AN HIV/STI PREVENTION PROPOSAL FOR LAUSD HIGH SCHOOL HEALTH EDUCATION

An Interactive Media HIV/STI Prevention DVD *Supplement* for African American Adolescent Women

A. *Specific Aims*

Despite the proven effectiveness of existing interventions, U.S. HIV infection rates remain at an epidemic level of ~40,000 per year (CDC, 2006). This statistic suggests two significant implications for public health: [1] HIV is spreading into new, more vulnerable populations and that [2] existing interventions are not significantly affecting these populations. African American adolescent (13-19 year olds) women, as a highly vulnerable example, accounted for ~7.7% of the U.S. adolescent population in 2004 (U.S. Census Bureau, 2004), yet they disproportionately accounted for ~28.4% of the adolescent HIV infections diagnosed in the same year (CDC, 2006). Clearly, an effective HIV/STI prevention intervention, which targets African-American adolescent women, needs to be developed.

A number of HIV/STI prevention interventions are still using dated approaches that have "one-size-fits-all" research designs that aren't effectively addressing particular issues within specific groups highly vulnerable to HIV/STIs, like African American adolescent women (AAAW). There are a few interventions, however, that *are* particularly designed for AAAW (DiClemente et al., 2004; DiClemente & Wingood, 1995; Jemmott et al., 1992; Jemmott & Jemmott, 1992) and they have described some compelling results. These "targeted" studies have significantly *increased* self-efficacy for condom-use, intentions to use condoms, condom application skills, and condom-protected sex acts and some were able to significantly *reduce* unprotected vaginal sex acts and the number of new sex partners.

Two distinct problems emerge, nonetheless, when analyzing the efficacy of current HIV/STI prevention interventions targeting African American adolescent women (AAAW). Problem [1]: targeted interventions for AAAW are often not *feasible* to implement widely, rendering them virtually inaccessible to the population for which they were designed. Most targeted interventions are designed and implemented at high cost, have an unreasonable number of sessions (most interventions have 2-4 sessions, minimally), and conduct these sessions for an extensive amount of time (some sessions run 4 hours!). Community-based organizations (CBOs) would have to cover the substantial expense of sending personnel to another city, for a 3-day training (i.e., "The SISTA Project", an intervention based on the 1995 DiClemente & Wingood study); in addition to paying for the considerable amount of equipment, materials, and salaries needed to implement and to continue implementing these interventions. Additionally, the notorious difficulty of recruiting, scheduling, and retaining willing *and* eligible participants of hard-to-reach populations is an extraordinary endeavor, as well**.**

Problem [2]: Most HIV/STI prevention interventions and even most interventions that target AAAW, fail to address the variables particularly correlated with risky sexual behavior specific to AAAW (i.e., whether or not they have steady partners {Crosby et al., 2000}, greater prevalence of STIs among partners {Berman & Hein, 1999},...). This could be a problem that is *stifling* the efficacy of existing interventions. They may be efficacious, but one of the glaring theoretical gaps of existing interventions is that the specific correlates *particular* to AAAW risky behavior are *not* being addressed. Existing interventions tend only to address standard variables of conventional prevention interventions (self-efficacy, condom skills,...); could an intervention designed to change the conventional *and* correlates *particular* to AAAW risky behavior help change the associated behavior, as well? Five of these particular correlates have been *empirically* associated with particular AAAW behaviors: whether or not there is a steady partner, future time orientation, normative beliefs favoring male decision making in relationships, parental monitoring, and personal barriers to condom use (Bettinger et al., 2004; Burns & Dillon, 2005; Crosby et al., 2003; Crosby et al., 2000; and Lawrence et al., 1990). We suggest that interventions, *specifically* targeting AAAW sexual behavior, need to *specifically* address the conventional correlates to risky sexual behavior (i.e., condom use skills), as well as the correlates *particularly* associated with AAAW sexual behavior (i.e., "future time orientation": an individual's predominant cognitive, affective, and behavioral orientation towards their own future).

This proposal addresses both issues with an innovative, yet feasible solution: *Interactive Media* DVD applications designed as sexual risk reduction interventions. Interactive Media (IM) can be used to develop computer applications that combine audio, video, text, graphics, and animation; where, it can portray lifelike scenarios, which compel users to become personally involved in simulated situations. Compared to the typical facilitator-led intervention, IM can be designed to be used as a one-on-one intervention, for a realistic amount of time, developed at a comparatively low-cost, implemented with considerably less expense, and AAAW have reasonably easy access to IM distribution platforms: ordinary DVD players. Additionally,

theoretically-based IM interventions can easily be tailored for AAAW and the particular correlates of their risky sexual behavior. Users assume the role of a character in a storyline, for example, making decisions throughout the narrative in situations particular to AAAW risky behavior, such as **when** and **how** to counter strong normative beliefs favoring male decision-making in relationships (for those AAAW with steady partners {Crosby et al., 2000}). Users receive particular feedback based on decisions that were made and are given appropriate behavioral skills training related to those decisions.

The **aim** of this proposal is to create an Interactive Media (IM) sexual risk-reduction intervention based on Bandura's Social Cognitive Theory (1986, 1994), 'appropriately' targeted for African American adolescent women (AAAW) and subsequently, to conduct a longitudinal (3-month) experimental study to test its efficacy. All students enrolled in a typical high school California Department of Education (CDE), 2535 Health Education course, with the mandated Content Area of "communicable and chronic diseases" as defined by the Health Framework of the California Basic Educational Data System (CBEDS) Health Education class will be tested for Chlamydia (CT) at the beginning and end of the course. During the "communicable and chronic diseases" Content Area of the Health Education course, at the beginning of the discussions of HIV and STIs, the randomly assigned AAAW **treatment** group will take the DVD of the IM intervention home along with an exercise booklet, completing both at home for two nights in private (of course, parents of the AAAW in the treatment group will have previously examined and approved of the DVD content and of the exercise booklet). The IM intervention DVD will appropriately address the 5 correlates, mentioned above, particular to AAAW sexually risky behavior. The effects of the treatment condition will be compared to the effects of the **control** condition: the AAAW attending the exact same high school CDE 2535 Health Education course who did NOT take home the IM intervention DVD or exercise booklet. For ALL students attending the Health Education course, immediately before the "communicable and chronic" Content Area begins (baseline), a confidential questionnaire assessing demographics, attitudes, and behavior will be administered. The day after the Content Area of "communicable and chronic diseases" is finished being taught, all students will fill out another confidential questionnaire (the immediate-post) in class. 3 months after the IM intervention DVD was used, a confidential questionnaire (the follow-up) will also be administered to the students in the Health Education class.

Primary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of sexually risky behaviors (i.e., inconsistent condom use) compared to those of the control condition at the 3-months follow-up questionnaire.

Secondary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of cognitions correlated with high-risk sexual behavior particular to African American adolescent women (i.e. perception of fewer girlfriends using condoms) immediately after the interventions *and* at the 3-month follow-up questionnaire.

Tertiary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of CT acquisition at the end of the Health Education course.

B. *Background and Significance*

Obviously, traditional efficacious sexual risk-reduction interventions are failing African American adolescent women (AAAW), as 83% of those diagnosed in 2004 were infected from high-risk heterosexual contact (CDC, 2006). A new approach with great potential for sexual risk-reduction is *Interactive Media*; computer applications that can feasibly be targeted to address the particular needs of AAAW and can be widely, as well as inexpensively, be distributed on DVD. There are a few studies, which have developed efficacious Interactive Media (IM) sexual risk-reduction interventions, but they don't target African American adolescent women (AAAW); and the efficacious interventions that *do* target AAAW are typically unfeasible to implement. Our aim is to develop a feasible Interactive Media sexual risk-reduction application based on the Social Cognitive Theory and targeted for AAAW. We will test the effects of the experimental condition on sexual cognitions, behavior, and clinical outcomes of high school AAAW and compare them to the effects of the control condition; the Content Area of the "communicable and chronic diseases" of a typical California high school Health Education course with or without the IM intervention DVD.

B1. Background

Although African American adolescent women (AAAW) are highly vulnerable to HIV/STI infection, there are extremely few interventions targeting their specific needs. However, the few interventions that *are* particularly designed for AAAW (DiClemente et al., 2004; DiClemente & Wingood, 1995; Jemmott et al., 1992; Jemmott & Jemmott, 1992) have yielded some compelling results.

Jemmott & Jemmott (1992) developed a pre-post, "culturally-sensitive" AIDS prevention intervention designed to increase intentions to use condoms for sexually active AAAW', using the Social Cognitive Theory as their conceptual framework. They also attempted to make the intervention culturally-sensitive by interviewing adolescents from the community to determine a culturally appropriate way to present the AIDS program. The 5-hour intervention significantly improved all of the variables measured.

The 1992 Jemmott et al. experiment assigned AAAW into one of three conditions: [1] a Social Cognitive condition, which was "culturally & developmentally" appropriate, [2] an information-alone intervention, or [3] a general health promotion intervention. Adolescents in the social cognitive condition increased AIDS knowledge, perceived self-efficacy, outcome expectancies, and intentions of condom use significantly more than participants in the other two conditions. The study did not describe how the cultural/developmental-appropriate material and exercises were developed.

DiClemente & Wingood (1995) integrated the Theory of Gender and Power, as well as, the Social Cognitive Theory into a five 2-hour session social skills intervention targeting young Black women (including adolescents). The *Theory of Gender and Power* accounts for gender-based differences in male-woman relationships and addresses the effect of women adopting risk-reduction strategies in their relationships. The participants in the experimental condition increased consistent condom-use, self-control, sexual communication, sexual assertiveness, and partner's norms of consistent condom use significantly more than participants in the other two control conditions.

DiClemente et al. (2004) compared the effects of a four 4-hour session social skill-building intervention based on the Social Cognitive Theory and the Theory of Gender and Power to the effects of a four 4-hour session comparison condition, emphasizing exercise and nutrition. Participants in the experimental condition reported significantly more consistent condom use, more condom use at last vaginal intercourse, higher percentage of condom-protected vaginal acts, significantly less numbers of unprotected vaginal intercourse and vaginal sex partners than participants in the comparison condition.

- *Those few HIV/STI prevention interventions that efficaciously reduce AAAW risky behavior, however, are typically unfeasible to develop***.**

Interventions targeting AAAW are not often *feasible* to implement: they are designed and disseminated at high cost, they typically have a large number of sessions (many interventions require up to 5 sessions), and each session often involves a significant amount of the participant's time (many sessions run a minimum of 2–4 hrs). "The SISTA Project", for example, a CDC nationally promoted program, is a sexual risk-reduction intervention targeting African American women and is based on the 1995 DiClemente & Wingood study. It requires participants to attend five 2-hour sessions. The Jemmott & Jemmott (1992) intervention consisted of three 2-hour sessions. How feasible will recruitment and retention of AAAW be for these programs in local settings? Community-based organizations would have to cover the substantial expense of sending personnel to another city for the 3-day training *plus* pay a considerable amount for equipment, materials, and salaries needed to implement efficacious interventions. The notorious difficulty of recruiting, scheduling, and retaining willing *and* eligible participants of hard-to-reach populations in a longitudinal study, is a tremendous challenge, as well**.**

- *Although efficacious, HIV/STI prevention interventions targeting AAAW do not explicitly address any of the particular correlates of AAAW risky sexual behavior.*

Most interventions that claim to target African American adolescent women (AAAW), fail to address particular variables statistically correlated with sexual behavior specific to AAAW. Yet, if these particular correlates of AAAW risky behavior were experimentally manipulated, there's a good chance that the efficacy of the conventional and the traditionally 'targeted' intervention could increase significantly. In cross-sectional studies, Crosby et al. (2000) found that AAAW engaging in unprotected vaginal sex depended on [1] particular personal barriers to condom use, [2] normative beliefs favoring male decision-making in relationships, and [3] whether or not they had a steady sexual partner. Additionally, Burns & Dillon (2005) found that [4] AAAW with stronger "future time orientations" engaged in safer sexual practices and Lawrence et al. (1990) found that [5] the inability to discuss their past sexual history was associated with AAAW risky behavior. Only one of those 5 correlates has been addressed (DiClemente & Wingood, 1995) and that study's effect size (ES) for reducing "normative beliefs favoring male decision-making" (ES=.603) was almost twice as large (ES=.363) as the ES of a similar study which measured, but did NOT address the correlate during the intervention (Lauby et al., 2000). The studies' effect sizes for "increasing consistent condom use" was significant as well; [ES(1995)=.491 vs. ES(2000)=.324]. Because reducing risky sexual behavior of all of its students, especially those particularly vulnerable, is a priority of the Los Angeles County Unified School

District, our proposal directly attempts to show that manipulation of particular correlates of AAAW behavior will dramatically increase the efficacy of interventions 'appropriately' targeting AAAW.

- *Interactive Media shows promise in reducing risky sexual behavior of specific populations and can be feasibly designed as an HIV/STI prevention intervention.*

Interactive Media (IM) may be of use when psychological phenomena are particular to a certain community, ethnicity, or population, which may have limited access to HIV/STI prevention services or have disengaged from mainstream medical institutions. In these cases, IM can *feasibly* [read: designed to be used in a reasonable amount of time, developed at relatively low cost, and is considerably less expensive to implement than traditional interventions] be customized as a targeted intervention; tailored for the specific needs of a particular group (i.e., African American adolescent women) and then widely (and cheaply) distributed on DVD, providing easy access to that intervention.

In fact, Interactive Media (IM) as an HIV/STI prevention intervention, which targeted specific populations, has already shown promising results. IM interventions targeting men who have sex with men have significantly reduced White men's risky anal sexual behavior and significantly increased their protected anal sexual behavior (Read et al., 2006). IM interventions targeting adolescents have significantly *increased* HIV knowledge, self-evaluative outcome motivation, intentions of condom use, availability of condoms, condom use, and abstinence, as well (Kiene & Barta, 2006; Evans et al., 2000). These interventions have also significantly decreased reported condom failures (demonstrating an improvement in condom skills) and acquisitions of STIs (Downs et al., 2004).

B2. Innovation and Significance

The results of Interactive Media (IM) sexual risk-reduction interventions targeting a specific population are few, but distinctively positive. To date, however, no IM intervention has targeted AAAW; one of the highly vulnerable populations that needs it the most! An IM HIV/STI prevention intervention targeting AAAW has the potential to provide a valuable supplement to the facilitator-led intervention/Health Education course. In addition to targeting correlates particular to AAAW risky behavior, IM interventions can be designed, developed, accessed, and implemented feasibly with comparatively low expense.

The Proposed Study. The **aim** of this proposal is to create an Interactive Media (IM) sexual risk-reduction intervention based on Bandura's Social Cognitive Theory (1986, 1994), 'appropriately' targeted for African American adolescent women (AAAW) and subsequently, to conduct a longitudinal (3-month) experimental study to test its efficacy. All students enrolled in a typical high school California Department of Education (CDE), 2535 Health Education course, with the mandated Content Area of "communicable and chronic diseases" as defined by the Health Framework of the California Basic Educational Data System (CBEDS) Health Education class will be tested for Chlamydia (CT) at the beginning and end of the course. During the "communicable and chronic diseases" Content Area of the Health Education course, at the beginning of the discussions of HIV and STIs, the randomly assigned AAAW **treatment** group will take the DVD of the IM intervention home along with an exercise booklet, completing both at home for two nights in private (of course, parents of the AAAW in the treatment group will have previously examined and approved of the DVD content and of the exercise booklet). The IM intervention DVD will appropriately address 5 correlates particular to AAAW sexually risky behavior. The effects of the treatment condition will be compared to the effects of the **control** condition: the AAAW attending the exact same high school CDE 2535 Health Education course who did NOT take home the IM intervention DVD or exercise booklet.

The hypotheses are that participants in the Interactive Media treatment condition will report significantly lower levels of sexually risky behaviors (i.e., inconsistent condom use) compared to those of the control condition at the 3-months follow-up questionnaire. Also, that participants in the Interactive Media treatment condition will report significantly lower levels of cognitions correlated with high-risk sexual behavior particular to African American adolescent women (i.e. lower normative beliefs favoring male decision making in relationships) immediately after the interventions *and* at the 3-month follow-up questionnaire. Finally, that participants in the Interactive Media treatment condition will report significantly lower levels of CT acquisition at the end of the Health Education course.

The Theoretical Components of the Interactive Media (IM) Application.

The structure of the IM *narrative* was informed by the *review of literature* (the results of which are outlined in section B. "Background & Significance" of this proposal) as well as by the *formative research* conducted (in Fall 2007) with 18-24 year old adolescents who were extensively interviewed about their high school attitudes, behaviors, and subsequent consequences, which involved activities leading to risky sexual behavior.

The DVD is introduced by two guide characters, which explain the objectives of the DVD and set up the story for the user. The guides are attractive AAAW intended to appeal to the target audience. AAAW who use the DVD are asked to identify with the main character and are given the opportunity to make choices, ask questions, and guide their character's actions. Throughout the encounter, the user is in control and is able to govern the behaviors of her character. Initially, the user chooses to assume the character of "Tawanna," a high school AAAW who has invited over to her house (parents not home) either her boyfriend of 2 months, "Tracy" or a friend "with potential", "Jamal". The story begins as Tracy or Jamal comes over to Tawanna's house after school. The two go to her room, set up their homework on her bed, and begin to talk. Tracy and Jamal are attractive, sexually aggressive characters whose objectives are to have sex with Tawanna as soon as possible. The user's objective is to help Tawanna negotiate safer sex with Tracy or Jamal. As Tracy/Jamal make sexual advances (e.g., offers vodka that he's brought over, kisses and touches Tawanna, etc.), the user faces choice points at which she makes decisions regarding how the action will progress. An "advice" option, which is given by the guide characters, is always available. If the user is unsure of how to bring up the topic of safer sex, for example, the guides are there to offer possible strategies and lines that Tawanna could utilize to ensure safer sex with Tracy/Jamal. In addition, if the user chooses one of several risky options, such as drinking the vodka or having unprotected vaginal sex, the user will receive *unsolicited* advice from the guides (i.e., a mandatory intervention). For example, the guides would warn of the dangers of unprotected vaginal sex and/or alcohol leading to bad decision-making. Positive feedback is also given when the user makes good decisions, such as choosing to use condoms.

Correlates Specific to AAAW Risky Behavior. Five correlates (Crosby et al., 2003; Crosby et al., 2000; Burns & Dillon, 2005; and Lawrence et al., 1990) have been shown to be particularly associated with AAAW risky sexual behavior: [1] personal barriers to condom use, [2] normative beliefs favoring male decision making in relationships, [3] whether or not there is a steady boyfriend as opposed to a casual partner, [4] "future time orientations" (predominant cognitive, affective, and behavioral mind-sets that tend NOT to plan for the future), and [5] the inability to discuss past sexual history with partner.

Social Cognitive Theory. The sexual risk reduction component of the high school Health Education class, as well as the Interactive Media (IM) intervention, will be theoretically based in the primary conventional theory of behavior change. Guided by the well-established, efficacious HIV/STI prevention approaches of the Social Cognitive Theory (Bandura, 1986, 1994), numerous researchers (for reviews see DiClemente & Peterson, 1994; Fisher & Fisher, 1992, and Kelly, 1995) have demonstrated that interventions, which successfully manipulate [1] an increase in the amount of *knowledge* about HIV and STIs, [2] an increase in the perceived *social norms* of protection against HIV/STI infection [3] an increase of the level of perceived *self-efficacy* and [4] an increase in beliefs that engaging in sexual risk reduction behaviors lead to positive outcomes (*outcome expectancies*) and [4] an increase in *behavioral skills* of safer sex will all significantly reduce high risk sexual *behaviors*.

Context-Dependent Behavior (Inherent to IM). Both Gollwitzer (1990), as well as Mischel & Shoda (1995), provide the foundation for understanding context-dependent learning when addressing Interactive Media as a vehicle of reducing risky sexual behavior. Both theories suggest that two components (although they may be called by different names) need to be addressed in any successful behavior change intervention: *self-regulatory plans* and *mind-sets*. Individuals who organize a strategy for reducing sexually risky behavior (a self-regulatory plan) are more likely to engage in that behavior. Where an intention to perform a behavior establishes a precise end-state; the self-regulatory plan organizes a specific goal-related strategy that involves a person's decision to execute particular behaviors in a particular situation. Gollwitzer and Mischel & Shoda also include the concept of mind-sets: cognitive interpretations of situations that accentuate environmental and conceptual cues when performing a particular behavior. A mind-set involves an individual's mental orientation through which distinct information processing (associated with certain cues) produces a somewhat consistent, almost automatic, behavior in response to a situation with those environmental and conceptual cues. Interactive Media can create a plethora of contextual (environmental and conceptual) cues (i.e., visual, auditory, the sexual nature of a situation, etc.) when reducing sexual risk behavior is learned during the IM intervention. An individual interpreting those contextual cues in an appropriate situation will activate the mind-set that compels, almost automatically, the individual to engage in the self-regulatory plans learned in the IM intervention.

Adolescent Risky Decision Making (Inherent to IM). Brain maturation of adolescents is a developmental process that, literally, is still in progress. Under ideal circumstances, adolescents are quite capable of making rational decisions, even about engaging in sexual risk reduction behaviors. Yet, in the heat of the moment

with a sexual partner, in the presence of peers, or in some other stressful situation, adolescents are likely to reason more poorly than adults (Reyna & Farley, 2006). Simply as a matter of biology, adolescents under pressure will tend to make risky decisions in a non-deliberative, almost automatic fashion; where the consequences of those decisions are typically deleterious. Interactive Media has the potential to mitigate harmful decision making of adolescents under pressure. Gollwitzer (1990) and Mischel and Shoda (1995), in their work mentioned above, attribute the effect of *self-regulatory plans* and of *behavioral mind-sets* to the links that they create between situational cues and behavior. The cognitive process assumed, here, is that the "individuals pass on the control of goal-directed behavior to environmental cues thus facilitating the initiation of goal-directed actions". That is, the initiation of behavior is no longer an *effortful* cognitive operation that an adolescent must consciously control and *deliberately* execute. Rather, the self-regulatory plan and the behavioral mind-set allow an adolescent to relinquish responsibility for this initiation to a particular situation, where the situation, in and of itself, acts as a cue to signal the adolescent to perform a particular behavior. As IM can provide a rich array of realistic situational cues within a simulated sexual encounter, AAAW (who have used the IM sexual risk reduction application) might be likely to non-deliberatively activate learned behavioral responses of safer sex practices in real situations, even the stressful ones.
Behavioral Rehearsal (This type of rehearsal is inherent to IM). The Social Cognitive Theory (Bandura, 1986, 1994), supported by evidence from modeling research (Bandura, 1977), proposes that learning a behavior occurs when we actually *observe* others performing the desired behavior. Emotional Processing Theory (Foa & Kozak, 1986) and evidence from systematic desensitization/exposure research (Kazdin, 1986), indicate that exposure to *actual* stimuli is associated with learning significantly greater emotional regulation than is exposure to mental representations of those stimuli. Results from the above research explain why most behavior change interventions include a "role-playing" component; clients can *observe* as well as *practice* the desired behavior in a safe environment with *actual* stimuli. As a potential vehicle of modeling, Interactive Media (IM) can be developed with virtual scenarios where desired sexual behavior can be observed. More importantly, IM compels the user to become a *participant* within the scenario with the ability to *observe*, as well as, *rehearse* the desired behavior with actual stimuli provided by the simulated environment - usually a lot more realistic and less awkward than role-play. IM can also provide rehearsals of sexual risk reduction skills, which are conducted in a private, personal space with no embarrassment created by "role-playing" in front of people (typical of most "role-playing" exercises in traditional interventions). And as we learned from the Social Facilitation Theory (Zajonc; 1965, 1980), with a newly learned behavior, performance is *inhibited* when people are watching (as they are in traditional role-plays). Not surprisingly, then, IM should be more likely to enhance learning of a new behavior skill, as there is no audience to increase the participant's arousal interfering with the performance of that newly learned behavior.

C. *Preliminary Studies / Progress Report*

C1. Collaborative History & Feasibility

This team has a great deal of experience in conducting clinical trials relevant to the current proposal, including one that is currently ongoing. Mary Nwosu (PD/PI), Dr. Read (my faculty advisor), and Dr. Miller have successfully collaborated on several CDC- and NIH-sponsored clinical trials over the past number of years, all of which directly relate to and inform the proposed research of this application. Drs. Read and Miller have been collaborators for over 20 years, publishing over 40 articles, chapters, and books together. This team has the experience to successfully conduct the research outlined in this application. I, Mary Nwosu (PD/PI), have been a Research Assistant in the Psychology Department and the Annenberg School of Communication, where I collaborated with Drs. Read and Miller on several clinical trials mentioned below.

In terms of the feasibility of producing an Interactive Media (IM) intervention, two points should be noted: [1] I have been an RA on several projects of Drs. Read and Miller, developing IM specifically as HIV/STI prevention interventions and have access to the IM development facilities of their lab, as well as to their considerable knowledge and assistance. Also, [2] I am a double major (a Ph.D. candidate in Social Psychology *and* an M.F.A. student in the USC School of Cinematic Arts: the *Production* Division, with an emphasis on *Interactive Media*). The IM DVD of the proposed HIV/STI prevention intervention will be my Cinematic Arts *thesis* project (to be produced Summer 2008) of the M.F.A. and so I will have access to cutting-edge facilities and equipment, as well as the knowledge and assistance of IM and Production students and instructors within the USC School of Cinematic Arts. Assisting Drs. Read and Miller for *years* on projects that involve the creation, implementation, and analysis of IM sexual risk-reduction interventions; and having been trained in IM production at the country's #1 School of Cinema – the feasibility of producing another IM

intervention are high.

C2. Preliminary Studies / Progress Report

- *PI, Dr. Miller; "Multiple HIV Prevention Options: Minimizing Risk? When?"* CDC-funded, the purpose of the study was to evaluate a model for presenting young Latina and African American women with multiple options for HIV/STI prevention and to assess their acceptance and use of these options without undermining their use of the most efficacious prevention method.

As a trained interviewer, I approached and screened (determining eligibility for participants in the study) young African American women and Latinas in clinics of the greater Los Angeles area. Most of these clinics served predominantly Black and Latina clients. As a research assistant, I contributed to the research/intervention design, training and implementation of the pilot study. I participated in the intervention design strategy sessions, co-wrote the interviewing training manual, was co-facilitator of the interviewer training sessions, as well as, reporting and offering recommendations concerning field procedures to ongoing reliability sessions of the pilot study. I conducted all of the interventions of the pilot study (at Planned Parenthood: the Hollywood, CA & Santa Monica, CA sites), participated in the rewrite of the intervention, as well as assisting in the training of new interventionists. Additionally, I designed, created, and integrated the TELEforms/MS Access 2000 database configuration of the LA site and trained research assistants in the database management.

- *PI, Dr. Read; "Simulating Safer Sex: Interactive Video as HIV Intervention."* Funded by the University Wide AIDS Research Program of the State of California, the purpose of this study was to evaluate a traditional one-on-one HIV prevention intervention for men who have sex with men (MSM) compared to an intervention that included an Interactive Media (IM) component.

Funded as an APA Fellow (the Minority Fellowship Program), I coordinated the final phase of data collection & entry, conducted the parametric (SPSS) & non-parametric (S-PLUS) data analysis, and wrote sections of the resulting article, published in *Human Communication Research*, 32, 1-34, 2006.

- *PI, Dr. Miller; Co-PI, Dr. Read: "Virtual Sex: Real Sex Reduction for MSM."* An R01 funded by NIAID, the study currently focuses on developing and testing the efficacy of IM for sexual risk-reduction of 3 ethnic populations of MSM.

As a recipient of a NIAID Research Supplement for Underrepresented Minorities (PA-01-079), I participated as a research assistant on many aspects of the project. I outreached to the community of MSM in the greater Los Angeles area as a recruiter in West Hollywood, CA; interacting with and screening (determining eligibility for participants in the study) a tremendously diverse population of MSM. Trained as an interviewer and an interventionist, I administered the Baseline, the Immediate-post, and the 3-month Follow-up questionnaires; as well as conducted many of the 4 interventions. I coded (and have written the protocol for coding) the qualitative data of the study and for the 2005 International Communication Association (ICA) conference, I presented the preliminary design considerations of the *"Virtual Sex: Real Sex Reduction for MSM"* study on a session panel.

D: *Research Design and Methods*

D1. Overview and Design

We propose a randomized controlled trial with one treatment condition (n=70) and one control condition (n=70). [Sample sizes were estimated using repeated measures from Baseline to the Immediate-post and Baseline to 3-month Follow-up ("repetition=2"), alpha=.05, effect size=.2, correlation of repeated measures= .4, and power=.8 (from the application "G-Power")] The *treatment condition* consists of African American adolescent women (AAAW) NOT attending the sexual risk reduction component of their high school health education class; instead they take an IM intervention, lasting ~50 minutes, delivered on DVD (designed to reduce AAAW high-risk sexual behavior) home with them for two nights. This treatment group completes the IM intervention twice (once, for two nights) and fills out the appropriate exercise booklets (one booklet per night), which they return (in their health education class) the day after they complete the IM intervention. The *control condition* consists of AAAW ATTENDING the 2-day sexual risk reduction component of their high school health education class. The sexual risk-reduction component of the high school health education class will consist of 2 sessions, each lasting ~50 minutes, one day apart.

D2. Hypotheses

Primary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of sexually risky behaviors (i.e., inconsistent condom use) compared to those of the control condition at the 3-months follow-up questionnaire.

Secondary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of cognitions correlated with high-risk sexual behavior particular to African American adolescent women (i.e. perception of fewer girlfriends using condoms) immediately after the interventions *and* at the 3-month follow-up questionnaire.
Tertiary hypothesis: Participants in the Interactive Media condition will report significantly lower levels of CT acquisition at the end of the Health Education course.

D3. Design Considerations, Alternatives

If our hypotheses are wrong, there may be at least 2 reasons why this IM targeted intervention was NOT more efficacious than the traditional facilitator-led sexual risk-reduction intervention: [1] The Social Cognitive Theory was not integrated into the IM intervention correctly or [2] our method of 'targeting' African American adolescent women was faulty. The idea that IM interventions are typically more efficacious than conventional interventions has been supported through a myriad of studies, as well as in the meta-analysis "Interactive Media in Health Psychology: A Meta-Analytic Review" (Nwosu, application for publication pending). The idea that "targeted" interventions for particular populations are typically more efficacious than convention interventions has been also well documented, including the studies referred to in this proposal.

D4. Participant Population

Intervention Sites. We hope to work in collaboration with the Los Angeles Unified School District (LAUSD, with Ric Loya) and the Health Education Unit (HEU, with Kim Harrison Eowan and Ana Hernandez) of the Sexually Transmitted Disease (STD) Program in the Los Angeles County Department of Public Health. Since 1989, the HEU has developed an STI training curriculum for students at high schools in several LA area school districts. The HEC will train our 4 young African American women University of Southern California (USC) graduate students (from the departments of Psychology and Social Work) as Health Educators to teach the STI component of the Health Education courses of LAUSD high schools, if deemed necessary.
Participant Population. Our population will consist of willing heterosexual African American woman high school students of the LAUSD who [1] have reported to have had sexual activity in the previous 3 months, [2] have given informed consent/assent to participate in the study, [3] for those younger than 18 years old, have obtained written parental consent to participate in the study, and [4] are enrolled in a LAUSD 2535 Health Education course in the Fall 2008 semester.

D5. Screening, Recruitment, and Attrition

Screening & Recruitment. Participants will be recruited only through permissible means, but likely through advertisements in print, online media, high-school intercom announcements, and personal visits to high school Health Education classes of the LAUSD to explain the project. A table will be set-up, in a particular location and time of day designated by the high school principal, where screening/recruitment will occur. If eligible and willing, the student will be give an Assent/Consent Form, a Parental Consent (if required), both of which will be collected at Visit 1. 3 members of the Health Education Unit (HEU) in the STD Program in Los Angeles County Department of Public Health will assist in STI (CT) screening, as they have considerable knowledge of and experience with the procedure.
Attrition. We will over-recruit by ~20% to allow for dropout, so we will begin with N=166 and, theoretically, end with N=140; initially 88 participants per condition. To enhance retention, we are offering a financial incentive for study completion.

D6. Sample Size and Power

We propose a randomized controlled trial with one treatment condition (n=70) and one control condition (n=70). For the cognitive / personality measures [measured at Baseline and at Immediate-post and Baseline and at the 3-month Follow-up, a-priori power analyses indicate that when alpha=.05, Effect Size (ES) of IM on behavior (the value that Nwosu's meta-analysis gives for a fixed effects model)=.22, estimated correlation between repeated measures= .4 , non-sphericity correction =.1, and power=.8; the total sample size needs to be 140 participants. This estimate is based on tremendously conservative assumptions and so we're confident that N=140, will provide a sufficient amount of power to find an effect. Power analyses are done using the G-Power application (Buchner, Faul, & Erdfelder, 1997).

D7. Eligibility Criteria

Inclusion Criteria: Assented/consented and required parental consented African American adolescent women aged 13-19 years who have had heterosexual sexual activity in the previous 3 months and are enrolled in a LAUSD high school 2535 Health Education course.
Exclusion Criteria: Participation in any other sexual risk-reduction clinical trial.

D8. Description of the Treatment Intervention

The Interactive Media DVD. Formative research (*one-on-one interviews*) of African American adolescents on the nature of their sexually risky experiences was used to inform the *exact* structure and narrative of the IM DVD. The DVD is introduced by two guide characters, which explain the objectives of the DVD and set up the story for the user. The guides are attractive AAAW intended to appeal to the target audience. AAAW who use the DVD are asked to identify with the main character and are given the opportunity to make choices, ask questions, and guide their character's actions. Throughout the encounter, the user is in control and is able to govern the behaviors of her character. Initially, the user chooses to assume the character of "Tawanna," a high school AAAW who has invited over to her house (parents not home) either her boyfriend of 2 months, "Tracy" or a friend "with potential", "Jamal". The story begins as Tracy or Jamal comes over to Tawanna's house after school. The two go to her room, set up their homework on her bed, and begin to talk. Tracy and Jamal are attractive, sexually aggressive characters whose objectives are to have sex with Tawanna as soon as possible. The user's objective is to help Tawanna negotiate safer sex with Tracy or Jamal. As Tracy/Jamal make sexual advances (e.g., offers vodka that he's brought over, kisses and touches Tawanna, etc.), the user faces choice points at which she makes decisions regarding how the action will progress. An "advice" option, which is given by the guide characters, is always available. If the user is unsure of how to bring up the topic of safer sex, for example, the guides are there to offer possible strategies and lines that Tawanna could utilize to ensure safer sex with Tracy/Jamal. In addition, if the user chooses one of several risky options, such as drinking the vodka or having unprotected vaginal sex, the user will receive *unsolicited* advice from the guides (i.e., a mandatory intervention). For example, the guides would warn of the dangers of unprotected vaginal sex and/or alcohol leading to bad decision-making. Positive feedback is also given when the user makes good decisions, such as choosing to use condoms.

Exercise Booklets. During the DVD, the participant is instructed to complete sections of an exercise booklet, which consists of areas to write down the appropriate response of what the user "should" say at a risky decision point in the narrative. The point of these exercise booklets is to give the participant the opportunity to *examine* and *articulate* (real-time) what the safe response to a risky situation should be and then give a space where they can write (rehearse) it, regardless of the choice they make IN the DVD. The narrative will address all 5 of the correlates significantly associated with AAAW risky decision-making, but participants will have to *write* responses for situations *particularly* addressing [1] "future time orientation" questions (i.e., "Where do you want to be in 5, 10, and 20 years?" The booklet prompts participants to write specifically *what* (in detail) they would have to do to get there and *when* they would have to do it), [2] "normative beliefs of who makes decisions concerning sex in a relationship", as well as [3] "the inability to discuss past sexual behavior with partner" (the specifics of HOW these correlates are addressed, are in the following section). After the narrative ends, the guide character will [4] prompt the user to write down the numbers on a given screen of the DVD in the exercise booklet, which indicate the choices they made during the narrative. The numbers are coded, so users won't understand their meaning.

D9. Description of the Control Condition

The control condition is simply the Content Area "communicable and chronic diseases" taught in the 2535 Health Education course to randomly assigned AAAW in a LAUSD high school.

At the end of the Health Education course, all students are left with pamphlets about HIV/STIs facts and contraception. They are also provided with a toll-free hotline where they can talk to a Health Educator (via the 12 LA County STD Clinics) to ask more questions, request condoms via email, or get a referral for free or low cost clinics.

D10. Procedures

Personnel. Young African American women who are graduate student from the USC departments of Psychology and Social Work will be trained to administer recruitment screeners, interventions, all study questionnaires, assent/consent, enrollment, & retention forms (Please refer to section D5. for information on screening, recruitment, and attrition).

D11.Randomization Procedures

We shall follow the Consolidated Statement of Reporting Trials (CONSORT) guidelines appropriate to this study. Units of Randomization: the individual, the Health Education class, and the school.

D12.Visits

The entire intervention will take 6 visits. Visit 1: A brief description of the study and its purpose will be announced over the intercom (or the by the method designated by the appropriate school official) of each high school. Those who wish to participate will come to a table that we will have set up, specifically to read through the informed assent/consent form and to be given a consent form for their guardian to sign, if

necessary. Visit 2: Eligible participants hand in the appropriate consent/assent/parental consent forms and are then randomly assigned to an experimental condition. All students of the Health Education course complete the Baseline questionnaire and are screened for CT by the HEU. Visit 3: Immediately before the "communicable and chronic disease" Content Area begins, study participants of the treatment condition are given the DVD and Exercise Booklet #1 to complete that night. Visit 4: The next day, participants in the treatment condition hand in Exercise Booklet #1 and are given Exercise Booklet #2 to complete with the DVD for the next night. Visit 5: The day after Visit 4, all students of the Health Education course complete the Immediate-Post questionnaire and those in the treatment condition hand in their completed Exercise Booklet #2. Visit 6: 3 months later, all students in the Health Education course complete the 3-month Follow-up questionnaire and are screened for CT by the HEU.

D13.Timeline

07-08	TASK
Fall 2007	Conduct formative research;
Feb 2008	Analyze formative research;
March & April 2008	Identify AAAW correlates to risky behavior and assign what characters will address the conventional HIV/STI psych variables and those particular to AAAW
May 2008	Develop IM narrative description; Develop LAUSD proposal; Recruit & Train Study Facilitators & Data Managers;
June-mid July 2008	Write interactive script (with Ric Loya's input); Develop shooting schedule & budget; Recruit producer; Conduct auditions; Hire actors & cinematographer; Create storyboard & shot lists; Conduct rehearsals; Scout & secure sets; Hire set designer & artists; Purchase production supplies; Hire production staff & "Extras"; Design sets;
July 2008	Shoot footage; Edit footage; Begin programming DVD interface & structure;
August 2008	Finish Shoot; Finish Editing; Author DVD;
August 2008	Finish authoring DVD; Duplicate DVD; Get Ric Loya's & LAUSD approval of DVD;
Sept 2008	**MAIN STUDY**: Facilitators screen, recruit, schedule, & collect consent forms; LACDPH conduct STI screenings;

2008	TASK
October 2008	Facilitators administer questionnaires & conduct retention protocols; Data managers organize incoming data;
Nov 2008	Data managers organize, enter, & monitor incoming data;
Dec 2008	Facilitators administer the Follow-up; LA County Department of Public Health (LACDPH) conduct STI screenings; Data managers finish entering data;
2009	**TASK**
Jan 2009	Clean Data; Analyze Results;
Feb 2009	Finish Analyzing Results; Write Dissertation;
March 2009	Revise Dissertation; Coordinate Dissertation Defense;
April 2009	Successfully Defend Dissertation;
May 2009	Report results to LAUSD, LACDPH, CBOs, peer-reviewed journals, academic & CBO conferences;

D14.Measures Used in the Study (taken at Baseline, at Immediate-Post, &/or at the 3-month Follow-Up)

We chose measures that had been used in past research in the Social Cognitive Theory, as well as measures used to assess the particular correlates of AAAW sexual behavior: Stronger Normative Beliefs favoring male decision-making in relationships, Future Time Orientations, The Ability to Discuss Past Sexual History, Sexual Assertiveness, Self-Efficacy, Outcome Expectancies, Social/Behavioral Skills, Perceived Safer Sex Norms, Attitudes, Knowledge, Perceived Vulnerability, Behavioral Intentions**,** Sexual Arousal**,** Message Variables (positively- or negatively-framed, message quality, attitude-consistent information, ….etc.), Recall and Recognition of Intervention Material (from both experimental conditions), Evaluation of IM Guide, of the IM Characters, of the IM DVD, of the Health Class Intervention, and of the Facilitator, Presence (at Immediate-Post), Sexual Behavior**,** Acculturation/Cultural Identification, African-Centered Cultural Values, Relationship Interdependency, Initiation and Negotiation Skill of Condom-Use, General Demographic Questions (at Baseline), Depression, Self-Esteem, Social Support, Optimism, Locus of Control, and Life Satisfaction**.**

D15.Data Analysis & Statistics

Overview of Approach. The analyses of this type of design require multi-level modeling (or hierarchical linear modeling), as the participants are not completely independent from each other. Coefficients' standard errors resulting from analyses using logistic regression appear smaller than they actually are and multi-level modeling (MLM) corrects for that.

Because level factors of MLM typically contain 30 or more subjects, different estimation methods will be used depending on the size of the groups [i.e., The 'school' level factor, in this application, is 7 and the estimation method suggested for an atypical group of that size is the "restrictive iterative generalized least squares" (Browne & Draper, 2000)]. Decisions similar to these will be made in terms of statistical alterations. SPSS Graduate Pack 13.0 for MAC OS X will be used for the MLM.

Data Management. Hand entered by Data Managers into a database of SPSS, Inc.

Preliminary Analysis and Data Preparation. Prior to conducting the main analysis, all variables will be screened for inconsistent or abnormal values, and continuous measures will be assessed for skewness and outliers. Transformations to reduce heteroscedasticity or the effect of extreme values on the statistical analysis will be used, if necessary. Although we expect missing data rates to be significantly low, however, patterns will be assessed, as will correlates of "missingness" and a case analysis will also be conducted. Reasons for withdrawal from the study and loss to follow-up will be recorded as well.

D16.Dissemination of Results

We will disseminate research results to the LAUSD, the HEU, other high school districts, community bases organizations (CBOs), academic & community-based conferences, the LAUSD Title IV Collective & peer-reviewed journals.

D17.Limitations

Access to African American adolescent high school women in order to address sexual topics might seem a difficult task for most researchers. However, we have access to the valuable resources of Ric Loya, a High School Health Educator, a Teacher Advisor of the LAUSD, and a member of the California Health Education Standards Advisory Panel. He is in a position to facilitate the approval of the IM DVD dissemination throughout LAUSD Health Education courses during the Fall 2008 semester. Because LAUSD high schools are considerably structured and attendance is mandatory; conducting the proposed study, with the approval of Mr. Loya, should not be a problem.

D18.Review Criteria

Significance. The proposed study addresses an epidemic in U.S. public health – the increasing diffusion of HIV/STI transmissions into new, highly vulnerable populations. As there is no cure for HIV and some STIs, as no one knows if existing treatments may produce long-term effects or even remain effective for those with HIV, and as there are mutations of strains developing with the potential of (re)infecting more of the population; we hope the proposed research will illuminate the specific psychosocial factors that will behaviorally 'inoculate' African American adolescent women (who are especially vulnerable) against this epidemic. Ultimately, we hope that the proposed research will begin to provide a *template* for the design of interventions specifically 'targeting' other vulnerable cultures or particular groups in need of special attention for effective HIV/STI prevention.

Approach. We have proposed the use of a RCT, a powerful design that provides important scientific information concerning the causal relation between the intervention and the outcomes, as well as the feasibility and utility of the proposed intervention. The proposed measures are based on the assessment in the current literature relating to one of the most useful (by targeting to the most vulnerable), cutting-edge techniques for HIV/STI prevention: Interactive Media. The structure of the study suggests that the most appropriate technique for this type of study (individuals from different classes, from different high schools) is Multilevel Analysis and Hierarchical Linear Modeling.

Innovation. As a collaboration of Engineering, African American Studies, The School of Cinematic Arts, as well as Psychology (the PD's educational background), we also hope that this proposal will add to the interdisciplinary designs of innovative research. Interactive Media as an intervention may just provide the answer to HIV/STI prevention through development of an effective and inexpensive dissemination format (DVDs) and through seamless integration into the lifestyles and behaviors of this new generation.

Investigators. This research team has done much of the seminal work in the area of research demonstrating Interactive Media as an effective HIV/STI prevention intervention. They also have a great deal of experience in the highly sensitive conduct of sexual risk-reduction clinical trials on minority populations.

Environment. High schools of the Los Angeles Unified School District, with the guidance of Ric Loya, have

provided strong support for the effective Health Education of adolescents vulnerable to HIV/STI transmission.