Study Protocol Cover Page

Official Study Title: Assessing HIV Screening in African American Churches
NCT02529644
Latest IRB approval date: 12/5/2017
Note: IRB approval letter included and the 12/07/2017 date is the date the protocol was printed and saved. The actual document date and approval date is 12/5/2017.

UMKC
Office of Research Services

UMKC
5319 Rockhill Road
Kansas City, MO 64110
TEL: (816) 235-5927
FAX: (816) 235-5602

NOTICE OF CONTINUING REVIEW APPROVAL

Principal Investigator: Dr. Jannette Berkley-Patton
5030 Cherry st, Room 308
Kansas City, MO 64112

Protocol Number: 13-926
Protocol Title: Assessing an HIV Education and Screening Intervention in African American Churches
Type of Review: Designated Review

Date of Approval: 12/05/2017
Date of Expiration: 12/04/2018

Dear Dr. Berkley-Patton,

The above referenced study, and your participation as a principal investigator, was reviewed and approved by the UMKC IRB according to appropriate IRB regulations at 45 CFR 46 or 21 CFR 50 and 56. You are granted permission to conduct your study as described in your application.

This approval includes the following:

- Please note: Due to the newly approved policies (See SOP 3.11.1), the IRB now maintains a fixed anniversary date for studies at continuing review. You will notice that the newly stamped consent form has been approved from 12/05/2017 to 12/04/2018. Please note: the previously approved consent (approval dated: 12/05/2016 to 12/04/2017) should be used until it expires on 12/04/2017 of this year, at which point the newly approved version should be used.

Attachments

Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved

JBP R01 Resubmission, Cover Letter R01 study J Berkley Patton Dated 11-18-2013, CV Jannette BerkleyPatton November 2013, CCON LOS Version 1 Dated 11-24-2013, Church Letters of Support Version 1 Dated 11-24-2013, Citi Certificate Marvia Jones, Informed Consent Script R01 Appendix A Version 2 Dated 3-17-2015, Health Beliefs and Behaviors Survey Version 2 Dated 3-16-2015, Poster for Intervention Churches R01 Version 1 Dated 3.18.2015, Materials for Comparison Churches Version 1 Dated 3 18 2015, CHL Comparison Implementation Monitoring Form Version 1 Dated 3-16-2015, CHL Intervention Implementation Monitoring Form Version 1 Dated 3-16-2015, Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part1, Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part2, Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part3, Ronnie Blackburn CITI Biomedical Investigator training certificate, citi 2014 01 13 simon, Marcie Berman CITI, CITI Completion Report SDodda, Letters of Support 2.Palestine.NewBethel.ChristFellow.Canaan.Friendship.GBHS.MetroSpir.VictLife.Dated 6.19.2015, Health Beliefs and Behaviors 6 month amendment Version 1 dated 2-2-2016, Sunlight Missionary Baptist Church Signed MOA Wave 2, Glory Bible Fellowship and Destiny Life Center MOA, Paseo Baptist Church signed JBP MOA W2, Swope Parkway United Christian Church MOA W2, Calvary Temple Baptist Church MOA Wv2, Kingdom Word Ministries MOA Wv2, Memorial Missionary Baptist Church MOA W2, United Believers Community Church MOA Wv2, Good Samaritan Baptist Church MOA Wv2, Health Beliefs and Behaviors 12 month Version 1 Dated 8-2-2016, Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved12.05.16, Focus Group Discussion Guide Version 1 Dated 4.12.17, Focus Group Survey Version 1 Dated 4.14.17, Focus Group Informed Consent Script.Consent Form Version 2 Dated 4.17.17, Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016, Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean

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Copy Dated 2-10-2016_Approved, Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved

If a consent is being used in this research study you may find the stamped version in section 16 of your application.

The ability to conduct this study will expire on or before 12/04/2018 unless a request for continuing review is received and approved. If you intend to continue conduct of this study, it is your responsibility to provide a Continuing Review form prior to the expiration of approval or a final report if you plan to close the study.

This approval is issued under the University of Missouri - Kansas City's Federal Wide Assurance FWA00005427 with the Office for Human Research Protections (OHRP). If you have any questions regarding your obligations under the Board's Assurance, please do not hesitate to contact us.

There are 5 stipulations of approval:
1) No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (PIs and sponsors are responsible for initiating Continuing Review proceedings).
2) All unanticipated or serious adverse events must be reported to the IRB.
3) All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk. This includes any change of investigator.
4) All protocol deviations must be reported to the IRB.
5) All recruitment materials and methods must be approved by the IRB prior to being used.

Please contact the Research Compliance Office (email: umkcirb@umkc.edu; phone: (816)235-5927) if you have questions or require further information.

Thank you,

Cynthia Thompson
UMKC IRB

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* * * Continuing review * * *

To renew your protocol: 1. Complete this one-page form; 2. If necessary, update any sections of the protocol that need to be updated for the upcoming year (e.g., change in personnel, location) and attach any new supporting documents (e.g., other IRB approval letters); 3. Electronically "sign" the application by clicking in the check box on the "Obligations" page; 4. Remember to click "Submit Form" so that the IRB administrators receive your application. You must answer each question. Input N/A to answer any questions that are not applicable. NOTE: Documents that contain much of the information required to answer the participant number questions below can be found in the "Event History" section of each protocol.

1. **Summary: Number of Participants Associated with the Protocol:**

a. **Total number of participants approved to date:**

1540

b. **Number of participants studied since the last approval date:**

5 participants were enrolled during the Wave 1 focus groups sessions.

c. **Total number of participants studied since the beginning of the project:**

1505

d. **Number of participants remaining to recruit/enroll (total number of participants approved LESS the total number of participants studied to date):**

35

e. **Please explain if there is a discrepancy in participant numbers (e.g., more participants responded to a survey than had been approved):**

As part of our consent process, we review eligibility criteria and enroll our participants based on their self-reported information provided on the "Eligibility Form", which includes a series of questions based on the study selection criteria. We carefully review all eligibility form responses with the volunteering participants to ensure they have answered all questions appropriately and to determine if they have any questions. After consent, we give the participant the Health Beliefs and Behavior survey to complete that includes a question for them to report on their age. Once the survey is completed we give participants an envelope to put the survey in, seal and drop into a box. All surveys are stored in locked file cabinets in locked rooms until time of data entry. This process resulted in our recruitment of 1514 participants.

We have re-reviewed all completed eligibility forms for accuracy and found none reporting outside the eligibility criteria guidelines. However, based on current preliminary data verification of the 1514

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participants enrolled, we found:

3 participants under the age 18
9 participants over the age of 64
2 duplicate participants

This verification process has resulted in identifying 1500 qualifying participants who meet our eligibility criteria. The 14 participants who did not meet the eligibility criteria have been removed from the data set and hard copy surveys filed separately.

2a. Reasons and number of withdrawals from the research (both subject and investigator initiated) since the last approval date.

4 participants moved and 2 passed away

b. Number of subjects lost to follow-up since the beginning of the study.

None to report at this time.

c. Description and number of any protocol deviations/violations or unanticipated problems (UPs)/adverse events (AEs), particularly those that may have affected the risks to subjects since the last approval date.

Not applicable

d. Complaints about the research during the last year.

None to report.

3. A summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

Data entry is still on-going. Findings will be available with the next progress report.

4. Description of the remainder of project:

Y **Are research participants still being enrolled in the study?**

N **Have all enrolled research participants completed study participation?**

N **Is the research active only for long-term follow-up of enrolled participants?**

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Y Do you plan to recruit more subjects?

If "No," have all subjects completed all research-related interventions? Note: Protocols must be renewed to continue recruiting participants and/or collect data from already recruited participants.

N Are you in the data analysis stage?

Y Is the data de-identified?

(If you answered yes to these two questions you can stop and submit a Final Report. If you answered no to one of them please continue).

5. Has approval for this study expired? N

a. Why did approval lapse?

b. What will you do differently in the future to prevent this from happening again?

c. Were any additional research participants enrolled or data collected after the expiration date?

If Yes, describe all activities that continued including number of participants involved and any adverse event or incidents that occurred after expiration of approval.

NOTE: If renewal of the study does not occur before the expiration date of study approval ALL enrollment of participants and DATA COLLECTION must stop at the expiration date. Procedures and treatment needed for the safety of participants should continue but data collected during this time period CANNOT be used for research purposes.

6. Informed Consent:

a. Does this study use a consent form? Y

(if so please attach a copy of the previously approved "stamped" copy and a clean copy of the consent form)

7. Has there been additional or new information about this study which may affect a N

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subject's willingness to continue their participation, or that may need to be given to prior participants? (Such as safety information, complaints about the research, revised procedures, duration of study, recent literature, etc.)

If YES, please explain and describe how information was provided or is being provided to current or prior participants.

8. If this is a multi-center trial, has the most recent data safety and monitoring report or other summary report been submitted to the IRB since the last review?

If No, submit a current report.

9. Summarize all changes in the protocol since it was last approved (e.g., have you amended your protocol during the past year?). Are you requesting to make any changes for the upcoming year?

No changes are being requested at this time for the upcoming year.

Summary of the one amendment approved sine the last approval include::
Added and deleted study personnel
Added focus group evaluation component with use of electronic data collection method using REDCap application on tablets for short survey prior to focus group discussion

The focus group evaluation components are entitled "Amendment for post study focus group survey/discussion" for the following sections (and questions) throughout the protocol were applicable:
Personnel Information
Natasha Abduloju-Ajijola
Kelsey Christensen
Rayn Cutcher
Athira Jayan
Nia Johnson
Kartik Sreepada
Kayla Weru
Deleted
Marcie Berman
Therese Petty
Nia I. Thompson
Pang Vang
Victoria Poplin
Saige Stortz
Study Procedures
4a - provided explanation of focus group procedures (N=85)
4e - changed answer from "No" to "Yes" since we will be audio recording all focus group discussions
4i - provided description of focus group survey/discussion data analysis
Subject Population
6a - updated participant description

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6a - updated participant description
6e - provided inclusion and exclusion criteria for focus group participants
6f - provided screening criteria for focus group survey/discussion participation
7a - included additional participant reimbursement of $42 ($30 plus $12 est. meal) for post study focus group survey/discussion participation.
7b - added meal value
7c - added "For intervention evaluation" to clarify the text for the initial $45 total reimbursement pertains specifically to only the "first portion of the study" which is the intervention evaluation portion.
Recruitment Process
8a - updated participant recruitment strategies
8c - updated "other" response
Risks
9b and 9e: Maintained minimal risk and describe brief focus group survey on electronic tablet using the REDCap application.
Note for 9e: the response for the "Amendment for post study focus group brief survey and discussion:" section has been added as an upload entitled, "Response to Questions 9e for Amendment for focus group survey Version" due to limited space in the response section for this question.
Benefits
10a - updated focus group participation benefits for participants
Procedures to Maintain Confidentiality
11b - updated to clarify that unique identifiers will NOT be used during this phase of the study evaluation
11c - added how focus group discussion transcription and REDCap survey data will be stored
11d - added new study personnel names and deleted undergrads and staff no longer on the project
11e - updated to clarify that names will NOT be used on survey or during focus group discussion
11i - updated to confirm that no identifying info will be used to link data to participants
11j - noted, "not applicable"
11k- added description of REDCap download and storage
Attachments
Updated Informed Consent Form/Script with information on: a) whom to contact in the event of a research related injury, b) a statement that the participant may discontinue participation without penalty or loss or benefits to which they are otherwise entitled, and c) an explanation of the compensation the participant can expect to receive. Also, the text was edited to reflect a middle school reading level and a waiver of documentation of consent was submitted (see section 13). The updated consent form/script can be found as an attachment in "Other".

If necessary, proceed to the appropriate section(s) of the protocol and make your requested changes. Remember that if you are requesting to revise a document that is already attached, you must delete the already attached document and upload the revised document.

10. List of Protocol Sections (and questions) that have been changed/modified.

No changes or modifications made at this time.

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* * * Personnel Information * * *

Principal Investigator

UMKC defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.

Name of Principal Investigator	Degree (MD/PhD/BSN/etc.)	Title
Jannette Berkley-Patton	Ph.D.	Associate Professor
Email	**Phone**	**Fax**
berkleypattonj@umkc.edu		
Research Department	**UMKC Status** Check ALL that apply	**Mailing Address**
Psychology	X Faculty	5030 Cherry st, Room 308
	Staff	
	Other	

ALL research personnel are required to complete Human Subject Research training from CITI within the last 2 years prior to engaging in any research-related activities. Go to CITI Program to complete.

The Research Compliance Office will verify the last date of completion below.

CITI Training Date	Type of CITI training completed.
12/23/2013	Group 2 Social/Behavioral

Starred items indicate required fields whenever that section is completed.

Study Coordinator

Name of Study Coordinator	Degree (MD/PhD/BSN/etc.)	Title	Research Department
Carole Bowe Thompson	BS	Project Director	Psychology

Other Personnel

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Name of Other Personnel	Degree (MD/PhD/BSN/etc.)	Title	Research Department
Alexandra Booker	BS	Graduate Research Assistant	Psychology
Stephen Simon	PhD	Professor	School of Medicine
Annisah Thompson		Student Assistant	Other
Rita Reed		Research Assistant/Community Partner	Other
Allissa Patton		Student Assistant	Other
Sheil Lister		Research Associate	School of Medicine
Oluwashayo Oginni		Research Assistant	School of Medicine
Rachel Seymour		Research Assistant	School of Medicine
Nicole Tamer		Research Assistant	School of Medicine
Andrea Bradley-Ewing	MA, MPA	Research Assistant	Other
Johnique Jordan	BS	Research Assistant	School of Medicine
Jessica Gettleman		Research Assistant	School of Medicine
Joshua Williams		Research Assistant	School of Medicine
Tanisha Cobbs		Research Assistant	School of Medicine
Ashley Shaw		Research Assistant	School of Medicine
Cassidy Onukwuli		Research Assistant	School of Medicine
Juliet Gatiba		Research Assistant	School of Medicine
Jenifer Allsworth	PhD	Statistician	School of Medicine
Nia Johnson	BA	Research Assistant	School of Medicine
Natasha Aduloju-Ajijola	PhD	Post Doc Fellow	School of Medicine
Ryan Cutcher		Research Assistant	School of Medicine
Kayla Weru		Research Assistant	School of Medicine
Kartik Sreepada		Research Assistant	School of Medicine
Kelsey Christensen	BS	Research Assistant	School of Medicine

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Athira Jayan		Research Assistant	School of Medicine

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* * * Subject Checklist * * *

Subject Checklist

Select All That Apply :

- Children under 18
- Pregnant women
- Fetuses/neonates
- Prisoners
- Military personnel
- Adult Volunteers
- Economically/educationally disadvantaged
- Mentally Ill
- University students
- University employees
- Illiterate
- Homeless
- Public officials/candidates for public office
- Institutionalized patients/residents
- Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
- Healthy Individuals
- X Other (please specify):

Church-based adults

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* * * Study Location * * *

Study Location

Select All That Apply - NOTE: Check "Other" and input text: 1.) If your study location is not listed, or 2.) If you would like to list details of your already-checked location (e.g., specific school within a school district)

- X UMKC
- Truman Medical Center (TMC)

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Children's Mercy Hospital (CMH)

Other University/College

Other Medical/Health Care Facility

School/School District

X Other (please specify)

Calvary Community Outreach Network
African American Churches: Boone Tabernacle Church of God in Christ, Calvary Temple Baptist Church, Centennial United Methodist Church, Christian Fellowship Baptist Church, Concord Fortress of Hope Church, Grace Baptist Church, Jamison Memorial Temple Christian Methodist Episcopal Church, New Bethel Church, Palestine Missionary Baptist Church of Jesus Christ, Second Baptist Church, St. James United Methodist Church, St. John Missionary Baptist Church, St. Monica Catholic Church, St. Stephen Baptist Church, Trinity Temple Church of God in Christ, United Believers Community Baptist Church, and Zion Grove Missionary Baptist Church.

Added August 2016: Good Samaritan Baptist Church

Has this protocol been submitted to any other Institutional Review Board not listed above?	N
Is this a multi-site project? (A multi-site study is one where different PIs at different institutions are conducting the same study or aspects of the same study.)	N
Will UMKC function as the coordinating center or lead institution?	Y

(Please submit an IRB approval or Letter of Permission/Support from TMC or CMH if applicable, and for any site not under the jurisdiction of the UMKC IRBs.)

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* * * General Checklist * * *

General Checklist

Select All That Apply :

IRB Authorization Agreement (Please upload completed IAA form in Attachments section.)

X Federally Sponsored Project

Program Project Grant

Training Grant

Industry-Sponsored Clinical Trial

Project is associated with the School of Public Health (faculty and/or student)

X Cooperating/Collaborating Institution(s) Institution where recruitment will occur OR Institution where Collaborating PI will conduct associated research. — 14 African American churches

Interview

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X Questionnaire/Survey

X Subjects will be compensated for participation

Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval in Attachments section.)

Radioisotopes/radiation-producing machines, even if standard of care

Human blood, cells, tissues, or body fluids
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Tissues to be stored for future research projects
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Tissues to be sent out of this institution as part of a research agreement
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Human Embryos
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.
If applicable, PI should check with the IBC Compliance Officer to determine whether or not an application needs to be submitted to IBC

Use of Patient related equipment? If Yes, specify what equipment is being used.

Medical equipment used for human patients/subjects also used on animals. For questions regarding animal use approval, contact Jodi Troup, IACUC Compliance Officer: troupj@umkc.edu or 816 235-5669.

Protocol involves studying potentially addicting drugs.

Investigational drugs, reagents, or chemicals

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)

Investigational Device

This study involves drugs or devices regulated by FDA

Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).

Is the study posted on www.ClinicalTrials.gov? N

If Yes, Specify number:

If No, Explain the reason below.

The study is in Just-in-Time with the National Institute of Mental Health. Once a notice of award has been issued, the study will be posted on www.ClinicalTrials.gov.

Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.

The principal investigator or other research personnel have a financial, personal, or professional conflict of

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interest related to the study as defined in UMKC's Conflict of Interest Policy.
Class Project
Other (clarify in text box to the right)

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* * * Funding * * *

NONE--This project does not have any funding. If you want to add Funding for the study, please uncheck "NONE."

Funding

Add external and internal grant funding source(s) below: Federal Government, Other Gov. (i.e., State, local), Foundation or Other. Select "None" above if there is no external funding for the study.

UM Research Board

Federal Government

Name of Funding Source	National Institute of Mental Health
PeopleSoft Proposal Number	0034994
Title of Grant (if different from protocol title)	
Period of Funding	1-1-2014 to 12-31-2018

A copy of the grant/funding proposal and contractual obligations, if any, must be submitted for review with all funded research projects.

Other Gov. (i.e., State, local)

Foundation

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Other

Funding for this study was secured by the UMKC Grants Management Office

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*** * * Expedited Paragraphs * * ***

PLEASE READ: For Expedited Review, all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.

Select the following applicable categories to determine if your research project qualifies under Expedited Review. If none of the categories are applicable to your research project, a Full Committee Review will be required. For Expedited or Full Review, proceed to complete the following application.If none of the expedited criteria are appropriate for your project, please move to the next screen WITHOUT checking any of these criteria; your protocol will be reviewed by the full IRB. Note: The IRB will make the final determination if your protocol is eligible for expedited review.

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) and (b) are met.

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b) Research on medical devices for which

   i) An investigational device exemption application (21 CFR Part 812) is not required; or
   ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

   a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. **Prospective collection of biological specimens for research purposes by non-invasive means.**

Examples:

a) Hair and nail clippings in a non-disfiguring manner;

b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

c) Permanent teeth if routine patient care indicates a need for extraction;

d) Excreta and external secretions (including sweat);

e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

f) Placenta removed at delivery;

g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

j) Sputum collected after saline mist nebulization.

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4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b) Weighing or testing sensory acuity;

c) Magnetic resonance imaging;

d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimen) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

X 7. Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects - 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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* * * Summary,Purpose,Background,Study Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

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Complete Sections 1 - 16. Specify N/A as appropriate. Do not leave any required sections blank.

1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

CDC's HIV screening guidelines encourage routine screening of all individuals aged 13 to 64 in medical settings. However, many African Americans (AAs) have limited access to health care and barriers to HIV services may prohibit some from seeking HIV screening. The African American church is an institution with extensive influence in Black communities and may be an ideal setting for increasing reach of HIV screening beyond traditional medical settings; yet, no controlled studies exist on HIV interventions in AA churches. The primary aim of this study is to fully test a culturally/religiously-tailored, church-based HIV screening intervention (akaTaking It to the Pews [TIPS]) against a standard HIV information intervention on HIV screening rates at 6 and 12 months with adult AA church members and community members who use church outreach services. It is projected that 14 churches (7 churches per arm; 110 church and community members per church; 1,540 participants total) will be required to detect significant increases in HIV screening in the intervention arm. This approach includes church leaders delivering culturally/ religiously-appropriate HIV education and materials/activities (e.g., sermon guides, church bulletins) from a church-based HIV Tool Kit through church communication outlets (e.g., church-wide services, outreach groups) to motivate church and community members to seek HIV screening services.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

The purpose of this study is to fully test a culturally/religiously-tailored, church-based HIV screening intervention (TIPS) against a standard HIV information intervention on HIV screening rates at 6 and 12 months with adult AA church members and community members who use church outreach services. It is hypothesized that the TIPS intervention will significantly increase self-reported HIV screening rates vs a standard HIV information intervention in AA church-populations at 6 and 12 months. Our primary outcome is slef-reported receipt of HIV screening (tested vs. not tested) with church members and community members using church outreach services at 6 and 12 months. The role of potential mediators and moderators related to receipt of HIV screening will be evaluated and a process evaluation to determine modifiable implementation fidelity, facilitators, barriers, and costs related to increasing church-based HIV testing rates will be conducted. This intervention study could provide an effective, scalable model for HIV screening interventions in AA churches and could demonstrate signficant reach with AA church and community members. Additionally, this study expands our previously approved, completed study on Assessing Capacity for Developing HIV/AIDS Health Ministries in African American Churches (SSIRB Protocol # 016008).

3. Background

a) Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting

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the research. Include the rationale for the selected subject population.

Importance of HIV testing. HIV is one of the leading preventable diseases in the United States. The CDC estimates 1.1 million Americans are living with HIV, and 50,000 Americans are estimated to become infected each year. With the advent of effective HIV testing and treatment options, more HIV-positive (HIV+) individuals are experiencing reduced morbidity and mortality. However, to fully receive these benefits, individuals must know they are HIV+ early in the course of their disease. It is estimated 20% to 25% of HIV+ individuals are unaware of their status and may contribute to nearly 50% of all new HIV cases. Also, 32% of new HIV cases were considered to be late diagnoses. Studies conclude detection of HIV+ persons -- even in low-moderate HIV prevalence communities, is cost effective and an important strategy for HIV prevention. Also, early HIV treatment can greatly reduce disease transmission to HIV-negative (HIV) partners. A large portion of the US population has never been tested for HIV; and fewer are tested regularly. CDC updated their HIV screening guidelines to include routine screening of individuals aged 13 to 64 in health care settings in 2006. The goal of routine testing is to increase the number of persons screened for HIV whenever they have contact with medical settings. Using this strategy, individuals don't have to be perceived as "at-risk" for HIV screening referral. This is important due to changing demographics of HIV+ persons (e.g., heterosexuals, women) – particularly among AAs. However, universal, routine screening does little for AAs who do not have access to or do not regularly seek health services. Also, a national study found that only 29% of AAs received health care provider referrals for HIV testing. A primary goal of the National HIV/AIDS Strategy is to have 90% of all HIV+ persons aware of their status by 2015. To achieve this goal, nearly all US persons will need to know their HIV status.

HIV Disparities and African Americans (AAs). AAs continue to be disproportionately impacted by HIV/AIDS. HIV incidence rates were 8 times and 19 higher among AAs males and females than Whites, in 2008. Studies have found that AAs are more likely to experience delays in HIV treatment and are significantly less likely to receive effective treatment and other needed health services when they do get treatment as compared to Whites. Finally, AAs who die from AIDS-related diseases do so sooner than Whites and comprise almost half of all AIDS-related deaths each year. Effective, accessible HIV screening interventions for AA communities are needed to address these HIV disparities.

HIV Screening and AAs. Studies indicate that up to 68% of AAs have been tested for HIV in their lifetime as compared to up 49% of Whites; and 40% of AAs (versus 14% of Whites) reported getting an HIV test in the past 12 months. Despite higher HIV testing rates, AAs have disproportionately high prevalence of undiagnosed HIV (22%), indicating that more AAs could benefit from more frequent routine testing. Those unaware of their HIV+ status may significantly contribute to high rates of new AA HIV cases. However, many at-risk AAs often do not perceive themselves to be at risk, many have limited access to healthcare, and travel distance to HIV testing sites can be a barrier to HIV testing. With supportive tools and training, AA churches could offer support, motivation, and and availabe community-based HIV screening access to AA church members and hard-to-reach community members (e.g., high risk men, those not accessing healthcare). If proven effective, these strategies could exponentially expand efforts to motivate AAs to maintain their HIV-negative status and identify HIV+ AAs, facilitate linking them to care, and assist in meeting the National HIV/AIDS Strategy goal of having 90% of HIV+ persons be aware of their status.

Rationale for HIV Testing Interventions in AA Churches. There have been many calls from experts for AA churches to participate in promoting HIV education and screening. The AA church is a powerful institution with a history of mobilizing the community for social and political change and could provide an ideal venue for intervention with AAs who are at risk for HIV infection. Nationwide, studies indicate over 50% of AAs attend church once a week, with greater church attendance in the South and Midwest and with 65%

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representation by women -- a population highly disproportionately represented among new HIV cases. Furthermore, most AA churches: a) have three weekly services (e.g., Sunday services, bible study) and group ministries; b) share common religious activities (e.g., collective worship, preaching, testimonials, scripture reading, prayer); c) emphasize taking care of one's body -- seen as the "temple of God," d) have a history of coordinating health-related activities; e) have outreach ministries (e.g., clothing/food programs, social services, daycares) that reach adult community members at greatest risk for HIV; and f) have infrastructure capacity, such as meeting space, membership management systems, and volunteers, that could remove barriers and increase HIV screening access to AAs who may be at risk for HIV.

HIV Screening Intervention in AA Churches: Taking It to the Pews (TIPS) Pilot Study. Although most churches have participated HIV education activities with their members, few HIV screening interventions have been evaluated, and no well-controlled studies have been conducted in the church context. Our TIPS pilot study on church-based HIV screening aimed to increase slef-reported receipt of HIV testing among church members and community members from participating churches' outreach services. Trained TIPS church leaders delivered 1 to 2 tools per month and organized HIV testing events. Similarly, comparison churches delivered standard, HIV information (e.g., non-tailored brochures). Self-reported last 12-month HIV testing was significantly higher in the TIPS intervention group vs. comparison (22% to 59% vs. 19% to 41%, respectively; OR=2.04; CI (1.2-3.4); p=.007). Participants' reports on intervention exposure matched church liaisons' reports and archival records on their implementation activities. Increased intervention exposure was significantly related to receipt of an HIV test. This study could not demonstrate efficacy, as it was not fully powered with an appropriate sample size. However, the pilot study: demonstrated odds of HIV testing at 12 months were twice as high in intervention group vs. the controls, provided effect size estimates to determine power for proposed study, identified minimal stigma, identified needed new tools (e.g., linkage to care materials, HIV testing demonstration video), and allowed testing of several treatment fidelity monitoring strategies.

The current study expands the pilot study (Protocol #061008) into a full clinical trial with support from the Nationa Institute of Mental Health. Self-reported receipt of HIV screening is the primary outcome measure of interest.

4. Study Procedures (If this is a student project, the methods section of the thesis or dissertation proposal must be attached in section #16 - Attachment section.)

a) Describe sequentially and in detail ALL procedures in which the research subjects will be involved.

- **Include how the data will be collected (i.e. in person or online), number of sessions, amount of time per session, and duration or period of time over which the research will take place, etc.**
- **For school-based research where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and non-subjects will be located during the research activities.**
- **Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**
- **Use any diagrams, charts or tables necessary to make subject participation clear to readers. Attach additional pages if necessary.**

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- **Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.**

Please note: Do NOT respond "See Attachment Section". If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).

Determination of Number of Churches/Sample Size: Power Analysis. Sample size calculations were based on: a) change in expected self-reported HIV testing rates (primary outcome) from baseline to 12-month assessment and b) a group randomization and matched pair design based on a range of 5 to 7 paired churches (10 to 14 churches). To calculate power, we used Hayes' approach for cluster randomized trials through the specification of a coefficient of variation (CV) of cluster rates, which defines relative variation between clusters, rather than an intraclass correlation. We used our TIPS pilot study findings as the basis of our analysis (there are no other known studies on pre-post HIV testing rates with AA participants nested in churches) and expect similar HIV testing rates in the proposed study. Based on our CV estimates, we would have sufficient power with 10 to 12 churches (110 baseline participants per church; >65 participants at 12 months) to achieve 84% to 91% power, respectively, to detect this difference with a Type I error rate of 5%; these power calculations are conservative. However, we will include 14 churches to protect power against possible church attrition.

Recruitment of Churches. Seventeen KC urban churches provided letters of support to participate in the study (see Attachments) and will be approached to formally participate in the study. Eight churches have met criteria and agreed to participate in Wave 1 of the study (See their Memorandum of Agreements in Attachments). Selection criteria for churches include: a) a minimum of 150 AA church members, b) a pastor willing to assist in study delivery activities; c) ongoing outreach services (e.g., daycares, food/clothing programs, social services) to about 50 adult community members minimum, and d) not hosted and HIV-related event in the last year. To maximize church participation, all churches will receive: a) $3,000 for assisting in study delivery and recruitment-retention activities and; b) $1,600 for stipends for church liaisons coordinating study activities; and b) approximately $1,200 technology upgrades (e.g., phone message system for HIV/STD testing and survey event reminders); total of approximately $5,800. All churches will also receive promotional items (t-shirts, church fans).

Recruitment of Church/Community Participants. Impact will be tracked among 110 participants (approxiamtely 70 church members and 40 community members) from each of 14 AA churches, for a total of 1,540 participants (N = 770 intervention and 770 standard information church participants) assessed at baseline, 6, and 12 months. Similar to our pilot study, all participants must be: a) aged 18 to 64; b) willing to participate in 3 surveys after church services or community outreach events; c) willing to provide contact information (i.e., two phone numbers, mailing/email address, phone numbers for two persons with whom they have ongoing contact; and d) regularly attend church (>once a month) or use church outreach services (e.g., daycare services, food programs) > 3-4 times/year. Participants will receive $25 for completing baseline surveys (including $25 for additional waitlist baseline churches), $25 at 6-month, $30 at 12-month assessments, and snacks for their participation time and travel in completing the Health Beliefs and Behavior surveys. Participants will complete surveys (about 20-45 minutes) immediately after church services or during church outreach ministry events. They will receive compensation immediately after completing the survey at each time point.

Data collection. Data collection for this study consists of recruited Wave 1 participants completing a Health Beliefs and Behaviors survey assessment at baseline, 6 months, and 12 months. Wave 2 participants will complete the survey four times: baseline 1, baseline 2 (6 months), 12 months, and 18th months. The Health Beliefs and Behaviors survey instrument (see Attachment) was developed by the research team led by Dr. Berkley-Patton and tested for reliability/validity in the TIPS pilot study. The survey inquires

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participants about history of HIV/STD screening, facilitators/barriers to HIV screening, beliefs/social norms related to screening, risky behaviors associated with HIV/STDs, and exposure/satisfaction with study activities. Data collection procedures use the survey follow below.

1. Each participating church pastor will introduce the study PI (or research study coordinators) during the designated church service (e.g., Sunday morning or midweek service) and church community outreach event, which will be determined by each participating church's pastor. and leadership. The study PI (or research study coordinator) will then review the scripted consent form information (See Appendix A) during the church service with church membersand during the church outreach event with community members.
2. After the church services and church community outreach events, the research team will then review the informed consent script (See Appendix A) with willing adult members in the church's fellowship hall or large meeting room. The informed consent script will be used as a screening tool to identify eligible participants.
3. Once eligible volunteering participants have been identified, the research team member will review the informed consent form with the participant (See Appendix B). The form will include information about the study, the time commitment and reimbursement for participation, and how the survey information will be handled. The form will also inform the participant that their participation is confidential and completely voluntary. Additionally, the form will review the minimal risks for participating and PI and SSIRB contact information. They will be instructed to not include any personal identifiers on the survey and other survey materials.
4. If volunteering participants choose to participate in the survey data collection after the consent process, they will be given: a) the Health Beliefs and Behaviors Survey (used in our previous study Protocol 016008; See Attachement) to be completed in the church's fellowship hall or large meeting room at that time (they will be assured of ample room for privacy/confidentiality in completing the survey); and b) an unmarked manila envelope. The first section of the survey instructs participants to create their own study number (secret code) via a series of questions (e.g., first letter of your mother's first name). The survey includes questions regarding: their opinions on African American health screening behaviors (including HIV/STD screening) and preventive behaviors (e.g., exercise, not smoking, healthy eating), HIV/STD health risk behaviors, and beliefs about HIV/STDs. The survey also asks about religious activities, beliefs and knowledge about HIV/STDs, opinions on whether their church should be involved in HIV/STD-related activities and participant exposure to these activities, opinions about drug users and homosexuality, and their demographic information. Participants will also be asked about exposure and satisfaction to their relevant study treatment arm in surveys subsequent to baseline survey(s).
5. Upon completion of the survey, the participants will be asked to place the survey in the envelope and seal it. They will then be asked to place the sealed envelope in a large sealed box to further ensure anonymity. They will then be given the designated and thanked for completing the survey.

Feasibility/Program Evaluation Data Collected from Church Health Liaisons (CHL):
At least 2 church leaders, or church health liaisons, will coordinate implementation of their church's TIPS activities. These CHLs will be trained to monitor and report their church's implementation activities monthly over the 12-month study period by responding to questions on the CHL Intervention or Comparison Church Implementation Monitoring Form (Idependent on if they're in an intervention and comparison church; see Attachments). CHL's will complete implementation questions (no personal or behavioral information is requested) directly into REDCap, an online data entry database supported by UMKC's Center for Health Insights, which has been used extensively by research and community organizations around the world (see Section 11.c for further information about REDCap). CHL's at participating churches will have password access to this system to enter process data on intervention implementation information (e.g., number of persons attending events, location of events, organizations and resources assisting in implementing events, challenges and accomplishments related to the events). No personal health or behavioral data will be collected on intervention Implementation -- only program

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evaluation information. The online system will significantly reduce the amount of time needed for church liaisons to provide implementation data by allowing them to select responses from a pull down menu and provide short string text for open ended responses.

Research Design: We will use a 2-arm, research design with 14 churches (7 intervention and 7 standard information control churches) matched on church membership size, SES, and denomination. Matched churches will be randomly assigned to one of two Waves and then to intervention or standard information arms within their Wave. To optimize study management, 8 churches will be in Wave 1, and 6 Wave 2 churches will be 6-month waitlisted.

Intervention Arm. The intervention (Taking It to the Pews; TIPS) will be delivered through church-based multilevel (community, church-wide, ministry group, interpersonal/individual) activities by trained church leaders using religiously/ culturally-tailored study materials (sermon guides, responsive readings, educational games, brochures, educational/testimonials; see Attachments "Materials for Intervention Churches" and "Poster for Intervention Churches") packaged in a TIPS HIV Tool Kit and following a scripted, study implementation manual. Each church will appoint a Health Action Team (two church liaisons and other members) that will deliver study activities and organize HIV testing events with the Kansas City Health Department. Intervention churches will receive the TIPS HIV Tool Kit, including a study manual. These churches will hold a TIPS Kick-off event, where TIPS tools (e.g., a sermon, a responsive reading, an HIV testing video testimonial, two brochures, and a church fan) will be delivered along with the first HIV testing event. After the Kick-off, liaisons will deliver 1-2 Tool Kit materials/activities per month through targeted multilevel church activities); minimum of 24 tools over 12 months. Two additional HIV/STD screening events will be planned and will be open to all persons seeking screening, including study nonparticipants who are interested in free Kanas City Health Department HIV screening. Delivery of intervention components will coincide with existing, multilevel activities that occur in churches through: a) a communitywide outreach ministry events; b) churchwide services, b) inreach/outreach ministry groups; and c) individual level activities over 12 months.

Standard Information Control Arm. Our standard information churches will receive standard multilevel HIV education information similar in type to those provided to the intervention churches. These churches will receive: a) non-tailored project materials (brochures, see Attachment "Materials for Comparison Churches") collected from health organizations and b) standard, non-tailored activities (e.g., community-based HIV testing events) coordinated by their church liaisons. Similar to the intervention churches, control churches will distribute 1-2 nontailored, standard information materials each month. These churches will receive all HIV Tool Kit materials after the completion of 12-month assessments.

Church-based HIV/STD testing. The Kansas City Health Department will provide three free HIV/STD testing events at both the intervention and standard information control arm participating churches, as part of their usual church-based HIV/STD screening, using their standard community-based standard procedures. Church health liaisons will coordinate the screening events for their churches. Free HIV/STD testing is also provided at KCHD clinics and community clinics (e.g., KC CARE); church and community members who do not want to get tested in church can receive free HIV/STD testing at these location if they so chose. KCHD will follow-up with clients with their screening results as needed following their standard protocols. KCHD will report total number of persons tested/receiving results with aggregate, de-identified demographics (e.g., age, gender), and number of HIV+ tests given per church to study staff. Individual participants' results will not be shared with church leaders/members or study staff since KC Health Department will not be provided any information about study participants; therefore, they will not know whether persons voluntarily seeking HIV/STD testing are involved in this study. KC CARE Clinic's HIV Linkage to Care free services, following their standard community-based procedures, will also be available

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to church and community members with additional counseling and support for anyone in participating churches who newly (or previously) tested positive for HIV. KC CARE will report total number of persons receiving Linkage to Care services with aggregate, de-identified demographics (e.g., age, gender), and number and types of support provided (e.g., linked to insurance, health providers, social services) to study staff. KC CARE will not be provided any information about study participants; therefore, they will not know whether persons voluntarily seeking their services are involved in this study. All standard procedures and guidelines will be followed by KC Health Department and KC CARE in conducting community-based HIV/STD screening and linkage to care services in the church settings. The current study does not interfere with with their standard protocols in providing free, HIV/STD screening in church settings.

Amendment for post study focus group survey/discussion:
Church members and community members using church outreach services (N=85; aged 18 and older) from the 7 participating intervention churches will be recruited to participate in post study focus groups with accompanying brief survey. Post study survey/focus group discussions will help us better understand the accomplishments, challenges, and refinements needed for the intervention study. The brief survey will include the following items: demographics; church membership, HIV and other STD testing, beliefs/intentions/opinions, and exposure and satisfaction with TIPS intervention (See Post Study Survey). Participants will complete the survey using the UMKC REDCap application on on electronic tablets (For additional description and security information, please refer to comments provided in "Risks" and "Procedures to Maintain Confidentiality" sections).

The post study focus group discussions will consist of discussion on satisfaction with the study activities, challenges and benefits of the church's participation in the study, and improvement/refinements needed (See Post Study Focus Group Discussion Guide).

Survey/focus group participants will receive a meal (estimated value of $12) and $30 for participating in the survey/focus group activity. Brief surveys will be administered to the focus group participants during each focus group meeting just prior to the start of the focus group discussion. Surveys are expected to take about 20 minutes to complete. Focus groups are expected to last 1½ to 2 hours and will take place at designated participating churches. Participants will not include any identifying information on the brief surveys. Surveys information will be anonymous. Assistance will be provided to any participant needing help while completing the survey on an electronic tablet. All focus group discussions will be digitally audio recorded.

Participants will be given a pseudonym (not their own name) for use during the focus group discussions to maintain confidentiality; they will be instructed to not announce their names during the recording. Focus group activities will be led by the PI (or trained research team member). Focus group discussions will be transcribed from the digital recording verbatim without the use of participants' name; instead, pseudonyms will be use in the transcriptions.

b) Alternative Procedures. Describe alternative procedures, if any, that might be advantageous to the subject. Describe the important potential risks and benefits associated with the alternative procedure(s). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.

See description of the Standard Information Control Arm procedures above. All participants in the Intervention and Control Arms will have access to three HIV/STD testing events, which will be coordinated by church health liaisons. The Kansas City Health Department offers free community-based HIV/STD

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testing events throughout Kansas City and at the health department. Additionally, participants will be informed that they can seek HIV/STD testing for free at these and other locations throughout the Kansas City area.

c) **Will subjects be followed after their active participation is complete?** N

If yes, explain why and describe how:

d) **Will subjects have access to the study treatment/procedure after completing the study?** Y

If yes, explain why and describe how:

All intervention materials will be provided to all of the participating churches upon completion of the study. Churches will be provided with annual booster meetings and technical assistance will be available to the churches even after the completion of the study to sustain the intervention activities.

e) **Will subjects be audio recorded?** Y

f) **Will subjects be videotaped?** N

g) **Will subjects be photographed?** N

(Explicit consent must be obtained for the use of any of these methods.)

h) **Study Endpoint. What are the guidelines or end points by which you can evaluate the alternative treatments during the study? If one treatment proves to be clearly more effective than another (or others) will the study be terminated before the projected total subject population has been enrolled? When will the study end if no important differences are detected?**

The delivery of this intervention study will take place over 12 months at the participating intervention and control arm churches. All participant assessments will be conducted via a pen/paper Health Beliefs and Behaviors survey will take place at baseline, 6 months, and 12 months. The pilot study showed borderline effects at 6 months, but did not indicate significant effects until 12 months. Additionally, one of the goals of the study is to demonstrate that the TIPS intervention is scalable and has the ability to motivate many more AA's to seek HIV/STD testing. Therefore, we anticipate that the study will need to be completed over the designated 12 month timeline with participants completing 12-month surveys at which point the study will end -- even if non-important differences are detected.

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i) **Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).**

Data will be initially summarized using means, standard deviations, and percentages. Our primary outcome is self-reported receipt of HIV/STD testing (tested vs. not-tested) at 12 months. We'll also examine outcomes at 6 months. Churches are the unit of randomization and participants nested in churches will be the level of analysis. Therefore, differences between intervention and standard information groups will be analyzed using random effects logistic regression to account for the clusters and the pairing, or matching, of churches. Multilevel, multivariate models will include fixed-effect terms for experimental condition and potential mediators and moderators, as well as random effect terms for church nested in treatment condition and individual nested within church. This approach has been widely used in other church-based studies. Adjusted odds ratios for HIV testing (and confidence intervals) will be computed for mediators/moderators. Other covariates will be added as indicated by univariate analyses conducted on baseline data. A propensity score matched analysis will also be run using all available covariates.

Amendment for post study focus group survey/discussion:
Survey data will be summarized using means, standard deviations, and percentages. Focus group discussions will be audio-recorded, transcribed, and coded. Coding protocols will include initial transcription "open-coding" (e.g., identifying key words, themes, behavioral descriptions), category grouping (e.g., church-based health screening barriers), and code map development to further categorize and retrieve factors (e.g., challenges, facilitators) related to delivery/receipt of programming/services and intervention refinement strategies/tools. Intercoder agreement will be assessed with the kappa coefficient.

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* * * Drugs and Devices * * *

5. Drugs and Devices

Device

Will the study be registered on an online website? Y

If yes, state which website(s):

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ClinicalTrials.gov

If no, explain why not:

(If the study will be registered on ClinicalTrials.gov, the consent form must contain the required language about it.)

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* * * Subject Population (a-d) * * *

6. **Subject Population - In the space below, please detail the participants that you are requesting to recruit (include requested participant number and description of each group requested). (Input N/A if not applicable)**

a) **Requested Participant Description (Include number of participants that you plan to study and description of each group requested, if applicable).**

Participants will consist of 110 adults (70 church members and 40 community members) from each of 14 AA churches, for a total of 1,540 participants (N = 770 intervention and 770 standard information church participants) assessed at baseline, 6, and 12 months. All participants must be: a) aged 18 to 64; b) willing to participate in 3 surveys after church services; c) willing to provide contact information (i.e., two phone numbers, mailing/email address, phone numbers for two persons with whom they have ongoing contact; and d) regularly attend church (>once a month) or use church outreach services (e.g., daycare services, food programs) > 4 times/year.

Amendment for post study focus group brief survey and discussion: 85 church and community members will be recruited from the 6 participating churches. All focus group survey/discussion participants must be: a) African American, b) aged 18 or older, and c) from a participating church.

b) **What is the rationale for studying the requested group(s) of participants?**

Past HIV prevention efforts have targeted African Americans in educational, medical, public housing, social service, street outreach, and community-wide settings. Yet, the Black church has been a virtually untapped setting for HIV intervention research. Though increasing in practice, church-based HIV studies are still limited; no controlled trial studies exist on church-based HIV screening with church members and the community members they serve. Additionally, studies indicate over 50% of AAs attend church once a week, with greater church attendance in the South and Midwest and with 65% representation by women--a population highly disproportionately represented among new HIV cases. Furthermore, studies have

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demonstrated that church-based populations engage in behaviors that put them at risk for HIV at rates similar to the general population.

c) **If women, minorities, or minors are intentionally excluded, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.** N/A

Minors 18 and under are intentionally excluded since the intervention study has been designed specifically for adults with information of how HIV affects African American adult populations. To include children, additional intervention strategies tailored for this younger population would need to be designed -- and this is cost and time prohibitive with the resources allotted from the pending grant funding.

d) **State if any of the subjects are students, employees, or laboratory personnel. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.** X N/A

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* * * Subject Population (e-h) * * *

6. **Subject Population (Input N/A if not applicable)**

e) **Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)**

Identify inclusion criteria.

All participants must be: a) aged 18 to 64; b) willing to participate in 3 surveys after church services or during church outreach events; c) willing to provide contact information (i.e., two phone numbers, mailing/email address, phone numbers for two persons with whom they have ongoing contact; and d) regularly attend church (>once a month) or use church outreach services (e.g., daycare services, food/clothing programs, social service programs) > 4 times/year.

Amendment for focus groups survey/discussion: All participants must be: a) African American, b) aged 18 to 64, and c) a church or community member from one of the participating 7 intervention churches.

Identify exclusion criteria.

Exclusion criteria include participants who: a) are under the age of 18, b) are not proficient in reading/speaking English, c) cannot complete the survey independently, or d) who are not regular church members (attend church < once a month) or community members who do not regularly use participating

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members (attend church < once a month) or community members who do not regularly use participating church outreach services (< 4 times/year).

Amendment for focus groups survey/discussion: All participants who: a) are not African American, b) under the age 18, and c) are not a church or community member from one of the participating 7 intervention churches.

f) Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire) in the Attachment Section (#16).

Participants will be screened to ensure that they are 18 or older, willing to participate in the 3 surveys, willing to provide contact information (see above in e.), and regular church members or community members using church outreach services (see Attachment Informed Consent Script).

Amendment for focus groups survey/discussion: Participants will be screened to ensure they are: a) African American, b) aged 18 to 64, and c) a church or community member from one of the participating 7 intervention churches. (See Informed Consent Script/Consent Form).

g) Will bilingual or multilingual subjects be recruited? N

h) Will non-English speaking subjects be recruited? N

If yes, state language(s) spoken (other than English):

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* * * Subject Compensation and Costs,Recruitment Process * * *

7. Subject Compensation and Costs Section

a) Will subjects receive compensation for participation? Y

Total amount (in dollars or equivalent)

Wave 1: $80;
February 2016 Amendment - Wave 2: $105 (extra $25 for second baseline)
Focus Group $42 total reimbursment ($30.00 plus $12.00 est. meal)

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b) Form of Compensation:

- N/A
- X Cash
- Check
- Gift card/certificate
- Voucher
- Raffles/lotteries
- Course/extra credit
- Reimbursement only
- X Other (please specify):

T-shirts, pens, church fans

Amendment for focus groups survey/discussion: meal valued at est. $12.00

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

Wave 1 Participants will receive their cash reimbursement immediately after they complete each survey assessment: $25 (baseline), $25 (6-month), and $30 (12-month). Participants will receive payments at their respective church immediately upon submitting their completed survey (in an sealed envelope) in the sealed box.
Additionally, all participating churches will receive: a) $3,000 for assisting in study delivery and recruitment-retention activities and; b) $1,600 for stipends for church liaisons coordinating study activities; and b) about $1,200 technology upgrades (e.g., phone message system for HIV testing and survey event reminders); total of $5,800. Monetary incentives will be disbursed to churches quarterly over 12 months.

February 2016 Amendment - Wave 2 participants will receive their cash reimbursement immediately after they complete each survey assessment: $25 (baseline 1), $25 (baseline 2), $25 (12-month), and $30 (18-month). Similar to Wave 1, Wave 2 participants will receive payments at their respective church immediately upon submitting their completed survey (in an sealed envelope) in the sealed box. Monetary incentives will be disbursed to churches quarterly over an 18-month time period.

Amendment for focus groups survey/discussion: Participants will receive a meal (estimated value=$12) upon arrival at the focus group. For their time in participating in the focus group survey/discussion, participants will also receive cash reimbursement of $30 immediately after: a) they complete the brief survey and b) the focus group has ended.

d) For raffles include the number of prizes, nature and value of each prize.

N/A

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e) For course or extra credit, describe the available alternatives to participation in the research.

N/A

f) Will subjects or their health care providers be required to pay for any study related procedures or products? N

If yes, explain:

g) Who is responsible for costs incurred due to injury/harm?

Based on our previous similar study, no injury or harm was incurred. However, if a participant does incur an injury or harm, the cost of such incident will be the responsibility of the participant.

8. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- List any specific agencies or institutions that will provide access to prospective subjects.
- Identify who will contact prospective subjects and how.

Twenty-two churches have provided letters of support for the study (see letters of support in Attachments). Eight churches have met criteria and agreed to participate in Wave 1 of the study (See their Memorandum of Agreements in Attachments). Church participants will be recruited to participate in the Health Beliefs and Behaviors survey at their respective churches (see Letters of Support from participating churches) during a regularly scheduled church service and during church community outreach events (e.g., food/clothing pantry, social services). The participating churches will provide the study research team access to their church members, allow study investigators to share information about the study using the informed consent script (see informed consent script in Attachments) during church services, and allow investigators to recruit members individually after church services within their respective church. The PI along with assistance from trained research team members will explain the purpose of the study to interested church members after church services and during church community outreach events. The research team will review the informed consent script selection criteria with interested participants. They will then consent (see informed consent form in Attachments) up to the first 110 members from each church who express interest in the study and meet selection criteria. Participants will be informed that participation in the study is voluntary and they can discontinue participation at any time.

February 2016 Amendment:
Participating churches
- Sunlight Missionary Baptist Church
- Glory Bible Fellowship International Church(existing)/Destiny Life Center(new partner church)
Memorandum of Agreements (MOA) have been uploaded in the "other attachments" section.

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Memorandum of Agreements (MOA) have been uploaded in the "other attachments" section.

Only six of the eight churches that met the eligibility criteria participated in Wave 1. Palestine Missionary Baptist Church will not be participating due to other church priorities. Victorious Life Church was delayed due to other commitments and will participate in Wave 2. Therefore, Wave 2 churches will include 8 churches.

Church recruitment is ongoing for Wave 2 and additional churches will be added in subsequent amendments.

March 2016 Amendment:
Added participating churches
- Paseo Baptist Church
- Swope Parkway United Christian Church

August 2016 Amendment
~ Removed church name, El Shaddai International Ministries Church, previously listed under "March 2016 Amendment".
~ Added participating church, Good Samaritan Baptist Church

Amendment for focus groups survey/discussion: Recruitment of post study survey/focus group participants will take place in participating churches by the PI (or other research team member), who will attend participating churches' services/ministry meetings to share information about the post study focus groups. The evaluation procedures will be reviewed using an informed script/form (see Post Study Informed Consent Script/Form). Survey completion and focus group participation will be entirely voluntary.

b) Describe solicitation through the use of advertising. (Include plans for using posters, flyers, announcements, newspaper, radio, television or internet ads, face to face interactions, direct mail or phone contact, subject pools, etc.)

Participants will be recruited in Kansas City African American churches that have provided support letters for the pending grant. Eight churches have met criteria and agreed to participate in Wave 1 of the study (See their Memorandum of Agreements in Attachments; additional churches will be added for Wave 2). The PI will request opportunities to personally share information about the study in local churches during Sunday and Wednesday night services. In order to recruit community members, the PI will request opportunities to discuss the research study prior to and after church activities and outreach events that community members attend. Each recruitment information source will contain information on study objectives, selection criteria, time commitment, and PI contact information (see informed consent script in Attachments). Interested volunteers will be screened by the PI and other study staff; study objectives, selection criteria, and time commitment will be explained; informed consent will be obtained; and contact information collected. Enrollment of participants will occur prior to the start of any intervention/standard information group activities and will be triggered by expressed interest of the potential participant and the delivery of a completed baseline survey.

c) Planned Subject Identification Methods:

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N/A
Direct advertising
Chart/database review
Living conditions (e.g., nursing home residents)
Class participants
From PI's own practice/clinic
Circumstance (e.g., homelessness)
Referrals
Organization mailing lists
X Other (please specify):

Announcements and information shared by PI/trained study teamusing information in informed consent script during church services and church-related community outreach activities.

d) Planned Recruitment Materials/Methods:

N/A
Flyers/posters
Phone Scripts
Letters to providers/schools/organizations
Television ads
Newspaper ads
Letters to prospective subjects
Radio ads
X Oral Scripts
PowerPoint presentations
X Other (please specify):

Amendment for focus groups survey/discussion: Announcements and information shared by PI/trained study team using study informed consent script form during church services and church related community outreach activities.

***(All advertising must be submitted for review in its final printed/recorded form)**

e) Will the PI use a centrally coordinated advertisement program? N

f) Will a central 800# facility be used for recruitment? N

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If yes, identify the calling company:

Note: Attach copies of ALL recruitment materials in the attachment Section

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*** * * Risks * * ***

9. Risks (Input N/A if not applicable)

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) PI's evaluation of the overall level of Risk. (Please check one: minimal or > minimal.)

Y **Minimal (everyday living)**
> Minimal (greater than everyday living)

b) Discuss the risks of the proposed research. Specify the risks(s) associated with each procedure or test. Consider both physical and psychological/emotional risks. (If applicable, include possible breach of confidentiality.)

The risk of harm is minimal for participants in this protocol. Given that this is an expansion of previously approved study Protocol #061008, where there were no known risks, we continue to anticipate no additional risks. It is possible that participants could experience distress or discomfort caused by: discussing issues related to HIV risk, HIV testing, and other emotionally charged topics when completing questionnaires. Furthermore, participants could experience risk of loss of confidentiality regarding their survey responses if study surveys were seen by others. Participants in both the intervention and control conditions could voluntarily chose to seek HIV testing during the study which could possibly, regardless of result, cause discomfort and distress.

Amendment for focus group survey/discussion:
The risk of participating in the focus group survey/discussion is minimal. It is possible that participants could experience distress or discomfort caused by discussing issues related to HIV/STD risks and other emotionally charged topics when completing questionnaires. However, the survey does not include sensitive topics and survey completion will be conducted using an electronic tablet with a UMKC REDCap application, which will reduce potential breach in confidentiality of survey responses, since survey

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application, which will reduce potential breach in confidentiality of survey responses, since survey responses will be downloaded directly to a pasword protected UMKC fire walled server hosting the REDCap database used with this project. All survey data will be aggregated without personal identifiers in the survey reports, publications, and presentations. Research team members are trained to not divulge participants' information in anyway outside of the agreement upon original disclosure. In the event that a research team member is also a member of a participating church, other team members will administer the survey data collection at that participating church.

c) **How will subjects be assessed for adverse events?**

We do not foresee the occurrence of any serious adverse event; however, monitoring information for any such events experience by study subjects will include: a) report given by study subjects to study staff either in person or by telephone; b) report given to study staff by study subjects' family or friends either in person or by telephone; c) other persons, including study staff, that may have knowledge of such serious adverse event.

d) **Is there a plan to monitor study data for subject safety?** N

If yes, discuss who will monitor the study data and describe the monitoring plan:

e) **Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).**

To protect the security of responses on surveys, participants will be asked to construct a unique identifier using a series of questions (e.g., "first letter of your mother's first name"). Participants will write their unique identifier on all survey materials. Participants' unique identifier number will only be on collected survey data will serve as their study number. Participants will be assured they may skip evaluation items they do not want to answer. Participants will be asked to complete surveys at their participating church with plenty of space for privacy in either church sanctuary, fellowship hall, or meeting space. Participants will put completed surveys in an unmarked envelope and submit the envelopes in a sealed box. All surveys will be stored in a locked filing cabinet (in a separate cabinet from completed surveys) in our secured study office. Survey data entered on designated study university computers will be stored in databases in university password-protected, firewalled electronic files. All survey data will be aggregated without personal or church organization identifiers in the survey reports, publications, and presentations. Research team members are trained to not divulge participants' information in anyway outside of the agreement upon original disclosure. In the event that a research team member is also a member of a participating church, other team members will administer the survey data collection at that participating church. If any participant experiences distress while completing a survey, they will be given referral information that contains the names, addresses, and phone numbers of organizations they can contact for help, such as KC CARE Clinic and other community mental health services, and university counseling centers.

Participants will also complete a separate tracking sheet that will request identifying information (name, phone number, email address, contact numbers of others who have ongoing contact with participant, and church) for follow-up purposes at 6 months and 12 months. Tracking sheets will be stored in a locked filing cabinet (in a separate cabinet from completed surveys) in our secured study office. The study staff will be carefully trained to protect participant confidentiality. They will devise a plan with the participants for appropriate means of making contact with the participant. For example, what phone numbers they may

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appropriate means of making contact with the participant. For example, what phone numbers they may use and whether they may leave a message. Only appropriate study staff will have access to the locked study data.

The Kansas City Health Department customarily provides HIV screening in community settings, including church settings. Church leaders will coordinate directly with the Kansas City MO Health Department to have HIV screening events in their churches following health department standard procedures for churches. Partcipants, along with any other persons, will be able to seek free, HIV screening in their churches as offered by the Kansas City Health Department (per their standard procedures), if they so choose. Participants, along with any other persons, will also be able to seek confidential HIV screening at local health clinics or their private physicians, if they so choose. Seeking HIV screening in church-based or any other community or medical setting is totally voluntary and is not a requirement to participate in this study. The health department HIV screeners are appropriately trained to follow health department protocols in providing culturally-tailored, compassionate community-based testing and counseling while providing test results. All HIV screeners have completed State of Missouri HIV Counseling and Testing Training and will provide any referral to supportive or mental health services if determined that a person seeking screening is in distress.

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* * * Benefits * * *

10. Benefits

a) Discuss any potential direct benefits to subjects from their involvement in the project that would justify involvement of subjects in this study.

The participants receiving intervention and standard information group activities may improve their HIV knowledge and motivation to seek HIV testing. Participants in the intervention arm will receive several items to related to HIV education. This includes the opportunity to receive culturally-tailored HIV educational materials and information. They can also choose to receive free HIV risk reduction counseling and access to free, confidential HIV screening in their church setting. Individuals may benefit from knowing that their participation in the study will provide important scientific data. Churches in the standard information condition will receive standard HIV information and will also coordinate free, HIV screening events similar to intervention churches. The comparison churches will also receive intervention materials after completing one year in this condition.

Amendment for focus groups survey/discussion: The focus group participants may benefit from knowing that their participation in the focus groups will provide important feedback on the success and challenges of implementing an intervention and raise their knowledge about HIV and other STDs. They may also learn information that may be helpful in creating health promotion programs in their church and community.

b) Discuss any potential indirect benefits to society that would justify involvement of subjects in this study.

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The larger African American community will more likely benefit from the knowledge gained in understanding the effectiveness of intervention, particularly if proven effective and packaged for wider dissemination.

c) **Briefly assess the risk/benefit ratio of the subject's participation. (Include consideration of alternative therapy, benefit to the class of patients, and benefits to society. Describe the subjects' alternatives to participation in the study.)**

The potential risks to the participants are not significantly greater than those posed by exposure to HIV risk behavior and testing information and services available in their natural environments. Furthermore, we have taken steps to put safeguards in place to minimize anticipated risks. Therefore the evaluation of the risk:benefit ratio for this proposal is that the minimal risks are outweighed by a potentially benefits to the larger community.

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* * * Procedures to Maintain Confidentiality * * *

11. Procedures to Maintain Confidentiality

a) **If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.**

N/A: Subjects information will not be provided to any other entity (e.g., personal physician, government agency, or any other person/group).

b) **Explain how you will protect subjects' privacy.Note: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Please keep this definition in mind as you respond to this item.**

We will protect subjects' privacy by:
a) Not collecting any personal identifiers on the survey or on the survey envelope.
b) Having participants construct a unique identifier using a series of questions (e.g., “first letter your mother's first name”). Participants will write their unique identifier on all survey materials. The questions and formatting of responses have been edited to further reduce the possibility of disclosing participants’ identity and for participants to easily recreate the identifier for follow-up 6-month and 12-month surveys.
b) Having participants complete the survey in their church's fellowship hall/large meeting room to give them privacy in completing the survey.
c) Having participants put completed surveys in an unmarked envelope and submitting the envelopes in a sealed box at their participating church.
d) Aggregating all church survey data without personal or church or organization identifiers in the survey reports, publications, and presentations.

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They will also complete tracking (contact) sheets, which will request identifying information (name, phone number, email, address, contact information for two other persons who would know how to contact participant) for follow-up purposes. Tracking sheets will be stored in a locked filing cabinet in our secured study office and will be destroyed after all follow-up data is collected.

For post study focus group survey/discussion: Participants will not use personal identifiers during the focus group discussions. They will be given pseudonyms to use during the discussion. Transcriptions of the discussions will not include participants' names; instead the pseudonyms will be used in the transcriptions.

c) **Describe how you will maintain the confidentiality of subjects' information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.**

No personal identifiers (e.g., names, church names, organization names) will be collected on the survey or any other survey materials. If a participant happens to inadvertently write personal information on survey materials, the information will be removed. Only trained, appropriate study staff will have access to study data. Research team members are trained to not divulge participants' information in anyway outside of the agreement upon original disclosure. In the event that a research team member is also a member of a participating church, other team members will administer the survey data collection at that participating church. Participants surveys and tracking sheets will be stored separately in locked file cabinets in the PI's locked research lab in the UMKC Psychology Department. Only study team members (see below in section d) will have access to surveys and tracking sheets stored in paper copy form. Also, only study team members will enter survey data and have access to this data in password, protected univeristy firewalled electronic files on designiated university computers assigned to the PI. No personal identifiers are entered are linked during data entry of completed surveys.

All survey data is entered and stored on a password-proteced UMKC, firewalled, computer network. All survey data are entered and stored on a password-proteced UMKC, firewalled, databased system, REDCap (Research Electronic Data Capture) computer network. REDCap was developed specifically around
HIPAA-security guidelines. REDCap servers are housed in a local UMKC data center, and allwebased
information transmission is encrypted. Only study team members (see below in section d) will have access to surveys and tracking sheets stored in paper copy form. Also, only study team members will enter survey data and have access to this data in password, protected univeristy firewalled REDCap data files and electronic files on designated university computers/servers assigned to the PI.

For post study focus group survey/discussion:
Focus group survey data, audio-recorded discussions, and subsequent transcripts will be stored in UMKC network servers in firewalled and password-protected electronic files.

We will use the REDCap app on electronic tablets for participants to complete the brief focus group survey.The app employs encryption-at-rest on the mobile device's hard drive, so unauthorized users

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cannot access data in the app even if they gained access to the device's file system. Data transmitted to/from the app is done using a secure, encrypted transmission (SSL/HTTPS), the app verifies the SSL certificate of the REDCap server it's communicating with to validate the server's identity, no data can be stored on external hard drives connected to the mobile device, and there is a remote lockout feature. The app can be used to collect data offline, which would allow us to more efficiently collect our survey data in churches. The use of the app would also greatly reduce student/staff time and costs in data entry.

d) **Who will have access to study records or specimens? (Please identify specific team members by name.)**

Reserach team members in Dr. Berkley-Patton's research lab will have access to participants' surveys for purposes of storage, data entry, and data analysis. These team members include:
-Jannette Berkley-Patton
-Carole Bowe Thompson
-Marcie Berman
-Alexandria Booker
-Steven Simon
-Therese Petty
-Nia Thompson

February 2016 Amendment
-Annisah Thompson
-Pang Vang
-Rita Reed
-Allissa Patton

March 2016 Amendment
- Andrea Bradley-Ewing
- Jessica Gettleman
- Johnique Jordan
- Sheila Lister
- Oluwashayo Oginni
- Victoria Poplin
- Rachel Seymour
- Saige Stortz
- Nicole Tamer
-Joshua Williams

May 2016 Amendment
- added:Tanisha Cobbs

August 2016 Amendment
~ Added the following names: Jenfier Allsworth, Ashley Shaw, Cassidy Onukwuli, Juliet Gatiba
~ Removed the following CITI certified staff/volunteers: Samantha Dodda

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April 2017 Amendment
~ Added the following names:
Natasha Abduloju-Ajijola
Kelsey Christensen
Rayn Cutcher
Athira Jayan
Nia Johnson
Kartik Sreepada
Kayla Weru

~ Removed the following CITI certified staff/volunteers:
Marcie Berman
Therese Petty
Nia I. Thompson
Pang Vang
Victoria Poplin
Saige Stortz

e) **Will data be collected anonymously (i.e., NO identifying information from subjects will be collected, recorded, or linked to the study data)? If not, please explain.**

The survey data will be collected anonymously through participants' creation of their own study number (secret code) by answering a series of questions (e.g., first letter of mothers first name). They will recreate the secret code on their surveys at 6 and 12-month assessments. Although we will collect contact consent and contact information, this information will not be linkable to their survey data.

February 2016 Amendment
For participants in Wave 2 churches: Participants will also create their secret at baseline 1 (same as above with an additional time point), and will recreate their secret codes at baseline 2 (6 months); 12-month, and 18-month assessments.

For post study focus group survey/discussion: No names will be used on the electronic survey and pseudonyms will be used during focus groups to protect anonymity. At no times will any identifying information be used during the focus groups. Also, if any identifying information is stated during the focus group recording, it will not be included in the transcriptions.

f) **If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the proposed research. It includes data or specimens collected for research and non-research activities.**

N/A

g) **Will subjects be asked to give permission for release of identifiable data (e.g.,information, videotapes), now or in future? If so, explain here and include appropriate statements in consent**

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materials.

No, participants will not be asked to give permision for release of identifiable data now or in the future.

h) If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?

No, researchers will not be accessing existing data/biological specimens.

i) If identifying information will be collected and linked to data/specimens, explain at what stage identifiers will be removed from the data/specimens. If identifiers will be retained, explain why this is necessary and how confidentiality will be protected.

Study surveys will be tracked by unique identifiers created by participants by answering a series of questions (e.g., initial of mother's first name). The questions and formatting of responses have been edited to further reduce the possibility of disclosing participants' identity and for participants to easily recreate the identifier for follow-up 6-month and 12-month survey assessments. If participants include any personal identifying information (e.g., name, church name) on their surveys, this information will be removed (e.g., cut out, white out, permanent marker used to mark out). We will not be able to link the unique identifiers on participants' surveys to their tracking sheets due to participants will create the unique identifiers by answering a series of questions whose series of responses will be unique to each participant. Yet, we will still file surveys with unique identifiers in separate locations to increase safety of protecting participants' privacy.

For post study focus group survey/discussion: not applicable. There will be no identifying information collected or linked to data.

j) If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.

All survey instruments and tracking sheets will be in a hard-copy format for ease of use and accessibility for participants. Participants' hard-copy, completed surveys and tracking sheets will be stored in separate locked file cabinets in the PI's locked research lab in the UMKC Psychology Department. Trained research team members listed on this protocol will have access to the key identifiers.

For post study focus group survey/discussion: Not applicable. There will be no identifying information collected or linked to data.

k) Explain why, where, in what format, and for how long data/specimens will be retained. Data storage must comply with UM System data <a href="http://www.umsystem.edu/ums/fa/management/records/guide/rrg01801"target="_blank"> retention and <a href="http://infosec.missouri.edu/classification/"target="_blank"> security policies. Please contact UMKC Information Services with questions (email: callcenter@umkc.edu, phone:

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816-235-2000).

All survey instruments and tracking sheets will be in a hard-copy format for ease of use and accessibility for participants. Participants' hard-copy, completed surveys and tracking sheets will be stored separately in locked file cabinets in the PI's locked research lab in the UMKC Psychology Department. All electronic research data will be stored on a university computer, in order to ensure proper data security and confidentiality measures have been taken. All survey data will be entered and stored on a password-proteced UMKC, firewalled, computer network. All electronic research data will be stored on a university computer and the university REDCap system, in order to ensure proper data security and confidentiality measures have been taken.

No personal identifiers are entered during data entry of completed surveys. All survey data and tracking sheets will be stored for seven (7) years after the completion of the study. The surveys and tracking paper sheets will be completely shredded after 7 years.

For post study focus group survey/discussion:
After downloading all focus group survey data into our university REDCap system from the electronic tablets, the tablets will NOT retain any survey data. All electronic research data will be stored on a university computer and the university REDCap system, in order to ensure proper data security and confidentiality measures have been taken. All survey data will be entered and stored on a password protected UMKC, fire walled, computer networks. No personal identifiers are entered during data download of completed surveys. Since their will not be any paper documents used in the study, we will not need to destroy any paper items associated with conducting the focus group survey discussion.

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* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

a)	N	Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?
b)	N	Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?
c)	N	Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?
d)	N	Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited

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to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) N Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) N Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

Significant Financial Interest: Please check Yes or No for each item below.

g) N Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) N Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

Minimizing Risks and Disclosure to Subjects

i) N Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?

If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

By submitting this form, you are attesting that you have read the UMKC HRPP Policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise,

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and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Link to UMKC's Conflict of Interest Policy: http://ors.umkc.edu/office-of-research-services/conflict-of-interest.

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* * * Informed Consent * * *

13. Informed Consent

See sample consent forms at http://ors.umkc.edu/research-compliance/irb/irb-forms

Please provide consent process background information below.

Informed Consent

Title		Informed Consent Script/Consent Form Post Study Focus Groups with Church and Community Member Participants
Consent Information Type		Waiver of documentation of consent
Consent Document	X Attachment	Focus Group Informed Consent Script.Consent Form Version 2 Dated 4.17.17

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Waiver of documentation of consent Regulations

An IRB may approve a consent procedure which does not include, or which alters (alteration of consent), some or all of the elements of informed consent, or waive the requirement to obtain informed consent (waiver of consent), if the research meets either of the criteria, as provided in 45 CFR 46.117(c).

N The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. Yes, the only record linking the participant and the research would be the consent document and the principal risk could be potentially harmful if there is a breach of confidentiality.

Y The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.The research presents no more than minimal risk of harm to participants (i.e., the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) and involves no procedures for which written consent is normally required outside of the research context.

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Title	Consent	
Consent Information Type	Consent	
Consent Document	X Attachment	Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016

Consent Form Samples

Will subjects be deceived or be incompletely informed regarding any aspect of this study?

If applicable, describe the type of deception you will use, indicate why it is necessary for this study. Provide a copy of the debriefing script you will use and explain when and how it will be used:

no

Will informed consent be obtained from all research subjects (and/or their parents or legally authorized representatives)?

yes

Who will obtain subjects' consent? (Check all that apply)

- [ ] Principal Investigator
- [X] Co-Investigator
- [X] Study Coordinator
- [ ] Research assistant(s)
- [ ] Other research staff
- [ ] Contracted Data Collection Firm
- [ ] Other (please specify):

If subjects are not able to give legal consent, explain how and from whom consent will be obtained.

n/a

If consent is being obtained from non-English speaking subjects, explain the translation process for all documents seen by subjects, including consent documents. Describe the consent process in these circumstances.

n/a

Note: Provide copies of translated and back-translated consent documentsand provide the translator's credentials. Translators must be certified or have proof of cultural competency education/training.)

*** * * Attachments * * ***

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16. Attachments

Attach relevant documents here. These could include:

- Collaborating Investigator's IRB approval and approved documents
- Conflict of Interest information
- Debriefing Script; Grant/Sub-contract
- HIPAA Authorization Form from HIPAA-covered entity
- Interview/Focus Group Questions
- Investigator's Brochure
- Letters of Agreement/Cooperation from organizations who will help with recruitment
- Methodology section of associated Thesis or Dissertation project
- Questionnaires
- Radiation Control Office approval material
- Recruitment Material (e.g., flyers, email text, verbal scripts)
- Sponsor's Protocol; Surveys
- Other files associated with the protocol (you can upload most standard file formats: xls, pdf, jpg, tif, etc.)

Please be sure to attach all documents associated with your protocol. Failure to attach the files associated with the protocol may result in this protocol being returned to you for completion prior to being reviewed. Students: Be sure to attach the Methods section of your thesis or dissertation proposal. If this protocol is associated with a grant proposal, please remember to attach your grant.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	**Other Documentation**
Attachment	JBP R01 Resubmission
Document Name	JBP R01 Resubmission

Document Type	**Cover Letter**
Attachment	Cover Letter R01 study J Berkley Patton Dated 11-18-2013
Document Name	Cover Letter R01 study J Berkley Patton Dated 11-18-2013

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Document Type	**Other Documentation**
Attachment	CV Jannette BerkleyPatton November 2013
Document Name	CV Jannette BerkleyPatton November 2013

Document Type	**Other Documentation**
Attachment	CCON LOS Version 1 Dated 11-24-2013
Document Name	CCON LOS Version 1 Dated 11-24-2013

Document Type	**Other Documentation**
Attachment	Church Letters of Support Version 1 Dated 11-24-2013
Document Name	Church Letters of Support Version 1 Dated 11-24-2013

Document Type	**Other Documentation**
Attachment	Citi Certificate Marvia Jones
Document Name	Citi Certificate Marvia Jones

Document Type	**Verbal Script**
Attachment	Informed Consent Script R01 Appendix A Version 2 Dated 3-17-2015
Document Name	Informed Consent Script R01 Appendix A Version 2 Dated 3-17-2015

Document Type	**Other Documentation**
Attachment	Health Beliefs and Behaviors Survey Version 2 Dated 3-16-2015
Document Name	Health Beliefs and Behaviors Survey Version 2 Dated 3-16-2015

Document Type	**Other Documentation**
Attachment	Poster for Intervention Churches R01 Version 1 Dated 3.18.2015

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Document Name Poster for Intervention Churches R01 Version 1 Dated 3.18.2015

Document Type Other Documentation

Attachment Materials for Comparison Churches Version 1 Dated 3 18 2015

Document Name Materials for Comparison Churches Version 1 Dated 3 18 2015

Document Type Other Documentation

Attachment CHL Comparison Implementation Monitoring Form Version 1 Dated 3-16-2015

Document Name CHL Comparison Implementation Monitoring Form Version 1 Dated 3-16-2015

Document Type Other Documentation

Attachment CHL Intervention Implementation Monitoring Form Version 1 Dated 3-16-2015

Document Name CHL Intervention Implementation Monitoring Form Version 1 Dated 3-16-2015

Document Type Other Documentation

Attachment Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part1

Document Name Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part1

Document Type Other Documentation

Attachment Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part2

Document Name Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part2

Document Type Other Documentation

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Attachment Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part3

Document Name Materials for Intervention Churches R01 Version 1 Dated 3.18.2015_Part3

Document Type Other Documentation

Attachment Ronnie Blackburn CITI Biomedical Investigator training certificate

Document Name Ronnie Blackburn CITI Biomedical Investigator training certificate

Document Type Other Documentation

Attachment citi 2014 01 13 simon

Document Name citi 2014 01 13 simon

Document Type Other Documentation

Attachment Marcie Berman CITI

Document Name Marcie Berman CITI

Document Type Other Documentation

Attachment CITI Completion Report SDodda

Document Name CITI Completion Report SDodda

Document Type Other Documentation

Attachment Letters of Support 2.Palestine.NewBethel.ChristFellow.Canaan.Friendship.GBHS.MetroSpir.VictLife.Dated 6.19.2015

Document Name Letters of Support 2.Palestine.NewBethel.ChristFellow.Canaan.Friendship.GBHS.MetroSpir.VictLife.Dated 6.19.2015

Document Type Other Documentation

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Attachment Health Beliefs and Behaviors 6 month amendment Version 1 dated 2-2-2016

Document Name Health Beliefs and Behaviors 6 month amendment Version 1 dated 2-2-2016

Document Type Other Documentation

Attachment Sunlight Missionary Baptist Church Signed MOA Wave 2

Document Name Sunlight Missionary Baptist Church Signed MOA Wave 2

Document Type Other Documentation

Attachment Glory Bible Fellowship and Destiny Life Center MOA

Document Name Glory Bible Fellowship and Destiny Life Center MOA

Document Type Other Documentation

Attachment Paseo Baptist Church signed JBP MOA W2

Document Name Paseo Baptist Church signed JBP MOA W2

Document Type Other Documentation

Attachment Swope Parkway United Christian Church MOA W2

Document Name Swope Parkway United Christian Church MOA W2

Document Type Other Documentation

Attachment Calvary Temple Baptist Church MOA Wv2

Document Name Calvary Temple Baptist Church MOA Wv2

Document Type Other Documentation

Attachment Kingdom Word Ministries MOA Wv2

Document Name Kingdom Word Ministries MOA Wv2

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Document Type	**Other Documentation**
Attachment	Memorial Missionary Baptist Church MOA W2
Document Name	Memorial Missionary Baptist Church MOA W2

Document Type	**Other Documentation**
Attachment	United Believers Community Church MOA Wv2
Document Name	United Believers Community Church MOA Wv2

Document Type	**Other Documentation**
Attachment	Good Samaritan Baptist Church MOA Wv2
Document Name	Good Samaritan Baptist Church MOA Wv2

Document Type	**Other Documentation**
Attachment	Health Beliefs and Behaviors 12 month Version 1 Dated 8-2-2016
Document Name	Health Beliefs and Behaviors 12 month Version 1 Dated 8-2-2016

Document Type	**Other Documentation**
Attachment	Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved12.05.16
Document Name	Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved12.05.16

Document Type	**Other Documentation**
Attachment	Focus Group Discussion Guide Version 1 Dated 4.12.17
Document Name	Focus Group Discussion Guide Version 1 Dated 4.12.17

Document Type	**Other Documentation**

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Attachment	Focus Group Survey Version 1 Dated 4.14.17
Document Name	Focus Group Survey Version 1 Dated 4.14.17
Document Type	**Other Documentation**
Attachment	Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved
Document Name	Informed Consent Form Amend R01 APPENDIX B HBB Survey Version 5 Clean Copy Dated 2-10-2016_Approved

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* * * Obligations * * *

Obligations

Obligations of the Principal Investigator include the following:

Provide all subjects a copy of the signed consent form, if applicable.

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel.Training must be updated every two (2) years.

Submit the Continuing Review Form in order to maintain active status of the approved protocol. This form must be submitted to the IRB at least 30 days (AHSIRB) or 45 days (SSIRB) prior to the date of expiration.

Submit the Protocol Violation Form to report protocol Deviations/Violations or the Event Reporting Form to report Adverse Events (AEs) or Unanticipated Problems that occur in the course of the protocol.

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Final Report - The IRB will be notified when the study is complete. To do this, complete the IRB Exempt Report Form and select the "Final Report"

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the UMKC IRB.

I agree that no subject will be enrolled nor will any data intended only for research use be collected prior to issuance of an IRB approval.

I understand that I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all of the applicable policies and regulations.

I understand that for the purposes of the UMKC IRB "anonymous" means the HIPAA definition of de-identified data. (See Help Screen for definition)

I have completed the CITI Human Subjects Research Protection Course and the certificate is either attached to this application. A copy of current CV must also be included.

This study will not begin until the investigator receives written final approval.

X The Principal Investigator has read and agrees to abide by the above obligations.

Please click "Check for Completeness" to your left to continue to the next step. If the protocol is complete and ready for submission, please click "Submit Form" to your left to submit your protocol for IRB Review.
