficacy*, implicating considerations to integrating and engaging clients in improving perceived self-efficacy to optimize medication adherence rates and outcomes (p. 408-409). The instruments utilized in the study are: HIV Adherence Self-Efficacy Scale (HIV-ASES) (Johnson et al., 2007), 30-day Visual Analog Scale for Medication Adherence (Walsh, Mandalia, & Gazzard, 2002), and a Single-Item Self-Rating of Adherence Scale (Lu et al., 2007). This study provides the exemplar model research design for this thesis.

Examining relationships of social-cognitive variables and demographic factors with ART adherence among HIV populations, a cross-sectional, descriptive study (n= 116) conducted by Brown, Littlewood & Vanable (2013), (n=116), indicated that women and racial minorities are more likely to report medication adherence rates that are suboptimal. Findings of bivariate analyses concludes that participants with optimal adherence levels exhibit characteristics such as greater self-efficacy with ART adherence, greater perception of risk and negative outcome expectancies from non-adherence to ART, had overall higher levels of optimal ART adherence (p.5). Multivariate analyses reinforce the above findings, indicating that ART adherence greater than 95% was associated with increased level of treatment self-efficacy (p.5). Instruments for measurement in this study were self-report ART adherence measurement (Simoni et al., 2006) and ART Adherence self-efficacy questionnaire (Johnson et al., 2007).

A meta-analysis (in concordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses) conducted by Langebeek et al. (2014), examined 207 studies published between 1996 and 2014, to examine predictors and correlates of ART adherence for HIV infected populations. Analyses of common factors pooled from the studies indicated that adherence self-efficacy had the strongest association with ART adherence rate. Other significant correlates including presence of substance use, concerns with treatments, provider-patient relationship, and medical beliefs about importance of treatment, depression, stigma related to HIV diagnosis, and presence of social support (p. 3-4).

Emphasis on exploring cognitive-behavioral factors in ART adherence was supported by a cross-sectional study by Adefolalu et al. (2015), that surveyed HIV-infected individuals on current ART in South Africa (n=232). Examined variables in the study were treatment adherence self-efficacy, measured by HIV Treatment Adherence Self-Efficacy Scale (Johnson et al., 2007),

Beliefs about Medicines Questionnaires (BMQ) (Horne, Weinman, & Hankins, 1999), and ART adherence, measured by the adult AIDS Clinical Trial Group follow up questionnaire (Chesney et al., 2000). Study findings elucidate that HIV adherence self-efficacy is statistically significant as a variable in the prediction of ART adherence, and implicates that interventions should consider socio-cognitive behaviors and factors in conjunction with demographic traits as potential barriers to optimum ART adherence (Adefolalu et al., 2015, p. 284).

Waldrop-Valverde, Dong & Ownby (2013) conducted a longitudinal study (n=99), inclusive of interviews and surveys at 4-week intervals for a total study period of 6 months that measured medication adherence and ART taking self-efficacy. Instruments used for this study included, the Self-Efficacy for Taking Antiretroviral Medication Scale (Purcell et al., 2004) and Medication Event Monitoring Systems (MEMS), utilizing electronic bottle caps that record events of opening the medication bottle, tracking time and frequency; an instrument shown to have good reliability in predicting ART adherence (McNabb et al., 2003). Findings from this study conclude that *medication-taking self-efficacy*, older age, increased monthly income was associated with higher levels ART adherence, congruent with literature review findings.

Major Variables Defined

Demographic Variables. The following demographic variables are defined in this section. Adults are inclusive of individuals that are at least 18 years and older. Gender is defined as either male, female or other; individuals may identify themselves as transgender/transsexual and is identified as such. *Age* is based on the chronological age of the individual. *Ethnicity* is the individual's referred ethnic background or also known as *race*, which can include Asian/Pacific Islander, African-American/Black, Hispanic/Latino, Native American, White/Anglo-Saxon, or other. *Education level* is segmented by tiers (based on education levels in the United States) and

are specified as follows: 11th grade or less, High School or GED, 2-year college/Associate's Degree completion, 4-year college/Baccalaureate degree completion, Master's degree or Doctorate degree completion. *Occupation status* is defined as currently working in an occupation/position/employment for pay. *Health Insurance* is whether the individual has active and useable health insurance coverage (including federally funded, healthcare provision programs, i.e. Medicare).

Adherence. The definition of *adherence* for this project is based on the model study by Nokes et al. (2012) in conjunction with the World Health Organization (2003) definition of adherence as it relates to long-term therapies (applicable to antiretroviral treatment, requiring long-term therapy). Nokes et al. (2012), defines adherence as the "…complement of actions taken to comply with intervention recommendations…" (p. 404). Furthermore, the World Health Organization expresses adherence as "the extent to which a person's behavior taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (World Health Organization, 2003, p.3).

The definition for *ART optimal adherence rate*, is determined based on a longitudinal study conducted by Paterson et al. (n=99) that indicate for ART adherence to be optimal, treatments (medication doses) must be taken ≥95% of total prescribed doses

[(Number of doses taken)/ (Total prescribed doses)] x 100 = % adherence. Optimum adherence is achieved by measure of viral suppression, viral load below levels of detection (e.g. HIV RNA <20 to 75 copies/mL) (Department of Health and Human Services, 2015).

Self-Efficacy. Nokes et al. (2012), defines *self-efficacy*, specifically HIV treatment self-efficacy as "…the confidence held by an individual in his/her ability to follow treatment

recommendations and includes any action that the person living with HIV does to promote health…" (p. 404).

Theoretical Framework

Guiding this research study is the theoretical framework of Albert Bandura, *The Self-Efficacy Theory*. The foundational basis of this theory stems from *social learning theory* (also known as *social cognitive theory*), posits the act of learning consists of cognitive processes that extends beyond the inner drives, needs and essentially motivations of an individual. The theory identifies *determinants of behavior*—cognitive, behavioral, and environmental factors (influences)—that dynamically interact to form human function or behavior (Bandura, 1971). This interplay of influences is what is known as *triadic reciprocality,* with emphasis on the role of cognition in affecting human capabilities. Furthermore, Bandura focuses on this idea of "being human" as to describe individuals possessing the following cognitive abilities:

Symbolize. Humans have the ability to extract and infer from the environment, reflect upon experiences, situations, and circumstances that can affect behavior and foresee impact or consequences of actions. Symbolically representing thought can be stored for future reference to behaviors and provides structure for thoughts and ideas (Bandura, 1971, p.2).

Self-Direction or Forethought. With the capability of symbolizing, individuals are able to anticipate, plan and guide actions, set goals, considering the consequences of actions.

Vicarious Learning. By keen observation of the world, people are able to draw and learn observed behaviors without the actual attempt of the task and is stored mentally for future guidance. This requires the retention of the (observed) behavior, recognizing the value of such behavior, and to engage in integrating the behavior into purposeful action (Bandura, 1971, p.3).

Self-Regulation. People are self-regulatory, continuously evaluating and assessing the actions and performed behaviors, behavior changes that are deemed necessary (Bandura, 1971, p. 3).

Self-Reflection. Human beings are unique in exhibiting the ability to self-reflect, or provide appraisal of one's experiences, insight into one's own cognitions, beliefs, and have the ability to self-evaluate and produce changes in behavior (Bandura, 1986).

Central to these cognitive abilities that affect human function, resulting in behavior is the theory of *Self-Efficacy*. An individual's *perceived self-efficacy* is "…beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives" (Bandura, 1994). Generally, people that have high levels of self-efficacy will attempt tasks and challenges as areas to achieve mastery rather than fear-provoking or threats, resulting in avoidance of such endeavors. Characteristics of self-efficacious individuals are resilience (in regard to outcomes), attributes failures as requiring additional effort, knowledge or practice which are realistically attainable (1994). Contrary to this, people with low levels of self-efficacy, are vulnerable to poor commitment to goals, easily dissuaded by failures, and often result with "stress and depression" (1994).

Self-efficacy is influenced by four distinct constructs: *mastery experience, vicarious experience, verbal persuasion* and *physiologic (somatic and emotional) state*. These constructs or processes contribute individually and collectively to form self-efficacy.

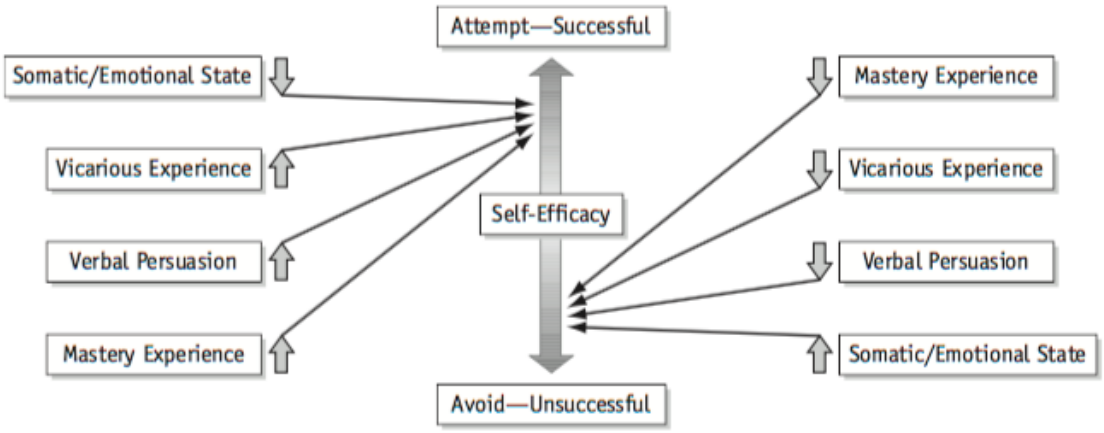
Mastery Experience. Successful completion of tasks reinforces positive self-efficacy in people. Adversity, difficulty and incompletion of tasks serve as points from which self-efficacious individuals can learn, develop skills, and become *stronger* from perseverant efforts (Bandura, 1994).

Vicarious Experience. By social modeling, an individual can observe others in similar circumstances that influence thought, and believe that they too possess the ability to fulfill those same tasks; by observation, there is a transfer in knowledge to the observer that results in a sense of *empowerment* to be able to accomplish the sought goals (Bandura, 1994).

Verbal Persuasion. Individuals can provide self-persuasion as well as input from that they are capable of achieving and mastering the intended task. Additionally, persuasion in terms of convincing one's self to attempt challenging tasks, and situate in an environment that promotes achievement based on improvement rather than comparing themselves to others (Bandura, 1994).

Physiologic States. Reactions to tasks, stress-responses and physical responses (e.g. fatigue, strength, stamina) all influence an individual's perception of self-efficacy. How one perceives physiologic state can positively or adversely affect perceived self-efficacy (Bandura, 1994).

Figure 1. Albert Bandura's Self-Efficacy Theory model



Note. Permission obtained from author to use. (Hayden, 2009, p. 10) (Appendix H).

Summary

Review of the literature provides ample evidence that varying correlates affect the level of ART adherence among HIV/AIDS populations. A dynamic interplay between cognitive and personal factors, behavior, and environmental aspects influences the behavior of treatment adherence. Despite evidence of statistically significant variables as barriers to treatment adherence, as a single correlate, treatment adherence self-efficacy yields a consistent association to treatment adherence that transcends much of literary studies and reviews.

The Self-Efficacy Theory (Bandura, 1977;1994) derived from *The Social Learning Theory* (Bandura, 1971) describe the dimensions that produce human function and behavior and thus is utilized as a pragmatic model for this research study.

CHAPTER THREE: METHODOLOGY

Introduction

There are numerous instruments that measure for treatment adherence, not limited to antiretroviral treatment and have global applicability to various settings and environments. The instruments utilized in compliance with the aims of this research are all self-report based questionnaires that are feasible for low-cost studies, and are relatively easy to administer on various participant groups (Buscher et al., 2011).

ART adherence self-efficacy will be measured by utilizing the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES) (Johnson et al., 2007) (Appendix B). Treatment adherence scales utilized are adaptations from Walsh, Mandalia, and Gazzard (2002) including the 30-day Visual Analog Scale (Appendix C). Additionally, an instrument by Wilson et al. (2013), a 30-day 3-Item Adherence Scale will also be utilized in this study to measure treatment adherence (Appendix D).

Exploring the relationship between treatment self-efficacy and ART adherence will be analyzed with inferential statistical methods and demographic data will be examined by descriptive statistics.

Research Question

“For adults living with HIV/AIDS (PLWHA) as clients in a local San Diego County HIV/AIDS resource clinic, is there a relationship between treatment adherence self-efficacy and individuals’ self-reported anti-retroviral treatment (ART) adherence?”

Identification of Setting

The setting for this research study will be conducted in a HIV/AIDS community resource center located in central San Diego County (Hillcrest). *Being Alive* is a non-profit organization that provides support services including peer advocacy and counseling, assistance with accessing public health provision programs such as AIDS Drug Assistance Program (ADAP) and Comprehensive AIDS Resource Emergency Act, Health Insurance Premium Payment Program (CARE HIPP), emergency food resources, recreational and educational workshops/activities. All services aim to provide a safe environment for individuals, access to emotional support systems, peer guidance and community resources to facilitate growth and improve quality of life among HIV/AIDS clients.

This research study will support the development and implementation of a *Client Education Program* that is an additional service-line in the facility. This program aims to provide assistance in navigating through healthcare services, chronic disease (i.e. HIV/AIDs) management and treatment adherence, and to provide information on ancillary services such as psychiatry, counseling, financial and employment assistance, etc. This program will be delivered in a didactic setting at the facility, approximately one-hour sessions every week for a total duration of 12 months. Additional content and delivery methods may vary depending on client and staff feedback to appropriately and effectively address deficits and as requested by the community.

Active clients in *Being Alive*, are adults, 18 years and older, with HIV/AIDS infection (diagnosis) that are on current anti-retroviral treatments. The resource center consists of 5 employed staff with 10 volunteers, providing services to approximately over 3,000 clients within San Diego county (A. Gadia, personal communication, December 7, 2015).

Research Design

The research design that will be used in this study is a quantitative, cross-sectional study, to explore the relationship between *self-efficacy* and anti-retroviral treatment adherence. A pen-paper, survey questionnaire will be administered including collection of demographic information (Appendix A) with the HIV Adherence Self-Efficacy Scale (HIV-ASES) (Johnson et al., 2007), 30-day Visual Analog Scale (VAS) (Walsh, Mandalia, & Gazzard, 2002), and the 30-day 3-Item Self-Rating Adherence Scale (Wilson et al., 2013).

Population Sample

Participants will be selected by a convenience sampling method, by recruitment at *Being Alive* HIV/AIDS Resource Center. All participants are clients in this resource center, must be 18 years and older, diagnosed with HIV/AIDS and are on currently prescribed antiretroviral treatment (medications), proficient in reading and writing English. All participating clients will be approached by an appointed counselor (as the designated research assistant), and approval will be received by the client prior to initiation of the study. Exclusion criteria are clients that are younger than 18 years old or adults with cognitive dysfunction and as a result are unable to complete the study requirements.

The required total sample size for this study will be 109 participants from the total number of clients at the prospective HIV/AIDS resource center. The sample size (n=109) is determined based on utilizing a correlational, bivariate normal model (two-tailed test) to achieve a power of .80, with a significance level of .05, and a selected effect size of .30 (Faul et al., 2009) (Figure 2). An additional 40% of sample size was added to factor in attrition during this study.

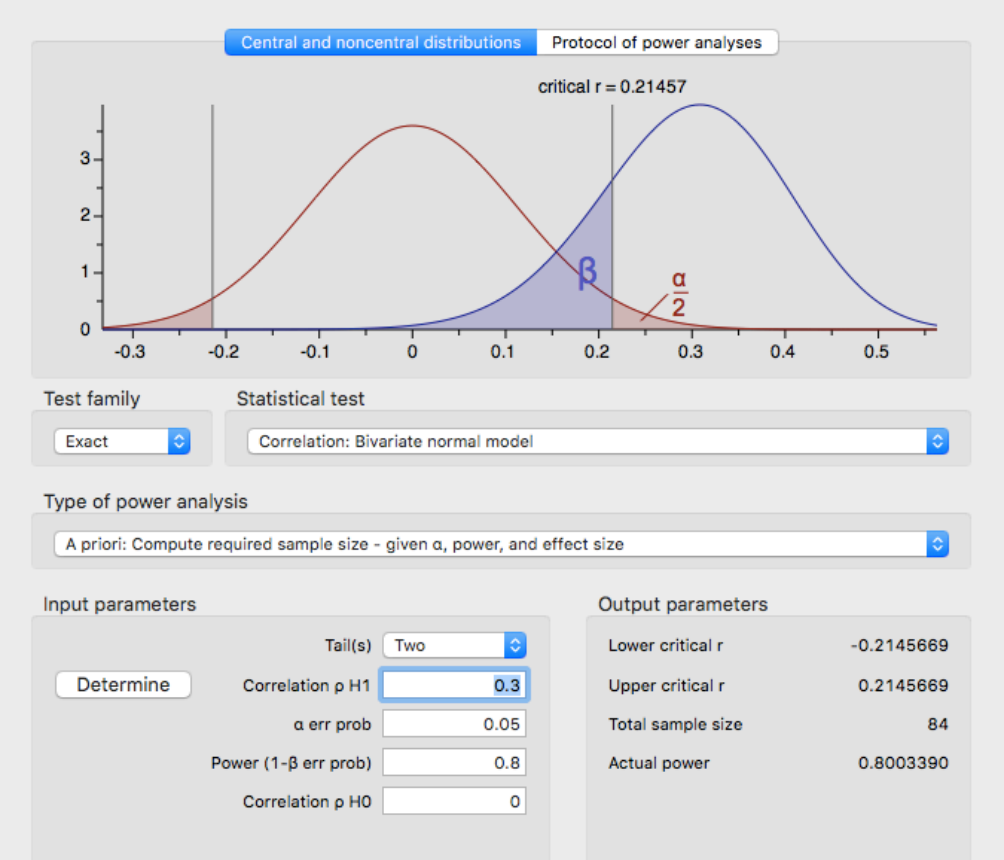


Figure 2. Power analysis for data collection (Faul et al., 2009)

Measurement Methods

A pen-paper survey questionnaire includes basic demographic information which will consist of the following: age, gender, ethnicity, highest education level attained, occupational status, and presence of health insurance coverage (Appendix A).

The following instrument scales will be included in this study: HIV Adherence Self-Efficacy Scale (HIV-ASES) (Johnson et al., 2007), 30-day Visual Analog Scale (Walsh, Mandalia, & Gazzard, 2002), and a 30-day 3-Item Adherence Scale (Wilson et al., 2013). The HIV-ASES instrument, the 3-day and 30-day VAS are accessible in the public domain, whereas the Single-Item Self-Rating Adherence Scale will be requested for permission to use for this study. Authorizations for use of mentioned instruments are currently pending.

The HIV Adherence Self-Efficacy Scale (HIV-ASES) consists of 12 questions that rates the individual's treatment adherence behaviors, specifically the confidence related to successful adherence to treatments (Johnson et al., 2007, p. 3). Each question is asking the individual to rate on an ordinal scale whether a behavior may or may not be completed or achieved (Appendix B). Each question is presented as Likert-type scale, ranging in numerical value from "0" (defined as "cannot do at all"), to "05" (defined as "moderate certain can do"), and to "10" (defined as "complete certain can do"). The HIV-ASES scale has been previously analyzed for reliability and validity; Johnson et al. (2007), indicates that the instrument demonstrates generally good fit of the model χ^2 (N=205) = 89.55, p <.0001; CFI=.95, RMSEA=.06, and SRMR-.05 (p. 6). Additionally, *global composite internal reliability* for the instrument was *strong* (p=.91; 95% CI=.89, .93). (p. 6). Studies conducted such as Kang et al. (2014) have determined the HIV-ASES to have a Cronbach's alpha of .89. Concurrent and divergent validity was assessed, comparing thematic factors in the HIV-ASES scale ("*integration* of treatment in daily lives", and "*perseverant* in adhering to their treatment regimens"); the findings found correlations consistent with literature findings on *self-efficacy*, for example: positive correlation of adherence self-efficacy with "self-reported adherence, positive problem solving, coping, social support and CD4 T-cell counts" (Johnson et al., 2007, p. 6).

The 30-day Visual Analog Scales (VAS) are based on the study by Walsh, Mandalia, & Gazzard (2002). The visual analog scale assesses the "proportion of doses taken in the preceding month" as self-rated by the individual (p. 270) (Appendix C). The VAS has been tested against other adherence instruments to affirm validity and reliability. In several studies, the visual analog scales are found to have moderate to high levels of correlation to determine ART adherence rates when compared to other instruments such as the unannounced pill counts (r=.76) and inversely

correlated with HIV viral load (r=-0.49) (Giordano et al., 2004;). Similarly, Oyugi et al. (2002) and Kalichman et al. (2009), validated the VAS with multiple measures of adherence (e.g. electronic medication monitoring, unannounced monthly pill counts, 3-day structured self-report); all methods of measurement did not indicate significant differences in mean ART adherence rates. Furthermore, all instruments compared in the study were significantly correlated with viral load measurements. The visual-analog scale has been tested in numerous studies with adherence measures. Badiee et al., compared the VAS with a Medication Event Monitoring System (MEMS) and the Aids Clinical Trial Group (ACTG) Questionnaire, and found the VAS and MEMS with higher correlation, Spearman's p=0.56 compared to the ACTG and MEMS with p=0.48 (2012).

The 30-day 3-Item Adherence Scale developed by Wilson et al. (2013), comprises of 3 questions that assess HIV medication taking and adherence within the last 30 days (Appendix D). Three forms of survey testing were conducted to provide validity and reliability measures in the study; web-based survey (assessed for single-medication regimen and multiple/combination medications regimen) and pen-paper survey (Wilson et al. 2013). All three methods yielded high reliability measures, with Cronbach's alpha 0.86-0.89 respectively (Wilson et al. 2013).

Data Collection and Process

The Institutional Review Board (IRB) at California State University San Marcos (CSUSM) will be requested to review and approve this proposed research study (Appendix E). It is determined that there is no IRB that exists for the proposed site of the study; rather the managing supervisor of the HIV/AIDS resource center will be requested for approval to conduct this study (Appendix G). Pre-determined staff members of the resource center will be appointed to assist with conducting this research study. The staff members will be required to complete an

IRB workshop and seek approval by the supervising administrator of the study site to participate as a research assistant in this study. The determined research assistants will be following a scripted guideline wherein instructions will be read to the client regarding the research process and throughout the duration of the study. An informed consent sheet will be provided to the client to review and sign which explains the research study and participation details, including risks and benefits, and process of obtaining study information and results will be provided for each prospective client (Appendix F). The client will have the opportunity to review the informed consent, ask any questions, upon which then the client can agree to participation in the research study. The consent form will be analyzed for readability and will be assessed to produce a Flesch-Kincaid Grade Level of 8. Upon receiving appropriate consent, the pen-paper survey questionnaire will be administered to the client. The survey will include, demographic data as mentioned in Chapter 2 (*Demographic Variables*) to describe the sample population, as well as the selected instruments utilized for this study.

Coding and Scoring

The HIV-ASES (Johnson et al., 2007), 30-day Visual Analog Scale (VAS) (Walsh, Mandalia, & Gazzard, 2002) and the 30-day 3-Item Adherence Scale (Wilson et al., 2013) will be scored according to the respective authors' instructions. The HIV-ASES consist of 12 questions, with total scores ranging from 0 to 120, where the total score is calculated from the sum of each rated question (Johnson et al., 2007) (Appendix B).

The 3-day and 30-day Visual Analog Scale is scored according to the percentage rated and marked by the individual, a single percentage score between the range of 0 to 100% is possible for each respective 3-day and 30-day VAS (Walsh, Mandalia, & Gazzard 2002) (Appendix C).

The 30-day 3-Item Adherence Scale (Wilson et al., 2013) comprises of 3 questions: Question 1 is scored based on self-reported number of days a dose of any HIV medications were missed (one numeric answer). Question 2 is scored where each response category is given scores 0 – "Very Poor", 20 – "Poor", 40 – "Fair", 60 – "Good", 80 – "Very Good", 100 – "Excellent". Lastly, Question 3 is scored similarly to the previous question, where each response category is given scores 0 – "Never", 20 – "Rarely", 40 – "Sometimes", 60 – "Usually", 80 – "Almost Always", 100 – "Always", where a score of 100 indicates the highest (Wilson et al., 2007, p. 90) (Appendix D).

Any survey questionnaires that are left incomplete will be excluded from data analysis. Variables are coded as scale, ordinal or nominal and will be coded according to the designated classifications. Summary of the data analysis variables with coding and scoring are provided:

Table 1. *Coding and Scoring*

Variables	**Description**	**Type**	**Coding**
Age	Ages in years	Scale	
Gender	Male Female Transgender Other	Nominal	M=0 F=1 T=2 O=4
Ethnicity	Asian/Pacific Islander African-American/Black Hispanic/Latino White (Non-Hispanic)/Anglo-Saxon Other	Nominal	AP=1 AF=2 HL=3 WA=4 OT=5
Highest Education Level	11^{th} grade or less High school of GED 2-year college/Associate's Degree 4-year college/Bachelor's Degree Master's Degree or Doctorate	Ordinal	S=0 H=1 A=2 B=3 G=4
Occupation Status	Working	Nominal	No=0 Yes=1

Variables	Description	Type	Coding
Health Insurance	Health insurance coverage	Nominal	No=0 Yes=1
30-day 3-item Adherence Scale	*Question 1:* *Reported days missed doses*	Scale	0-30
	Question 2: *Self-rating of adherence to treatments*	Nominal	Very poor=0 Poor=20 Fair=40 Good=60 Very good=80 Excellent=100
	Question 3: *Self-rating of frequency of taking medications as prescribed*	Nominal	Never=0 Rarely=20 Sometimes=40 Usually=60 Almost always=80 Always=100
3-day Visual Analog Scale	Percentage	Scale	0-100%
30-day Visual Analog Sclae	Percentage	Scale	0-100%
HIV-ASES	Question 1-12	Ordinal	0-10

Note: The coding and scoring are samples for this research study are subject to change accordingly to the data collected.

Data Analysis

Data analysis (descriptive and inferential statistics) will be conducted through IBM Statistical Package for the Social Sciences (SPSS) software edition 22.0 (2013). The analyses that will be used for this study are as follows: descriptive statistics, frequency distributions (with histogram charts), and bivariate correlation (two-tailed) test. The significance level will be set at $p<.05$.

Descriptive statistics will provide descriptive data on the sample population for this study, including mean, median, mode, standard deviations, skewness for each variable as applicable. The scores from each instrument utilized in this study will also be calculated using descriptive statistics. Frequency distributions will be conducted to determine normality of data and presence of data skewness. The level of measurement for analysis will be classified in the following: nominal and ordinal data for demographic information collected, interval and ordinal data for scoring HIV-ASES (Johnson et al., 2007), 3-day and 30-day VAS (Walsh, Mandalia, & Gazzard, 2002) and 30-day 3-Item Adherence Scale (Wilson et al., 2013).

Bivariate correlational modeling will be used to determine correlation coefficients, Pearson's *r* to provide a value that will indicate the *strength* and *direction* (Kellar & Kelvin, 2013, p. 265) of the relationship between the independent variable (treatment adherence self-efficacy) and dependent variable (treatment adherence). The *coefficient of determination,* as denoted by r^2 will be calculated to determine the amount of variance the dependent variable is explained by the independent variable (p. 265). If the collected data does not meet the assumptions for a Pearson Correlation, then the alternative method of Spearman Correlation Coefficient (p. 267) will be analyzed for inferential statistics.

In this study, the α-level is selected to be at .05, the degree of freedom (*df*) for *r,* will be determined by number of participants subtracted by 2 (n-2); yields *df*=107. Statistical significance for the correlation will be determined if the calculated *r,* is greater than the absolute value of the critical value corresponding to the 107 degrees of freedom for a two-tailed test (Kellar & Kelvin, 2013, p. 271).

This research study will use a correlational model, and thus pose potential temporal ambiguity. It may be unclear whether the independent variable stated precedes the dependent

variable identified in this study despite results of the statistical analyses. To control for this factor, testing a directional hypothesis and utilizing linear regression analysis (for interval data) can be considered to determine variable precedence (Kellar & Kelvin, 2013).

Bias

The convenience sampling method that will be utilized in this study is a potential source for bias, as clients can consent or decline to participate which may affect the representation of the sample to the general population being studied. Homogeneity versus heterogeneity of sample population is considered due to the nature of the convenience sampling method. Descriptive statistics of the sample population will be collated and if possible, compared to compiled statistics collected by the site of study to indicate any significant differences in the population characteristics.

The principal investigator will not be directly present at the time of administering the study survey questionnaire and will be relying on instructions and delineated study procedures provided to the research assistant. There may be inconsistencies in information delivery, consenting and administration of surveys. Thus, to control for this, meticulous review and practice of an outlined research protocol and a scripted guide will be utilized during review (practice) sessions that will be identical for use during the actual research study.

This study will be limited to examining the relationship between treatment adherence self-efficacy and ART adherence. Though consistent with literature findings, previous studies have analyzed other potential correlates and predictors of ART adherence that are not analyzed and included in this particular study and may provide basis for future study to examine these correlates.

Ethical Consideration

The CSUSM Institutional Review Board (IRB) will need to approve this research study prior to conducting. All participants will be required to be 18 years and older, be able to consent for participation and must meet inclusion criteria. Although HIV/AIDS populations are considered a vulnerable population, an expedited IRB approval will be sought. Informed consent sheets explaining the research and potential participation will be provided for the client to review prior signing the consent form. Incentives include $10 VISA gift cards that will be provided for participation and completion of study requirements. The participants will be required to complete the survey at the intended research study site to maintain confidentiality. The informed consent will explain that there will be no identifiable information asked for during the survey, and that all surveys will be kept in a locked container only accessible by the principal investigator and the research assistant. All data collected will be transcribed electronically in a designated portable computer device (laptop) that is password protected and will only be accessed by the principal investigator in the academic research setting. At the conclusion of the study and report of findings, any paper surveys and electronic data will be properly destroyed.

Summary

To appropriately address the purpose of this study, to explore the relationship between treatment self-efficacy and HIV/AIDS treatment adherence, the selected research design and methodology will be employed to ensure purposeful data for descriptive and inferential statistical analyses. Application of specific instruments will quantitatively measure the independent and dependent variables on the selected sample population. Though limitations exist for this study, threats to validity and systematic bias will be considered and controlled to strengthen the rigor of this research study.

CHAPTER FOUR: GRANT ELEMENTS

Potential Grants

The American Foundation for AIDS Research (amfAR) was formed in 1985 with the unification of the AIDS Medical Foundation and the National AIDS Research Foundation. The program has since invested nearly $400 million in programs and has provided over 3,300 grants awards to teams globally. The amfAR Scientific Advisory Committee reviews proposed projects based on the scientific relevance, merit and applicability and has guided the foundation in investing over $300 million in programs and supported more than 2,000 research teams (American Foundation for AIDS Research [amfAR], 2017).

The Health Resources and Services Administration (HRSA) is a federal agency of the U.S. Department of Health and Human Services with a mission to "improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs" (Health Resources and Services Administration [HRS], 2015.) Specifically, the Ryan White and Global HIV/AIDS Programs has awarded numerous grants and funding to support comprehensive programs and systems to ensure continued access to essential health care services, support services and treatments. Research grants have been awarded to support the various parts of the program to optimize interventions, develop innovative workforces and provide quality access to critical HIV/AIDS services (2015).

The California HIV/AIDS Research Program (CHRP) was founded in 1983 to address the increasing epidemic of HIV/AIDS. The organization supports and facilitates innovative research that addresses initiatives including, reduction in incidences of new HIV infections, testing and evaluating Pre-Exposure Prophylaxis (PrEP) and developing effective and evidenced-based interventions and programs to provide critical services and reduce racial disparities. This

organization actively advocates in legislative bodies to impact state policy to support HIV/AIDS care services. Historically, CHRP has funded over 2,000 research projects and distributed $275 million in grants (California HIV/AIDS Research Program [CHRP], 2014).

Selected Grant

The principal investigator has selected to pursue a grant funded by the National Institute of Health. The grant announcement number is PA-17-182, Innovations in HIV Testing, Adherence, and Retention to Optimize HIV Care Continuum Outcomes (R01), issued by the Department of Health and Human Services, and the agency is the National Institute of Health. The PA-17-182 is seeking applications for projects that include formative basic behavioral and social sciences to gain understanding as a step in the continuum of care or the multiple phases in the HIV care continuum, initial development and pilot tests for innovative approaches to interventions and trials to determine efficacy of intervention (Grants.gov, 2017). PA-17-182 was initially posted on February 28, 2017, and is available for applications until January 7, 2020. Currently there is no information provided regarding estimated total program funding, award ceiling or award floor.

Budget

Primary Investigator. Marc Rensis L. Fontanares, MSNc, RN, PHN will serve as the principal investigator for this research study. He has extensive experience in clinical nursing in various specialty departments including medical-surgical, orthopedic, oncology, family practice/primary care and infectious disease. Fontanares has worked for Kaiser Permanente San Diego Medical Center for 4 years and Kaiser Permanente Outpatient Medical Office – Primary Care for the past 2 years and currently enrolled at the California State University, San Marcos School of Nursing, Master of Science in Nursing degree in a Family Nurse Practitioner specialty

program. Fontanares has completed requisite courses including biostatistics (with inferential statistics) and the California State University, San Marcos Institutional Review Board workshop on November 5, 2015. Role responsibility will include overseeing the conduct and process of the research study, provide formal presentations to selected facility setting administration and staff, training sessions with research assistants (current staff personnel at the site of study), data collection and analysis, and dissemination of research findings. The study will be conducted over a course of 5 months, with an estimated commitment of 320 hours at $50 per hour, including fringe benefits at 48% with a total amount salary requested of $23,680.

Research Assistants. Two research assistants (RAs) will be designated for this research study and to assist the principal investigator throughout the duration of the project. The research assistants will be pooled from currently staff counselors at the research site and will be voluntary and approved by the facility administrator. The RAs will meet with the principal investigator on pre-determined sessions to receive proper training and extensive review of the research process including guidelines/protocols to follow during the study as well as complete the California State University, San Marcos Institutional Review Board workshop. The duties of the research assistants include recruitment of participants for the study, collating and organizing survey questionnaires, providing information regarding the study, providing and ensuring informed consent and consent forms are completed, administering surveys and data collection. The RAs will be utilized for the duration of study, estimated commitment of 320 hours at $30 per hour with fringe benefits at 48%, yielding a salary request of $14,208 per research assistant (total of $28,416 combined for both assistants).

Client Educators. Two appointed facility staff members will be trained and designated as client educators. This position will require the staff to work directly with the principal

investigator and facility director to develop and implement educational content and curriculum that will provided in didactic sessions with clients. Education may also be provided during client counseling appointments. The client educators will be utilized for 12 months, yielding a salary request including fringe benefits at 48% of $37,000 per client educator (total of $74,000 combined for both educators).

Consultants. Dr. Denise Boren, PhD, RN is the committee chairperson for this research study and will be the faculty mentor for the duration of the project. She will receive a stipend of $5,000.

Dr. Linnea Axman, DrPH, MSN, FNP-BC, FAANP is that statistician elected for this study. Dr. Axman's role includes statistical analysis of collected data. Pertinent data are collected and inputted to SPSS software. She will provide a total of 50 hours of statistical consultation at a rate of $150 with an estimated salary of $7,500 for duration of the research project (Table 2).

Equipment and Supplies. The supplies required for this project include a portable laptop with HIPPAA compliant encrypted drive and mouse, encrypted thumb drive, SPSS for statistical analysis software costs are approximately $3,360. Office supplies which includes a copier and print costs, paper, ink, pens and other miscellaneous items are estimated at $250.

Other Expenses. Expenses include registration for the annual American Association of Nurse Practitioners conference cost of $545. Poster presentation print cost and portable storage for the conference is approximately $300.

Travel. The principal investigator is required to travel from home to the research with a roundtrip travel distance of 62 miles. The standard mileage reimbursement rate per mile traveled is 53.5 cents (IRS, 2017). Total mileage costs for the duration of the study is approximately $2,629. Travel and airfare costs to the annual American Association of Nurse Practitioners

(AANP) conference held in Philadelphia, PA is approximately $1,300. Lodging and hotel accommodations costs are approximately $1,200.

Incentives. Participants that complete the survey questionnaire and requirements of the study will be given a VISA gift card amounting to $10 per participant. There will be a total of 109 participants given a $10 VISA gift card for a total cost of $1,090 (Table 3).

Table 2. Initial Budget for Research Project

Program Director/Principal Investigator (Last, First, Middle): Fontanares, Marc Rensis L.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM TBD	THROUGH 5 months

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Fontanares, Marc Rensis	PD/PI	5				16,000	7,680	23,680
Research Assistant	RA	5				9,600	4,608	14,208
Research Assistant	RA	5				9,600	4,608	14,208
Client Educator	Education	12				25,000	12,000	37,000
Client Educator	Education	12				25,000	12,000	37,000
SUBTOTALS →								126,096

CONSULTANT COSTS Boren, Denise PhD, RN (faculty mentor); Axman, Linnea DrPH, FNP-C (Statistician)	12,500
EQUIPMENT *(Itemize)* Encrypted thumb drive, computer with HIPPAA compliant encrypted drive, SPSS v.22.0	3,360
SUPPLIES *(Itemize by category)* Supplies – copy costs, printer, paper, ink, postage, poster board, organizing folders, locked storage container	650
TRAVEL Mileage reimbursement, travel and lodging to AANP conference for research dissemination	5,129
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* VISA Gift cards Registration to AANP conference	1,635
CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	$ 149,370
CONSORTIUM/CONTRACTUAL COSTS — FACILITIES AND ADMINISTRATIVE COSTS	5,708
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ 155,078

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Table 3. Entire Proposed Budget for Project

Program Director/Principal Investigator (Last, First, Middle): Fontanares, Marc Rensis L.

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: *Salary and fringe benefits. Applicant organization only.*	126,096				
CONSULTANT COSTS	12,500				
EQUIPMENT	3,360				
SUPPLIES	650				
TRAVEL	5,129				
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	1,635				
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*	149,370				
F&A CONSORTIUM/ CONTRACTUAL COSTS	5,708				
TOTAL DIRECT COSTS	81,399				
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					$ 155,078

Timeline

This cross-sectional research study will occur throughout the course of 5 months with data collection at each client scheduled appointment visits for routine counseling services.

Phase I. This phase will occur from January 1, 2019 to February 28, 2019. Prior to initiating this study, designated personnel (existing counselors at the research site) will have been selected to be part of the research team and assume the role of research assistants (RA) and the

Client Educators (CE) for the entire study duration upon receipt of approval from the site administrator. Requisite training and extensive review of roles and responsibilities of the research assistants, client educators and procurement of all required supplies and equipment are completed prior to the start of the study. For Phase I, the principal investigator will initially be present for two days for at the facility to oversee and coordinate the research processes. The research assistants under the supervision of the principal investigator will recruit participants from the daily scheduled appointments for counseling service, administer the survey questionnaires, complete the appointment agenda per facility protocol and provide VISA gift cards at the completion of study participation. All paper forms will be secured in a locked container in the administrator's office for storing only to be accessed by the research team.

Phase II. This phase will occur from March 1, 2018 to May 8, 2018. Ongoing client recruitment for participating in this study will continue, and conduct study requirements including surveys and will be provided VISA gift cards after completing the study requirements.

Phase III. This final phase will occur from May 9, 2019 and concludes on May 31, 2019. This phase will require input of collected data, and the hired statistician will assist in further data input into the IBM SPSS program for statistical analysis. All data input in the computer will be password protected without client identification and all paper forms will be destroyed appropriately. Publication of this study and findings will be considered and dissemination of findings at a national conference will be completed.

Table 4. Research project timeline

Phase I	**Phase II**	**Phase III**
January 1, 2019 through February 28, 2019	Mar 1, 2019 through May 8, 2019	May 9, 2019 until completion of project in entirety
Appointed research assistants and research team formed	Continue participant recruitment	Utilize hired statistician
Appointed client educators and develop education curriculum and materials	Complete data collection	Create poster-format presentation board for national conference
Procurement of supplies and equipment	Input and *clean up* data, coding and scoring	Publication and dissemination of findings at the annual selected conference
Recruit participants		
Initiate study requirements – administration of surveys and data collection		

Note: Projected timeline for research study treatment self-efficacy and HIV/AIDS treatment adherence. The timeline is subject to change due to the course of the research study.

Plan for Dissemination of Findings

Conferences. The prospective conference to disseminate the research project findings is at the National American Association of Nurse Practitioners annual conference held in Philadelphia, PA. This is an ideal avenue to present the studied concepts and disseminate findings from this study to provide clinicians valuable data and insight that has potential to impact current practices with treatment adherence specifically HIV/AIDS populations and antiretroviral therapies. Furthermore, the concepts involved, theoretical framework, screening instruments and analysis of data is pertinent to current practices among providers, outside the boundaries of HIV/AIDS management; counseling and screening for overall treatment adherence both pharmacological and non-pharmacological means.

Professional Publications. Peer reviewed journals and scholarly organizations are potential outlets for disseminating findings of this research study. Despite the depth of research involvement in the field of HIV/AIDS management, there continues to be deficits in adherence in therapies and gaps in provision and access of essential care services extending to the global arena. This research study focuses on socio-behavioral concepts of adherence and efficacy and HIV/AIDS management. The implications of this study are but not limited to approach in optimizing medical management of HIV/AIDS, insight on psychological factors that contribute to efficacy and adherent behaviors and potential to impact current practices related to HIV/AIDS management and continuity of care. Examples of peer reviewed journals for dissemination include the American Association of Nurse Practitioners, AIDS and Behavior, AIDS Education and Prevention: An Interdisciplinary Journal, Journal of AIDS/HIV, AIDS Care: Psychological and Socio-medical Aspects of HIV/AIDS and American Journal of Public Health (American Psychological Association [APA], 2017).

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Appendix A

Demographic Factors (Items) Collected

Demographic Information

Age
Gender
Male
Female
Transgender
Ethnicity
Asian/Pacific Islander
African-American/Black
Hispanic/Latino
White (Non-Hispanic)/Anglo-Saxon
Other
Highest Education Level
11th grade or less
High School or GED
2-year college/Associate's Degree
4-year college/Bachelor's Degree
Master's Degree or Doctorate
Occupation Status
Working/employed for pay
Not working/employed for pay
Health Insurance
Has health insurance coverage
Does not have health insurance coverage

Appendix B

HIV Adherence Self-Efficacy Scale (HIV-ASES)

HIV-ASES Items

I am going to ask you about situations that could occur during your treatment for HIV. Treatment can involve different things for different people. Sometimes, this might refer to taking medications, and other times it could refer to other things that you do to deal with HIV such as diet and exercise or taking vitamins. So, in these questions, when I ask you about your ‘‘treatment’’ or your ‘‘treatment plan,’’ I am talking not only about any medications that you might be taking for HIV, but also other things that make up your self-care.

For the following questions I will ask you to tell me in the past month, including today, how confident you have been that you can do the following things. Use this response scale ranging from 0 (‘‘cannot do at all’’) to 10 (‘‘completely certain can do’’).

Note: The term ‘‘clinic’’ may be replaced by ‘‘doctor’s office’’ if participant does not receive care in clinic settings.]

00 **Cannot do at all**
01
02
03
04
05 **Moderately certain can do**
06
07
08
09
10 **Completely certain can do**

In the **<u>past month</u>**, how confident have you been that you can **(please circle a number)**:

- Stick to your treatment plan even when side effects begin to interfere with daily activities?

0 1 2 3 4 5 6 7 8 9 10

- Integrate your treatment into your daily routine?

0 1 2 3 4 5 6 7 8 9 10

- Integrate your treatment into your daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV-infected?

  0 1 2 3 4 5 6 7 8 9 10

- Stick to your treatment schedule even when your daily routine is disrupted?

  0 1 2 3 4 5 6 7 8 9 10

- Stick to your treatment schedule when you aren't feeling well?

  0 1 2 3 4 5 6 7 8 9 10

- Stick to your treatment schedule when it means changing your eating habits?

  0 1 2 3 4 5 6 7 8 9 10

- Continue with your treatment even if doing so interferes with your daily activities?

  0 1 2 3 4 5 6 7 8 9 10

Appendix C

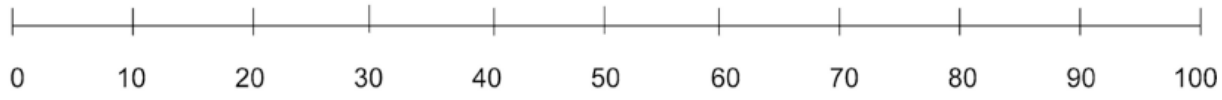
30-day Visual Analog Scale

Put a mark on the line below at the point that shows your best guess about how much of your prescribed HIV medication you have taken in the **last month**. We would be surprised if this were 100% for most people

Examples: 0% means you have taken no medication

50% means you have taken half your medication

100% means you have taken every single dose of your medication



Appendix D

30-day 3-Item Adherence Scale (in the past 4 weeks)

In the last 30 days, on how many **days** did you miss at least one dose of any of your HIV medicines?

Write in number of days: _____ (0 – 30)

In the last 30 days, how good a job did you do at taking your HIV medicines in the way you were supposed to?

- ☐ Very poor
- ☐ Poor
- ☐ Fair
- ☐ Good
- ☐ Very good
- ☐ Excellent

In the last 30 days, how often did you take your HIV medicines in the way you were supposed to?

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Usually
- ☐ Almost always
- ☐ Always

Appendix E

CSUSM Institutional Review Board (IRB) Application

California State University SAN MARCOS

Application for Approval for Research Involving Human Subjects:
Full or Expedited Review

Submission Procedures:

1. The researcher completes application
2. If the researcher is a student, their faculty advisor must review the application and **sign the application in IRBNet**. Additional instructions can be found on the last page of this application. **
3. The researcher submits the application and accompanying documents to IRBNet. http://www.csusm.edu/gsr/irb/forms.html

For assistance completing this form, please review the resources located at www.csusm.edu/irb.
If you have any questions, please refer to the IRB website or contact the IRB staff at (760) 750-4029 or irb@csusm.edu.
Please answer each section completely and as concisely as possible. Use lay terms as IRB members have diverse backgrounds.

☐ Full Review ☑ Expedited Review Proposed Start Date

Project Title: The Relationship Between Treatment Self-Efficacy and HIV/AIDS Treatment Adherence in People Living with HIV/AIDS

Faculty/Staff Investigator:

Name | Department/College
Phone Number | E-mail
Date CITI Completed

Student Investigator: *(if the student is the primary investigator)* **

Name: Marc Rensis L. Fontanares | Department/College: CEHHS - School of Nursing
Phone Number: (858) 353-3003 | E-mail: mfontanares88@gmail.com
Date Training Completed | ☐ CITI ■ IRB Workshop

Faculty Advisor Name: Dr. Denise Boren | Department/College: CEHHS - School of Nursing
Phone Number | E-mail: dboren@csusm.edu | Date CITI Completed

Checklist: Check which of the following items are included, as applicable:

☐ Certification of Human Subjects Protection training for each researcher and the faculty advisor.
☐ Letter/email of organizational support (Required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSUSM.) If sent in an email, must include organization and position of the person who approved.
☐ Recruitment flier(s) or advertisements, scripts for radio or TV.
☐ Survey(s), questionnaires, or interview questions. If this is an online survey, please provide a pdf copy ofthe survey.
☐ Consent and/or child assent form(s) or information sheet(s).
For online surveys, provide a pdf copy of the introduction/information screens.
1. Provide unique forms for each population in your research.
2. Use official letterhead or the masthead found in the samples on the IRB website
3. Include contact information for the Researcher, faculty mentor, and IRB office.
4. Be sure the information in your consent/information sheet MATCH your application information!

☐ **Students Researchers *ONLY*:** Faculty advisor has approved the project and has signed the application in IRBNet.

Ed.D Students *ONLY*: Attach the required UCSD-CSUSM-JDP IRB Cover Sheet, Please be sure to ***sign*** the form, scan it, and submit it with your application as a separate document.

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1. Purpose of Project and Project Background

Describe your research question, including **why** the question is important, and **how** your study will attempt to answer it. Include how your literature review supports this with at least three citations. (Do not exceed one page--Use lay language.)

In order to optimize health outcomes, HIV/AIDS must be managed with appropriate modalities (conventionally with use of HAART) requiring consistent adherence to achieve and maximize the intended viral suppressive benefits. Similar to other disease processes, HIV infection is approached as a chronic illness, that must be managed with daily treatments to suppress the infection sequelae and improve health outcomes (Nokes et al., 2012)

Despite interventions and initiatives for HIV prevention, rates of infection have remained stable in the United States. The inception of antiretroviral therapies has provided improved quality health outcomes, prolonging life and decrease mortality related to HIV/AIDS (Brown et al., 2013). However, for treatment to successfully suppress viral loads, strict adherence to ART must be achieved and maintained, and literature reinforces the paucity of improving medication adherence through specific and effective interventions. The necessity for high levels of medication adherence are required to prevent adverse disease sequelae and premature death, however, epidemiological surveys are finding sustained and increasing number of patients that are sub-optimal in treatment adherence and do not achieve nor maintain appropriate levels of ART adherence resulting in poor health outcomes (Langebeek et al., 2014).

The purpose of this research study is to explore the relationship of self-efficacy on the rates of treatment adherence among adults living with HIV/AIDS that are currently prescribed anti-retroviral treatments

2. Recruitment Procedures & Participant Population

A) List the expected number of participants for each population group included in this study.

Expected number of participants at 109 eligible individuals.

B) Describe all characteristics relevant to being selection of participants. (e.g., demographics, ethnicity, vulnerabilities, etc.) Explain why you are targeting this specific population.

Participants will be selected by a convenience sampling method, by recruitment at Being Alive HIV/AIDS Resource Center. All participants are clients in this resource center, must be 18 years and older, diagnosed with HIV/AIDS and are on currently prescribed antiretroviral treatment (medications), proficient in reading and writing English. All participating clients will be approached by an appointed counselor (as the designated research assistant), approval will be received by the client prior to initiation of the study. Exclusion criteria are clients that are younger than 18 years old or adults with cognitive dysfunction as result is unable to complete the study requirements.

C) Indicate whether anyone might be *excluded* from participating and explain why.

Exclusion criteria are clients that are younger than 18 years old as this is the focus of the study is specifically on adult populations. Additionally individuals with cognitive dysfunction as result are unable to complete the study requirements and thus excluded from the study.

D) How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Submit flyers, posters, or other oral or written invitations used to recruit potential participants.

All participating clients will be approached by an appointed counselor (as the designated research assistant), approval will be received by the client prior to initiation of the study.

E) Will you be offering an incentive?

(●) Yes ( ) No

If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.

Participants that complete the survey questionnaire and requirements of the study will be given a VISA gift card amounting to $10 per participant.

3. Informed Consent Process.

Explain for each population participating in your research.
See the IRB web page on Informed Consent. See also Language Requirements.

A) How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

The study and the required elements of Informed Consent will be explained by the facility counselors as appointed research assistants prior to their appointment. The determined research assistants will be following a scripted guideline wherein instructions will be read to the client regarding the research process and throughout the duration of the study. An informed consent sheet will be provided to the client to review and sign which explains the research study and participation details, including risks and benefits, and process of obtaining study information and results will be provided for each prospective client. The client will have the opportunity to review the informed consent, ask any questions, upon which then the client can agree to participation in the research study.

B) How much time will participants have to consider participating between the explanation described above, the receipt of the consent document, and the beginning of study?

The client will be provided 5-10 minutes to consider participating in the study.

C) If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

There are no subjects that are less than 18 years of age.

D) If you are requesting a Waiver of Consent or a Waiver of Documentation of Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, etc.).

n/a

E) Indicate the primary language(s) of your participants. If any participants' is not fluent and comfortable with English, explain how you will ensure that participants' understanding of the activity for which they are giving consent.

The primary language(s) of the participants are English and Spanish. Spanish speaking participants will be provided interpretation by a qualified Spanish interpreting research assistant.

4. Procedures and Methodology

Provide descriptions of each distinct procedure and each population group.

A) Provide a step-by-step explanation of your research activities and methodologies that involve human subjects. Be thorough.

Phase 1 - This phase will occur from January 1, 2018 to February 28, 2018. Prior to initiating this study, designated personnel (existing counselors at the research site) will have been selected to be part of the research team and assume the role of research assistants (RA) and the Client Educators (CE) for the entire study duration upon receipt of approval from the site administrator. Requisite training and extensive review of roles and responsibilities of the research assistants, client educators and procurement of all required supplies and equipment are completed prior to the start of the study. For Phase I, the principal investigator will initially be present for two days for at the facility to oversee and coordinate the research processes. The research assistants under the supervision of the principal investigator will recruit participants from the daily scheduled appointments for counseling service, administer the survey questionnaires, complete the appointment agenda per facility protocol and provide VISA gift cards at the completion of study participation. All paper forms will be secured in a locked container in the administrator's office for storing only to be accessed by the research team.

Phase II. This phase will occur from March 1, 2018 to May 8, 2018. Ongoing client recruitment for participating in this study will continue and conduct study requirements including surveys and will be +

B) Where will the research will be conducted? Describe any risks or confidentiality issues related to using this location.

The study will be conducted at "Being Alive HIV/AIDS Resource Center" in San Diego, California. Risks or confidentiality issues are minimized as clients are seen individually in private rooms and any consent forms are made anonymous and confidential and will be stored in a locked container.

C) State the specific dates/timeframe in which you plan to conduct your research.

The time frame of this research study is from January 1, 2019 to May 9, 2019.

5. Participant Debriefing or Feedback.

If deception is involved in your research, participants should be debriefed about the nature of the study as soon as possible.

Participants should be given the opportunity to request a copy of the results of the study/your final report.

A) Describe any feedback or information you will offer participants.

Participants will be given a copy of th results of the study as requested.

6. Risks

List risks for each population participating in the research and for each methodology.

Please be sure the risks listed here match the risks mentioned in your consent letter or information sheets.

Consider all risks very carefully. For more information on risks, see Examples of Risk.

A) Explain potential risks to your participants. Risks may be physical, psychological (e.g., strong emotional reactions to research questions), or inconveniences (e.g., time required).

Potential risks will include a moderate-strong emotional reaction and concerns for safeguarding survey answers. Also inconveniences including additional time is required in order to participate in the study which will lengthen the time required for their scheduled appointments.

B) Vulnerable Subjects: Select which , if any, of the following vulnerable subjects will be involved in your research.

- ☐ Pregnant women, human fetuses, neonates (see Federal Guidelines, 45CFR26, subpart B)
- ☐ Prisoners (see Federal Guidelines, 45CFR26, subpart C)
- ☐ Children (see Federal Guidelines, 45CFR26, subpart D)
- ☑ Other Vulnerable Populations such as persons with cognitive disabilities, economically or educationally disadvantaged persons, etc.

C) Describe and special risks to vulnerable populations or your population profile

Special risks involved are chronic illness that will require consistent utilization of health care services, pharmacological therapies and continuous health evaluations to ensure optimum health outcomes are met. This entails greater health care resource utilization and financial impact is greater due to the health burden with managing chronic illness such as HIV/AIDS. Furthermore, theses risks are enhanced with lack of health insurance or under-insurance, absence of consistent health care, societal factors (e.g. poverty, lack of housing or inadequate source of income, mental illness).

D) List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant's identify or personal information could be known by others

Risks may include unauthorized access to survey answers only.

E) Will any **personal identifying data** be recorded? If so, what information will be recorded?
(e.g., Social security number, drivers license number, student id, address, phone number, birth date, personal email address)

No personal identifying data will be recorded for this study.

7. Safeguard Procedures to Minimize Risks.

A) Please respond to each risk that you listed in #6 above. State how you will minimize each risk and protect confidentiality.

All survey forms will not include any identifiable information, participants will not be asked to provide any personal, identifying information. The survey forms will be reviewed by the research assistants after the participant has completed the the survey forms. Any forms with any identifiable information despite instructing participants to refrain from will be destroyed by the research assistant by proper disposal in a HIPAA compliant shred bin provided by the facility.

B) How you will safeguard data? Where/how will data be stored? Who will have access to the data? How will access be limited?

All completed and accepted survey forms will be stored in a locked container secured and accessed only by the principal investigator and the research assistant. The stored locked container will be retrieved after the end of each study and locked in a designated office storage in the facility. All data collected will be transcribed electronically in a designated portable computer device (laptop) that is password protected and will only be accessed by the principal investigator in the academic research setting. At the conclusion of the study and report of findings, any paper surveys and electronic data will be properly destroyed.

C) List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

Resources will include local health organization and community health clinics for evaluation, urgent care or emergency departments will also be utilized if deemed necessary by the research team and the facility manager.

8.Study Benefits

A) Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants. However, the study may contribute to the literature and/or future research.

This will establish the baseline level of self-efficacy and treatment adherence in the greater San Diego area. Procured data will be utilized in developing and supporting a client education program to increase self-efficacy and treatment adherence within the community.

B) Do the benefits from this study exceed the risks to participants? Please explain.

The benefits are expected to exceed the risks to the participants in that measures are taken to minimize risks to confidentiality, safety and well-being of each participant. The study will provide valuable data to establish baseline levels and to potentially examine the effects of the client education program.

9. Researcher(s) qualifications and experience.

A) Briefly outline the primary researcher(s)'s qualifications and experiences relative to the subject of this research.

Marc Fontanares, MSNc RN PHN is a current practicing registered nurse in an ambulatory family medicine practice in a health organization in San Diego county. He has experience in areas of medical-surgical, orthopedic, and oncology settings in which he has had experience in caring for patients with HIV/AIDS. He has collaborated in inter-professional teams that managed chronic illness across the lifespan.

B) If this is a student project, include faculty sponsor's qualifications.

Student Project Committee Chair - Dr. Denise Boren Ph.D, RN has been the past Director of the CSUSM School of Nursing and has experience in conducting research studies and grant-writing.

Student Project Committee Member- Dr. Linnea Axman DrPH, MSN, FNP-BC, FAANP is currently an adjunct faculty member for the CSUSM School of Nursing. She is a qualified researcher, involved in global health research, grant-writing and experienced bio-statistician.

C) If using student or research assistants, please state how you will ensure that these assistants are trained and qualified to assist. All assistants should complete the CITI training on the protection of human participants in research.

During Phase I (January 1 2019 to February 28, 2019), prior to initiating this study, designated personnel (existing counselors at the research site) will have been selected to be part of the research team and assume the role of research assistants (RA) and the Client Educators (CE) for the entire study duration upon receipt of approval from the site administrator. Requisite training and extensive review of roles and responsibilities of the research assistants, client educators and procurement of all required supplies and equipment are completed prior to the start of the study. For Phase I, the principal investigator will initially

Time to Review:

Expedited reviews are reviewed by one committee member with an average approval time of approximately three weeks. Questions from reviewers and approval paperwork will be sent to the email address provided on the application at the time of submission.

Full reviews are reviewed by the full committee at an IRB meeting. Approvals on full reviews may take 4-6 weeks. Questions from the committee and approval paperwork will be sent to the email address provided on the application at the time of submission. All "full review" applications are copied to Risk Management.

Faculty Advisor Approval: **

Once the student researcher has completed the application, they must e-mail their application to their faculty advisor for review. When the faculty advisor pre-approves the application, the student will upload their application and documents to IRBNet and share the package with the faculty advisor for official approval. The faculty advisor must have an account in IRBNet to approve the application. The faculty advisor will receive a notification via e-mail that the application package has been shared with them and that they need to sign off on the application package in IRBNet.

Instructions on sharing the project can be found on the IRBNet video training site. There is a section in the video called **Sharing This Project.** The link and the login for the training is on the CSUSM IRB website under **How to Submit to IRBNet** http://www.csusm.edu/gsr/irb/forms.html

Appendix F

Informed Consent

School of Nursing California State University San Marcos San Marcos, CA 92096-0001

Tel: 760- **Email:** fonta011@cougars.csusm.edu

Informed Consent – Medication Taking and Self-efficacy

Marc Fontanares is a graduate nursing student at California State University San Marcos, is doing a study that looks into how people take their treatments and medications and how confident they feel on being able to take their treatments/medicine. You are being asked to be a part of this study because you are an adult eligible. The goal of this study is to find out if there is a link between how confident a person feels they can do their treatments and to actually doing their treatments and taking medicines.

Requirements of Participation

You will be asked to fill out a survey of questions once on your visit, such as basic information about you, and then fill out a survey that asks questions about how well you are taking medications, how often, and how confident you are feeling about your treatments. In total, this study should take about 15 minutes to do.

Risks and Safeguards

This study may cause some emotional reaction, you may be worried about keeping your answers to yourself, and you may not want others to know your answers.

To make sure you are kept confidential, you will not put your name or any information that can be used to find out who you are. Your survey answers will be kept in a computer, locked with a password, only accessed by the researcher and while the study is going on. Only information about the answers will be put in the final report.

Benefits and Incentives

By being part of this study, you will be a part of useful information to use to find out how we can better help people in their treatments. There is no cost for you taking part in this study. You will be given a 10-dollar gift card for taking part in this study. You may only take part in this study for one time.

Voluntary Participation

Being part of this study is voluntary, there are no consequences of any kind if you do not want to join this study. If you do choose to take part in this study, you can back out at any time.

Voluntary Participation

If you have any questions you may ask them now. If you have any questions later on, please contact the researcher, Marc Fontanares at fonta011@cougars.csusm.edu. You will be given a copy of this form for your records. If you have any questions about your rights as a research participant, you may contact CSUSM's Institutional Review Board at 760.750.4029 or e-mail: irb@csusm.edu.

I am at least 18 years old and I agree to participate in this research study.

_____ _____

Participant Signature Date

Appendix G

Sample of HIV/AIDS resource center management/supervisor e-mail request for conducting the study

California State University
SAN MARCOS

To: Mr. James Cassidy
Director of Programs, *Being Alive San Diego*
jcassidy@beingalive.org

Greetings Mr. Cassidy, my name is Marc Rensis L. Fontanares, I am a graduate nursing student from California State University San Marcos. I am requesting your review and authorization to conduct a research study at your resource facility. This research study is in part a fulfillment of a Master's Thesis; titled, "Exploring the Relationship of Self-Efficacy and HIV/AIDS Medication Adherence". I believe that this is a relevant study topic for the population that your facility aims to provide vital services to. I have attached an information sheet that explains the study in further detail. I would greatly appreciate your review and consideration for this endeavor in hopes to collect valuable information in how we as providers can facilitate improving quality care, optimize treatment adherence and health outcomes among adult HIV/AIDS clients. I look forward to hearing from you soon.

Kind Regards & Happy Holidays!

Marc Rensis L. Fontanares, BSN, RN, PHN
California State University San Marcos, School of Nursing
Graduate Nursing Student – Family Nurse Practitioner
College of Education, Health & Human Services (CEHHS)
333 S. Twin Oaks Valley Road
San Marcos, CA 92096
Email: Mfontanares88@gmail.com
Mobile: (858) 353-3003

Appendix H

Permission to use visual from publication

Photo Research Permissions

To: mfontanares88@gmail.com, fonta011@cougars.csusrm.edu Cc: Lindsey Mawhiney Sousa

Re: Permissions for academic use

Hello Marc,

Your request to use Jones & Bartlett Learning material from:

Introduction to Health Behavior Theory
Author - Hayden
ISBN - 9780763743833

has been approved for gratis. A copy of your license is attached.

Sincerely,

Amy Spencer
Photo Researcher
Jones & Bartlett Learning
permissions@jblearning.com