



Date: Friday, April 28, 2017 7:33:32 AM

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Introduction Page

1 *** Abbreviated Title:**

CASA: Care and Support Access Study

2 *** Full Title:**

CASA: Care and Support Access Study for implementation of a palliative approach with HIV treatment

3 *** Select Type of Submission:**

IRB Application

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 **Original Version #:**

HP-00058180

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

View: v2_Research Team Information

Research Team Information

1 *** Principal Investigator - Who is the PI for this study (person must have faculty status)? *Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***

Carla Alexander

1.1 *** Does the Principal Investigator have a financial interest related to this research?**

☐ Yes ☒ No

2 **Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:**

Gregory Brogden

2.1 **Does the Point of Contact have a financial interest related to this research?**

☐ Yes ☒ No

3 **Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:**

Name	Edit Submission	cc on Email	Research Role	Has SFI?
Patrick Ryscavage	no	no	Sub-Investigator	no
Catherine Kelleher	no	no	Research Team Member	no
Mary Lynn McPherson	no	yes	Research Team Member	no
Debra Wiegand	no	no	Research Team Member	no
Yvonne Henley	no	no	Technician or Assistant	no
Sabrina N'Diaye	no	no	Research Team Member	no
Fiyinfolu Adetunji	no	no	Research Team Member	no
Linda Otieno	yes	yes	Research Team Member	no
Vera Carter	yes	yes	Research Team Member	no
Rebecca Brotemarkle	no	no	Research Team Member	no
Dawn Lockman	no	no	Research Team Member	no
Sylvia Huntley	no	no	Technician or Assistant	no
Christopher Welsh	no	no	Research Team Member	no
Sean Williams	no	no	Other	no
Mei Ching Lee	no	no	Research Team Member	no
Arin Judith Chwalow	no	no	Research Team Member	no

Renard Murray	no	no	Research Team Member	no
Peter Memiah	no	no	Sub-Investigator	no
Debra Elfenbein	no	no	Research Team Member	no
Ila Mulasi	no	yes	Sub-Investigator	no
Vicki Tepper	no	no	Research Team Member	no
Frank Oldham, Jr.	no	no	Other	no

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

View: v2_Resources

Resources

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:

The PI is aware that conducting the study requires that she allow time for starting and successfully completing this study to conform with good clinical and research practices. The time to be devoted will vary depending upon the activities of the study but she is committed to devoting the necessary time to conduct safe and effective research in keeping with milestones agreed upon with the sponsor.

Drs. Alexander and Raveis are Co-PIs for this study. They jointly chair conference calls, plan implementation and dissemination activities, and prepare all progress reports. Dr. Alexander leads the implementation of the CASA Study, overseeing selection and training of the interdisciplinary CASA teams, development of the palliative curriculum, and has oversight for the implementation effort (i.e., instruction, coaching and all-staff-service educational efforts) at the clinics. Dr. Raveis directs the evaluation activities to assess efficacy of the training and outcomes for staff and patients.

2 * Describe the facilities where research procedures are conducted:

DATA COLLECTION: Research discussions and interactions will take place in the examination rooms, offices and meeting spaces of each of the UMB-UMMC clinical sites where enrolled patients receive their outpatient care. These spaces represent an environment where confidentiality and privacy are routinely respected. Medical records at each of these sites are contained within electronic medical records that are password protected.

There are 2 study populations: 1) A selected multidisciplinary team of seven staff members will receive the educational intervention in a private educational environment on the UMMC campus. On-site expert coaching with that same team will take place every other week at the clinic receiving the teaching intervention in a private space; and 2) the second study population will be consented, enrolled adult patients who will complete surveys in a private space in the respective clinic.

DATA ANALYSIS will take place at the offices of the Psychosocial Research Unit on Health, Aging and the Community at New York University College of Dentistry, Office Location: 137 East 25th Street, 5th Floor, New York, NY 10010, Mailing Address: 138 East 26th Street, 5th Floor, New York, NY 10010, Telephone: 212-998-9805, Fax: 212-443-1349, E-mail: Victoria.raveis@nyu.edu. Professor Raveis is Director of the unit and is Co-PI for this study. Her team is responsible for data review and analysis in close collaboration with Dr. Alexander. The data is up-loaded directly from a pre-programmed touch-pad used to administer a survey to the patient. This data is encrypted and directly transmitted to an NYU secured internet site. The data is only accessible to selected members of the Research Team and is password protected. The only list with identifying information will be kept in a locked cabinet in the offices of the PI and this will be destroyed at the end of the study.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:

The UMB-IHV has physicians, nurses and counselors to cover both anticipated and unanticipated psychological or physical needs of participants. Both study sites are clinics located within 2 blocks of the primary UMMC hospital for unforeseen back-up needs. It is possible that data collection may trigger psycho-emotional responses for either patients or staff participating in this study. A protocol will be implemented to identify participants for whom the information is disturbing and to offer on-the-spot and/or referral counseling as needed. There is no blood drawn nor imaging studies performed for any of the participants as part of this study.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:

The sponsor is involved with oversight of this research and interested in protecting the rights of all participants. The Research Team is made up from professionals from multiple disciplines who have a history of extensive clinical involvement with the target populations. Members of the Core Research Team have reviewed the protocol and initiated regular telephone discussions to clarify and review study procedures and anticipate potential challenges. There will be regular telephone and face to face meetings among all members of the Research Team to keep everyone abreast of study status and changes.

In addition to UMB institutional requirements for participation in research such as HIPAA and CITI training, all study staff including the educational team and data collection staff will participate in group training by the NYU data team relative to confidential and appropriate research behavior.

ID: VIEW4DF83CB976400
Name: v2_Resources

View: v2_Sites Where Research Activities Will Be Conducted

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ☒ Multi-Site
☐ Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

☐ Yes ☒ No

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

☐ Yes ☒ No

3.1

Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other

IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date
There are no items to display		

- 4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)
☐ Yes ☒ No

- 5 * Institution(s) where the research activities will be performed:

Institute of Human Virology (IHV) Clinical Research Unit
 Other Sites
 University of Maryland Medical System (Select below)

* UMMS Sites:

University of Maryland Medical Center
 UMMC Midtown Campus (formerly Maryland General Hospital)

ID: VIEW4DF870DF2C000
 Name: v2_Sites Where Research Activities Will Be Conducted

View: v2_Other Sites Where Research Activities Will Be Conducted

Other Sites Where Research Activities Will Be Conducted

You selected "Other Sites," "Private Practice," "Community Mental Health Centers," and/or "Nursing Homes in Maryland" as a site where research will be conducted.

- 3.1 * Specify the name of the site(s):
 Psychosocial Research Unit on Health, Aging and the Community at New York University College of Dentistry
- 3.2 * Contact Person(s) for Other Site:
 Victoria Raveis PhD
- 3.3 * Phone (if no phone available, input "none"):
 1212 998 9805
- 3.4 * Email Address (if no email available, input "none"):
 victoria.raveis@nyu.edu

ID: VIEW4DF8712DB5800
 Name: v2_Other Sites Where Research Activities Will Be Conducted

View: v2_Funding Information

Funding Information

- 1 * Indicate who is funding the study:
 Private
- 2 * What portion of the research is being funded? (Choose all that apply)
 Staff
 Participant Compensation
 Other

- 3 Please discuss any additional information regarding funding below:

This proposal is funded by the Patient Centered Outcomes Research Institute (www.pcori.org) that was established in response to the Affordable Care Act. The Patient-Centered Outcomes Research Institute (PCORI) is authorized by Congress to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options

PCORI is funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF), which was authorized by Congress as part of the Patient Protection and Affordable Care Act of 2010 and receives income from two funding streams: the general fund of the Treasury and a small fee assessed on Medicare, private health insurance and self-insured plans. PCORI is expected to receive an estimated \$3.5 billion from the PCOR Trust Fund to fund patient-centered outcomes research through September 30, 2019, the date through which the Act authorizes the fund to remain in operation.

Each year, 20 percent of PCORTF funding is directed by the law to be transferred to the Department of Health and Human Services to support dissemination and research capacity-building efforts. Eighty percent of that amount is transferred to the Agency for Healthcare Research and Quality for these purposes. Additional details on how PCORI is funded are provided in the authorizing law in Sec. 1183 and Sec. 9511.

ID: VIEW4DF85DF452400
 Name: v2_Funding Information

View: v2_Private Sponsor Contact Information

Private Sponsor Contact Information

You indicated that this is a privately funded study.

- 1

* Name:

Patient Centered Outcomes Research Institute

* Address 1:

1828 L Street NW

Address 2:

Suite 900

* City:

Washington

* State:

DC

* Zip Code:

20036

* Country:

USA

* Contact:

Neeraj Aurora

* Phone Number:

202 627 1874

ID: VIEW4DF88F2BE3C00

Name: v2_Private Sponsor Contact Information

View: v2_Research Protocol

Research Protocol

- 1

* Do you have a research protocol to upload?

No, I do not have a research protocol and will use the CICERO application to enter my study information
- 2

If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000

Name: v2_Research Protocol

View: v2_Risk Level

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

- * Choose One:

Minimal - The probability & magnitude of harm/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/tests.

ID: VIEW4E02805225800

Name: v2_Risk Level

View: v2_Type of Research

Type of Research

- 1

* Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).
Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).
- 2

* Is this study a clinical trial?

A clinical trial is a biomedical or behavioral research study of human subjects designed to answer specific questions about

therapeutic interventions (drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe, efficacious, and effective.

☒ Yes ☐ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

View: v2_Lay Summary

Lay Summary

- 1 *** Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.**

SUMMARY: The CASA Study (care and support access) is a proof of principle study related to the early use of palliative, or supportive, skills to engage and retain patients in care. It is an educational intervention where clinic staff receive the intervention and patients who attend clinic complete serial quality of life surveys to see what impact the teaching intervention has on care delivered at the clinic.

This is an investigator-initiated study to measure the impact of an educational process for multidisciplinary staff members of an outpatient HIV clinic. The study aims to 1) refine a CURRICULUM for individuals who do not intend to specialize in palliative care faced with caring for persons living with chronic illness early in disease management and 2) assess the impact of this palliative educational training on outcomes for two target populations: a) STAFF (who may experience work-related stress, or burn-out) and b) PATIENTS (whose successful engagement in care may affect their mental health, and quality of life). It is hypothesized that training outpatient HIV staff in palliative skills will improve clinical outcomes for PATIENTS (specifically, HIV positive young men who have sex with men (YMSM) receiving care from the clinic. Quantitative data will be augmented by qualitative interviews of selected staff and patients in the final year of the study to better describe their response to the training.

Palliative care (PC) training is known to improve quality of life and even to lengthen how long a sick person might live in people with lung cancer. It has also been demonstrated in a randomized trial in African countries that patients with HIV disease have improved mental health and better quality of life if these skills are used by clinic staff early in the course of illness. The specific patient population being addressed in this study is HIV positive young men who have sex with men (YMSM) who are known to face multiple psychological and social issues, referred to as "psycho-social," that make it difficult for them to keep coming to clinic and taking their medications. By missing appointments and not taking medication regularly, they are at higher risk for developing other medical problems and may die sooner than they would if they could stay on the medical treatment.

Studies about YMSM have focused upon the use of support groups, YMSM as in-clinic mentors, personalized case management, and enhancing welcoming aspects of the clinic itself. This study intends to principally focus on the clinic staff many of whom may be stressed by being unable to retain these young men in care. The curriculum for the study is based upon standard US PC training used in teaching internationally for people living with HIV. One goal of the study is to develop the curriculum. This will be accomplished as a part of the study and will be submitted to the IRB to review before it is given to staff members who complete the consent process in the second year of the study.

BACKGROUND about PALLIATIVE CARE:

Palliative care* is defined as an approach to care, that is, a manner in which the care is delivered. It is supportive care for persons with any chronic, or life-limiting, disease across the full spectrum of illness, delivered by a team of mixed disciplines. This approach to care is a recognized medical sub-specialty in 11 disciplines certified by the American College of Graduate Medical Education (ACGME): anesthesiology, emergency medicine, family medicine, internal medicine, neurology, obstetrics and gynecology, psychiatry, pediatrics, physical medicine and rehabilitation, radiation oncology, and surgery. Palliative skills for individuals who have little, or no, formal training in palliative care are care strategies to relieve suffering and promote quality of life for persons with any chronic illness regardless of the life expectancy. This type of care is: a) patient-family-centered, meaning that the patient and his support system, regardless of their actual relationship to the patient, work together as a team; b) delivered by a multidisciplinary team that all contribute knowledge when making a plan of care for the patient; c) prioritized by life expectancy of the patient with regular, rather than reactive, "crisis-based" goal-setting; d) specializes in "symptom management" such as pain, depression or tiredness in addition to the use of treatment meant to control HIV disease; and d) incorporates activities that promote the ability to cope for those providing HIV care in recognition of the daily stress experienced in caring for challenging patients.

GOALS and PLAN of the study:

This study will refine and test palliative curriculum for staff members of an HIV clinic that can be integrated with outpatient care delivery. Staff of one clinic (the experimental group) will practice standard outpatient care and in addition, will receive the test curriculum training, while the staff at the second clinic (the control group) will practice only the standard outpatient care. There are 2 populations being studied: 1) staff receiving the training about integration of palliative care strategies; and 2) patients attending the experimental and control HIV clinics. The patients will be observed for any change in their overall quality of life measured before and after the staff either receives the palliative training intervention (experimental group) or does not receive the palliative training (control group). Qualitative data (structured interviews) will be collected from selected members of each target population (staff and patients) to measure and characterize the impact of the change provided by the delivery of the newly instituted palliative care curriculum.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

View: v2_Justification, Objective, & Research Design

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

- 1 *** Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:**

PURPOSE and RESEARCH QUESTION:

This study represents a proof of principle in the US. It is to refine and test an educational curriculum. It intends to measure the impact on patients of the clinic where staff have been trained with the curriculum.

SUMMARY: This is an investigator-initiated study to measure the impact of an educational process (the intervention) for multidisciplinary staff members of an outpatient HIV (human immunodeficiency virus) clinic. The study aims to 1) refine a curriculum for non-palliative clinicians caring for persons living with HIV disease (PLWH) to be introduced early in disease trajectory and 2) assess the impact of the educational intervention on outcomes for 2 target populations: a) staff (burn-out and caregiving stress) and b) patients (retention in care, mental health, and quality of life). It is hypothesized that training HIV clinical staff in palliative skills will improve care provided that might, in turn, improve clinical outcomes for YMSM receiving this care. Quantitative data will be augmented by qualitative interviews of selected staff and patients in the final year of the study to appreciate their response to the intervention.

Palliative skills have been successfully integrated early in HIV care in a randomized trial in multiple African countries and are known to improve quality of life and survival in selected US populations. The overall research question of this study is: "Does early implementation of palliative care skills with on-going HIV management, compared to standard care alone, improve patient outcomes for young men who have sex with men (YMSM) ages 18-35 years, who are known to be hard-to-engage and keep in

care making them at high risk for poor outcomes?"

SPECIFIC AIMS:

- 1) RELATED to CURRICULUM: To refine, deliver and determine the acceptability and applicability of an interdisciplinary professional education program to enhance patient outcomes, specifically for YMSM, who are known to be hard-to-engage and and to keep in outpatient HIV care.
- 2) RELATED to STAFF: To describe and measure the impact upon HIV clinic STAFF of training about early integration of palliative skills related to: a) reduced stress from providing care for difficult to engage patients, and b) obtain their insights regarding the training experience.
- 3) RELATED to PATIENTS: To describe and measure the impact of implementing palliative skills early in the care of PATIENTS (specifically HIV positive young men who have sex with men (YMSM)) meant to: a) increase retention in care measured by regular clinic attendance and treatment adherence (e.g. measured by complete viral suppression); b) improve mental health such as depression or anxiety and overall quality of life (QOL); and c) obtain insights that might be targeted with future research in YMSM.

HYPOTHESIS:

It is hypothesized that implementation of palliative skills with HIV outpatient management will improve patient outcomes. We will focus specifically upon YMSM who are not able to engage in care, initiate antiretroviral therapy (ART), or remain in routine follow-up and thus are at high risk for experiencing multiple health symptoms, poor clinical outcomes such as laboratory results indicating lack of response to ART; poor quality of life (QOL) and decreased survival. See Pictorial Timeline as Additional Documents Section.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

STUDY DESIGN:

This is a non-randomized, non-blinded, longitudinal descriptive study of the impact of an educational intervention for outpatient clinic staff (experimental) compared with a second outpatient clinic that receives no intervention (the control). The overall goal is to improve the outcomes of HIV patients attending one of two HIV clinics where staff at one of those clinics receives the intervention of palliative training.

The study uses a quasi-experimental design with pre-tests and post-tests for staff being trained. It provides a control group to directly compare the effects of the educational intervention upon the management of patients by measuring responses of patients before and after the staff is, or is not, trained. The Intervention Group (Clinic 1) and Control Group (Clinic 2) are non-randomly assigned. Both clinics agreed and looked forward to participating in the study, but one clinic had significant budget reduction that resulted in selection of the other clinic for the primary intervention. Ideally we would have used a cross-over design offering the intervention to the second site but the funding cycle for this proposal was reduced from 5 to 3 years and it is only feasible to offer one clinic the intervention. However, we intend to offer staff of the control site the palliative training at the end of the study period if the outcomes are shown to be beneficial. We will make a comparison of the two clinics at baseline to identify possible bias in the final analysis of data.

Following is a description of Study activities; at the end, the teaching intervention is described.

ITEMIZED RESEARCH ACTIVITIES: (See Timeline in Additional Documents)

The study is accomplished in 5 active phases with 3 desired outcomes: (A) staff will be able to use coping strategies as they integrate palliative skills with outpatient HIV care and treatment; (B) patients, specifically (YMSM), will be characterized in the era of successful ART with regard to mental health and quality of life; and (C) the curriculum, previously refined in international settings, will be re-adapted for use early in management of chronic illness in the US to engage and retain patients known to be difficult to keep in care.

PHASE 0:

Months 1-6

Usual study start-up activities including finalization of contracts, hiring of personnel, establishment of study offices, creation of the database and purchase of study materials.

PHASE 1: Patient Recruitment and Enrollment

Begins Month 7 of the study and continues through about Month 24.

A. STAFF: No staff are enrolled, taught or interviewed in the first Phase.

B. YMSM: The consent process, enrollment, and baseline data collection takes place at two HIV clinic sites to describe the YMSM population in Baltimore. Patients are enrolled until 102 are enrolled at each site (85 are needed for analysis and the 102 allows for anticipated drop-out). Each patient completes 3 surveys approximately every 6 months at his regular clinic visit.

C. CURRICULUM Refinement: An initial curriculum is attached in ADDITIONAL DOCUMENTS. The educational team will continue to review, test, and incorporate elements of the curriculum being re-adapted for the US from international teaching efforts used in federally funded implementation efforts of HIV care and treatment. Site #1 will be the INTERVENTION SITE. Directors of Site #1 have chosen to have a day-long educational session for All-STAFF to be introduced to CASA Study activity. The curriculum is attached in ADDITIONAL DOCUMENTS prior to being offered to All STAFF participants.

PHASE 2: Staff Recruitment [NOTE this refers to CASA Team – the trainers to be trained]

Begins Month 13 (November, 2014) of the study.

A. STAFF – There are 2 types of STAFF participants: 1) CASA Team (Trainers) and 2) All STAFF who complete 2 surveys:

1. The CASA Team (Trainers) - Recruitment of the selected 5-8 member CASA Team made up of clinic STAFF trainers to receive the intervention: (1 physician or nurse practitioner; 2 nurses; 1 nursing assistant; 1 social worker or counselor; 1 outreach worker; and 1 administrative staff) at the intervention site. These will be selected by the clinic Administrative Team and the Research Team using the following criteria: all disciplines represented; each person chosen should have full understanding of how the clinic functions; each should be selected for leadership qualities and teaching or supervisory experience.

Participants are asked to avoid intentional sharing of study content to avoid contamination of the control site. for purposes of Staff at the control clinic will have the option to experience the training at the end of the study if it is shown to be beneficial.

B. YMSM: Enrollment and data collection continue as described in Phase 1.

C. Curriculum: Finalization of curriculum is on-going through-out the study as feedback from Site 1 is used for final revisions.

PHASE 3: Educational Intervention (See document attached in ADDITIONAL DOCUMENTS)

January-February, 2015

A. STAFF: Initiation of educational process at Site #1. Directors of Site #1 have chosen to have a day-long educational session for All-STAFF to be introduced to CASA Study activity. The curriculum is attached in ADDITIONAL DOCUMENTS.

B. YMSM: Enrollment and data collection continue as described in Phase 1.

C. CURRICULUM - pre-finalized version to be delivered to staff at Site #1 as in-service education using usual pre- and post- training evaluation forms that reflect the content and will be used to further revise the curriculum.

PHASE 4: On-site Expert Coaching.

February 2015 through May to August 2016.

A. STAFF - The CASA Team (selected site-based staff) will meet bi-weekly with members of the trained external Expert Coaching Team to review progress with patients and with integration of palliative skills. These 2 teams will identify content for quarterly in-service education to be developed for all-staff of the clinic.

B. YMSM: Enrollment and data collection continue as described in Phase 1.

C. CURRICULUM: Final revisions of curriculum based upon staff feedback. This curriculum will be put together in manual form for the end of the study.

PHASE 5 - Post-educational interviews

Approximate Months 28 - 30

A. STAFF - Up to 25 staff members per clinic will be asked to participate in in-depth structured interviews to obtain reports of their experiences with, or without, CASA and its implementation, including their perceptions of its impact on their own behaviors and clinic practice. These staff interviews will include members of the trained CASA Team as well as other members of the clinic staff potentially impacted by the training. Up to 25 staff at each clinic will be recruited, consented and complete pre- and post-intervention surveys, in months 28-30. Participation of staff will be a voluntary process although staff will be reimbursed a token amount for completing an interview. A separate consent form will be developed. Details of these interviews will be developed following the MID-STUDY data review and this information will be uploaded in CICERO once the content is determined and prior to these interviews taking place.

B. YMSM - Selected patients will be offered the opportunity to participate in these interviews to understand their perceptions of care delivery and to possibly identify unique characteristics relevant to sustained retention in care. There will be a separate consent form developed and they will receive a small reimbursement for time and parking.

C. CURRICULUM: Final revisions being completed. NOTE: Staff at the second (control) clinic will be offered this curriculum if it appears to be beneficial.

FINAL PHASE: Data analysis and review

Months 30-36.

During this phase data analysis is taking place and final drafts of the study documents developed.

OVERVIEW of the INTERVENTION:

The intervention is to deliver staff education and training for early integration of palliative skills with ongoing HIV management. Palliative skills for individuals who have little, or no, formal training in palliative care are care strategies to relieve suffering and promote quality of life for persons with any chronic illness regardless of the life expectancy. This type of care is a) patient-family-centered, meaning that the patient and his support system, regardless of their actual relationship to the patient, work together as a team; b) delivered by a multidisciplinary team that all contribute knowledge when making a plan of care for the patient; c) prioritized by life expectancy of the patient with regular, rather than reactive, "crisis-based" goal-setting; d) specializes in "symptom management" such as pain, depression or tiredness in addition to the use of treatment meant to control HIV disease; and e) incorporates activities that promote the ability to cope for those providing HIV care in recognition of the daily stress experienced in caring for challenging patients. See Pictorial Timeline as Attachment.

DESCRIPTION of the EDUCATIONAL INTERVENTION:

The educational intervention is based upon 8 years' experience in training clinicians how to care for HIV patients using a "Train the Trainer" method and quality improvement to integrate palliative skills with HIV care and treatment. The model used for this training is standard in chronic disease management and was used by the UMB research team for 8 years in African settings. The curriculum (intervention) was refined in international (primarily African) settings. These skills can be applied to any chronic illness. There are 3 aspects of the training: 1) initial didactic/iterative meaning lecture/ participatory group discussion; 2) on-site mentoring by members of the Research Team who have specialty expertise in both HIV management and palliative care skills; and 3) all-staff shared group learning focused upon topics that the CASA team and the Expert Coaching Team choose to integrate palliative skills with on-going HIV management conducted quarterly. The Expert Coaching Team receives uniform training prior to the intervention in order to standardize their approach to coaching.

CONTENT of the INTERVENTION:

We recognize that staff members learning new skills may be stressed by making these changes. Using coping skills for care-givers or clinicians is integral to palliative education. We will ask staff members whether these coping activities impact their ability to integrate palliative care skills. In addition to these skills, palliative skills for HIV staff are grounded in respect for the individual and his support system as a unit of care. An interdisciplinary team is used to implement systematic, early goal-setting rather than crisis-based reactive management. Two other fundamental aspects of palliative training are 1) use of communication skills for discussing difficult to address, or taboo, topics; and 2) recognition of the patient's experience of symptoms, such as pain or depression, with equal focus upon control of these symptoms by the provider regardless of disease management strategies. In the case of YMSM, palliative skills offer support during multiple emotional transitions: 1) from adolescence to adulthood; 2) from a state of good health to chronic illness; and 3) from a world of heterosexuality to one of homosexuality. In this particular population there are multiple threats to building a trusting relationship with the provider, or with a team, reflecting childhood abuse, substance abuse or single-to-no parent homes resulting in homelessness or unstable housing. Staff accustomed to delivering routine HIV care may find this population more difficult to interact with in the short time available for outpatient clinic visits. Team problem-solving is used in the training.

DATA COLLECTION:

Cross-sectional data collection is ongoing throughout the study to describe the patient population of YMSM in Baltimore and, later, to clarify their perceptions of care delivery at the clinic where they receive HIV care. The data collected from staff targets 2 endpoints: 1) refinement of the curriculum to characterize effective elements of the teaching intervention and 2) clarification of the impact of using coping strategies to integrate palliative management.

SUMMARY: This is an investigator-initiated study to measure the impact of an educational process (the intervention) for multidisciplinary staff members of an outpatient HIV (human immunodeficiency virus) clinic. The study aims to 1) refine a curriculum for non-palliative clinicians caring for persons living with HIV disease (PLWH) to be introduced early in disease trajectory and 2) assess the impact of the educational intervention on outcomes for 2 target populations: a) staff (work-related stress and burn-out) and b) patients (retention in care, mental health, and quality of life). It is hypothesized that training HIV clinical staff in palliative skills will improve care provided that might, in turn, improve clinical outcomes for YMSM receiving this care. Quantitative data will be augmented by qualitative interviews of selected staff and patients in the final year of the study to appreciate their response to the intervention.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

RELEVANT PRELIMINARY DATA: According to the Maryland State Health Dept. publications, the HIV epidemic is being driven by new diagnoses primarily among those hard-to-engage in care-YMSM. Black and African American YMSM, are among the fastest growing sub-population of newly reported HIV infections in Maryland. In 2000, less than 20% of reported HIV cases among MSM were between ages 20-29 when diagnosed. By the end of 2009, young men aged 20-29 made up 51% of reported HIV diagnoses in MSM. High rates of HIV among YMSM were also reported in a locally-conducted 2009 survey, which found that 30% of the 135 YMSM (ages 16-24, mean age 21) tested HIV-positive. Of these, (130) YMSM identified as Black or African American. Local findings are higher than the estimated national rate of 25% of new HIV infections among young people ages 13-29.(10) The educational intervention (CASA) used in the study is based on an extensive literature in palliative care and was developed over a eight year period in Africa.

PRIOR EXPERIENCE: Human Immunodeficiency Virus (HIV disease) is now recognized as a manageable chronic illness for persons able to access and adhere with treatment.(25) Patient-identified outcomes focused upon quality of life (QOL) are preferred to simple tracking of viral response and prolonged survival. Patient's engagement in care is critical to the clinical management of HIV infection. Patients who missed visits within the first year of initiating outpatient treatment had more than twice the long-term mortality than those who remained in care.(104) A systematic review of multidimensional needs of HIV positive persons with early disease, within 6 months of diagnosis, identified persistent factors: a) having physical and psychological symptoms; b) impaired well-being; c) decreased peace and calm and increased thoughts of suicide; d) practical problems; e) lack of emotional support; and, f) fear of being rejected by families.(142) Those with chronic health needs are at higher risk for psychological and physical sequelae (8,86,112) and staff caring for them may suffer levels of stress in engaging and retaining these patients in care.(89,157)

A systematic review of successful engagement and retention activities for YMSM documents that personalized case management, YMSM as on-site mentors, and recognition of space-related barriers in the clinic itself are effective but not adequate alone. YMSM have voiced a need to "feel respected" by clinic staff.(79) Clinicians relying solely on laboratory and clinical indicators may perceive patient-centered activities to be time-consuming (33) and not acknowledge patient preferences for more individualized care or the suffering from physical or mental symptoms that patients can experience.(12) Persons with a history of abuse are known to have difficulties with trust and relationship building and actual "time spent with clients" was significantly associated with retention in care over a 6-month period.(95)

In light of the patient centered medical home (PCMH) approach, this proposal focuses upon the core intervention with the patient by introducing a mechanism for assisting health workers to adjust care delivery for populations outside those currently receiving HIV care and treatment. Use of a multidisciplinary team is fundamental to improving engagement and retention.(168) Internationally, PC for HIV disease is integrated across the continuum of illness rather than at end-of-life only.(63) The palliative approach has been integrated into management of multiple chronic disorders (12,71) in varied settings (3,35) and in international settings, it has demonstrated

improvement in patient outcomes even in early HIV illness.(92) When caring for persons with multimorbidity, staff must be flexible; have on-going collective learning opportunities; employ an iterative approach to creation of care plans; and engage in reflective case-based learning over time.(146) Care must be tailored to the delivery model by enhancing on-going communication with patients to allow therapeutic decisions to accommodate patient values.(109) The quality of patient-clinician relationship is directly related to the health of persons living with HIV infection (PLWH).(11,134) The palliative approach encourages effective engagement in care and goal setting with patient-family units (48) and is useful in facilitating life transitions.(40,45) Evidence exists that principles of planning and identification of challenges to success from other life-limiting conditions (38) can be applied in chronic illness.

A team-based approach to care recognizes the following principles: shared goals, clear roles, mutual trust, effective communication, and measurable process and outcomes.(72) Use of palliative domains as the basis of care delivery can be simplified for non-palliative learners and offers an opportunity for cross-disciplinary learning. The ability to provide patient-centered care depends upon key interpersonal provider skills including communication skills, empathy and sensitivity.(127) all characteristics of palliative care delivery. Routinization of care and division of labor among health professionals may impair flexibility from practitioners caring for persons with problems that challenge current care patterns.(11) Management strategies must evolve to prioritize patient preferences that enhance Quality of Life end-points.(4,20) Routine HIV providers may perceive patient-centered activities to be time-consuming (28) and not acknowledge suffering from physical or mental symptoms. Multidimensional assessment (68) or patient-centered care is preferred by patients and families.(6) It focuses attention on treating the person, not just the illness.(7) This requires a paradigm shift to highlight the patient's experience of illness with provider-patient relationships, shared decision-making, and continuity of care over time.(90)

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

RATIONALE and SIGNIFICANCE:

BACKGROUND: Early implementation of palliative skills is a complex interdisciplinary method for enhancing communication at the point of care and requires integration of attitudes and skills with comprehension of the underlying illness, in addition to operative disease-specific delivery models.(103,139) Palliative care (PC) has been documented to improve quality of life and survival in patients with lung cancer when provided concurrently with disease management. A randomized, controlled trial in African countries has shown positive outcomes for HIV patients when PC is integrated with early disease management. These are evidence of the value of PC as a management model for chronic illness.(6,43,47) The study training encourages effective engagement in care and goal setting with patients.(48) The proposed study is in line with the need for research to document the process of forming and training inter-professional care teams and represents an important advance in the field.(9)

RATIONALE: The impact on healthcare performance of the CASA study is reflected in the following discussion. Missed appointments increase overall health costs, resulting in lack of control of the HIV epidemic and increasing healthcare stigma against the population of YMSM. Modifications in health delivery methods are needed for clinicians as well as for the delivery system itself. To effect behavioral change and improve clinically meaningful patient-centered outcomes, we must consider a range of strategies at the patient, provider and system level. CASA specifically targets the first two levels and with successful demonstration may provide sustainable effects system-wide. Patient populations that are difficult to engage and retain in care impact the overall health of both individuals and the health delivery system. YMSM living in inner city Baltimore face multiple personal and health system barriers to achieving desirable control of HIV disease. These barriers may be generalizable to other hard to engage populations. Specifically in HIV disease, a lack of adherence with keeping outpatient appointments has a known association with lack of adherence to ART itself and failure to achieve viral suppression (a marker for disease control).

HIV care delivery has long relied upon a multidisciplinary approach (161) but the compassion seen in the early epidemic must now be re-directed toward YMSM who remain at risk for poor outcomes despite effective disease management strategies.(105) Findings from this study will improve patient mental health and QOL outcomes that can decrease the spread of HIV; improve staff stress related to working with hard-to-engage populations; and reduce waste of healthcare resources. In the context of disease management for chronic illness, successful integration of new care approaches is known to be enhanced by the use of cross-training and team-building for interdisciplinary teams; in-house training for staff; emphasis on continuity of care; and data-driven patient-level management (160) and these activities are all elements are integral to the palliative approach.(73) The CASA training will enable HIV staff to modify ART management approaches in a manner that may improve early antiretroviral control of difficult to reach populations. This type of care is desired for both cancer (46,99,15) and HIV care where recent studies have demonstrated improved QOL and prolonged survival.(92,150) In-depth understanding of the underlying illness is necessary to identify clinically appropriate timing of training as well as specific skills for reaching patients. Educational initiatives using the CASA approach for a variety of health conditions (e.g. congestive heart failure,(71) end stage renal disease,(12) ALS and chronic neurologic disorders, general surgery and intensive care units (3,35) have been effective.

In HIV disease the challenge remains to identify initiation strategies and appropriate timing for discussions with YMSM, their carers, and for clinicians to achieve improved outcomes.(143) YMSM may demand more time during an appointment if clinicians are not skilled in effective care provision or they may create missed appointment resulting in inefficiency for the health delivery system. In current economic conditions, clinicians are challenged to provide extensive care in limited visit time. For clinicians faced with non-adherent patients in the era of effective antiretroviral therapy this presents multiple dilemmas.

In the pre-ART era work overload and stress derived from social relationships at work were the main predictors of psychological distress, emotional exhaustion and depersonalization on the part of clinicians.(89) Patients requiring attention beyond that encountered in usual care delivery are likely to impact the workload in the ART era. The YMSM may have low self-esteem and a fear of failure or other individual barriers to engagement. Use of self-care strategies is one activity of the palliative approach that can benefit both persons hard to engage in care and the cadre of clinicians who care for them. Sharing one's story is one effective mechanism. Appreciation for the linkage between personhood and body image – important in this population – can be key toward promoting self-esteem.(23) Building in motivational activity to accompany routine medical care is another mechanism for engagement that can also respond to the call for patient-centered care.(94) Self-care for clinicians is documented as a method for prevention of compassion fatigue in nursing, social work and medicine. Profound emotional disturbances can occur in clinicians exposed to cancer, chronic illnesses and end-of-life care (139) and unexamined emotions can lead to provider burn-out and depression, thus compromising patient care.(41,100,138)

Coping strategies for clinicians, an integral part of the palliative approach, must be included during a change in care delivery strategies by improving the ability of clinicians to cope with frustrations inherent in engagement of YMSM in care.(30) Repeated exposure to emotionally sensitive issues can lead to symptoms consistent with post-traumatic stress syndrome in the clinician. Clinicians caring for persons with HIV disease before the use of ART experienced psychological difficulties likely to respond to interventions to improve work-related stress.(14) Confronting the emotional under-pinning of interactions with patients, family and staff; naming and recognizing emotions that threaten the individual, e.g. need to rescue; frustration and sense of failure at progressive illness; fear of becoming ill; grief and loss; powerlessness and being overwhelmed; and desire to avoid and escape are incumbent for successful management in emotional situations.(100) Without specific skills-building related to self-care, it is not likely that post-graduate clinicians will incorporate behaviors that might limit the occurrence of compassion fatigue, burn-out, or even suicide.(149) Given the emotionally charged backgrounds of many inner city YMSM, clinicians may be stressed when patients are hard to engage in care.

The relevance of care for individual patients is an important criterion in addressing new care delivery strategies. The CASA study will implement patient-centeredness into HIV treatment at the practice setting, as a means of keeping a hard-to-engage population (i.e. YMSM) in care. YMSM who are not engaged in care (e.g., have poor treatment adherence and low care retention) are unable to benefit from evidence-based treatment that can assure a near normal life expectancy and a good QOL. This health services intervention is expected to improve patient-level outcomes in this population. They remain at high risk for experiencing multiple symptoms, poor mental health and QOL, and decreased survival. The study will support site-based CASA teams in choosing interventions most relevant for this patient population. A 2009 Commonwealth survey of US healthcare showed that 42% of chronically ill Americans surveyed reported inefficient, poorly coordinated, or unsafe care. The CASA curriculum, consisting of multidimensional assessments accomplished by an interdisciplinary team documenting physical, psycho-emotional, social, and spiritual domains, integrated with planned goal-setting; and augmented by support efforts for both caregivers and health providers, can inform an effective care plan with regular review of care goals that reflect patient-centered outcomes specific for HIV, the underlying illness.(54) In this study, care strategies will be tailored to existing ART delivery models and, with an emphasis on communication, problem-solving skills and symptom management, will be appropriate for interface with difficult-to-reach populations, specifically HIV positive YMSM.(135)

Pain, a symptom that causes disability, suffering, and impaired quality of life, is particularly poorly addressed in patients with a history of substance abuse, representing a significant sub-population of the HIV epidemic.(78) Through enhancing HIV clinicians' communication with these patients and their own support system, therapeutic decisions that are patient-centered and accommodate patient values will be promoted.(131) The same approach can be applied to other problems that negatively impact QOL in the patient. Harding et al noted a persistent need for integrated care in the ART era related to: a) pain and symptom management; b) advance care planning; c)

psychosocial support; and, d) terminal care⁶⁶ and delineated care barriers related to the patient, clinicians, service delivery and disease despite the availability of ART. (66)

Behaviorally-infected individuals (130) cared for in adult clinics resemble the young adult or adolescent populations. Characteristics unique to this group include psychosocial issues, neurocognitive disorders, barriers to care related to stigma and disclosure, lack of health insurance, poverty, changing sexual health and identity, and HIV prevention. (39,156) Adherence with HIV management in these age groups is known to be (120,151,154) poor. Factors associated with better retention at 12 months include discontinuing substance use, decreased structural barriers, decreased unmet needs, and no negative beliefs about HIV. (15,128,155) Known barriers reflect the demographic group targeted. (24,102) Multidimensional assessment and management of YMSM includes: a) recognition and management of mental health issues e.g. depression or PTSD; (152) b) clarification and improved communication with existing social supports; c) attention to symptom management in the setting of substance use and effective referrals; d) recognition of impact of changes in physical appearance; (129) e) serious loss issues e.g. childhood sexual abuse or death of important support persons; (64 and, f) assessing issues of HIV-related stigma and disclosure. Mental health issues facing the outpatient with HIV and chronic pain range from individual coping capacity through severe mental illness (32,49,153,164) and affective mental health issues may be correlated with missed visits and earlier mortality. (104) While the majority of HIV outpatients do not suffer from severe mental illness, the stress of HIV illness alone may exacerbate problems ranging from altered self esteem, unresolved sexual identity, and early experience of abuse or other loss. CASA is designed to address the following PCORI questions: "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?" and "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

SIGNIFICANCE: This proposal is significant in several respects. First, it is conceptually innovative and grounded in a definition of palliative care tailored for persons with HIV disease that uses integration of palliative strategies early in disease management rather than at end-of-life alone. It recognizes the importance of relationships among HIV patients and members of the healthcare team (107) and the benefit derived from remaining engaged in regular HIV care and receiving and adhering to ART. (56) This training includes: a) a patient-centered approach grounded in a multidimensional assessment tailored for beliefs, values and priorities; b) "calendar-based," rather than "situational," adjustments to goal-setting (107) with goals based upon patient, family/significant other and staff input; c) management of symptoms that impact quality of life such as pain, depression, anxiety and loss factors; d) communication skills for clinicians regarding difficult-to-discuss topics; and e) attention to coping strategies and prevention of stress experienced by health workers when implementing change. The hard-to-reach and difficult to engage in care, e.g. HIV infected YMSM merit this attention. We are targeting HIV positive YMSM because they are at high risk for poor personal outcomes and are currently recognized as a significant barrier in efforts to prevent HIV infection in Baltimore, one of 20 US cities with high HIV prevalence.

Second, methodologically, we employ a collaborative research model (91) to introduce and evaluate effectiveness of tested palliative educational strategies to improve outcomes for patients and clinicians faced with providing their care. The training intervention is designed to empower site-based Care and Support teams (CASA means "home") through cohesiveness and participatory decision-making, augmented by regular on-site coaching from a trained expert interdisciplinary team, the Expert Coaching Team (ECT). HIV/AIDS education and training is known to change patient/client care by impacting the number/type of patients seen by providers and allowing for interpersonal interactions with patients/clients. (88) Coaching methods are informed by international HIV implementation activities for on-going ART management. Using core palliative skills, techniques and strategies adapted with on-going coaching, (52) we will longitudinally document patient-level outcomes relative to retention in care and adherence with viral suppression, decrease mental health issues, and improved quality of life. We will measure staff stress in integrating these additional care management activities.

Third, culturally, the study's cultural environment is an inner city with a high degree of homelessness, poverty, and IV drug use primarily in African Americans, a population group known to resist end-of-life and other planning for a number of reasons. (55) In the chronic outpatient setting, clinicians are a component of the patient's support system especially when patients do not have supportive social network. Young age on the part of clinicians may intensify work-related stress when patients appear to reject standard care.

Fourth, this study will have implications for implementation in the practice setting as it will take place in existing HIV treatment sites. This research intends to use interprofessional education as a mechanism for preparing clinical staff to improve outcomes for hard to engage and retain populations. Both the US federal government and the World Health Organization promote interdisciplinary healthcare delivery to improve patient outcomes yet it is an area of educational research that to date has received little attention. (106,118) Finally, it will inform policy related to effective care delivery models for vulnerable populations with chronic health compounded by situational issues.

With greater than 50% of clinical events and deaths experienced by PLWH despite their use of ART, clinicians must be more attentive to symptom management; evidence of effectiveness of PC exists for other chronic illnesses. (5,50,71) Only 18-28% (49) of ALL HIV positive individuals in the US have documented viral control, (148) with Baltimore ranking among the cities with the lowest percentage with viral control, with only 14% of HIV infected adults having documented viral control. (53) Chronic disease impacts the well being of patients, their families/informal support systems and professional caregivers (74) and the World Health Organization cited "patient-centered care" as one of four necessary health reforms. (165) Emphasis is placed upon the need for full integration of broader health and social needs to avoid neglecting holistic health promotion activities. (26) Symptom burden alone has been correlated with quality of life. (42) An international HIV review noted the need for integrated: 1) pain and symptom management; 2) advance care planning; 3) psychological support; and 4) delineated patient, clinician, and service delivery care barriers regardless of ART usage. (66) Regardless of whether a prior history of substance abuse exists, pain, a symptom commonly experienced with HIV, causes disability, suffering, and impaired QOL is poorly addressed. (37,38,55)

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

View: v2_Supporting Literature

Supporting Literature

- 1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Background and Significance (Ref 5 on CITED REFERENCES contains definitions regarding PC)

Currently 1.1 million people are living with human immunodeficiency virus (HIV) disease in the US with 18.1% being unaware of their infection and over 50,000 new cases continuing to be diagnosed yearly despite government prevention policies. (17) Baltimore, Maryland ranks fifth in HIV infection rates among US cities. (19) Men who have sex with men (MSM) continue to bear the greatest burden of HIV infection, and African Americans are disproportionately affected. (21) The most rapidly growing cohort of new HIV infections in the US is among young men who have sex with men (YMSM), (115) of whom young black men accounted for 55% of new HIV infections among YMSM. (21) African American YMSM living in Baltimore face multiple conditions such as a history of depression and childhood sexual abuse in addition to their young age for dealing with a chronic illness and potential sexual identity challenges rendering them at higher risk for morbidity or death. (18,53) Unless the course of the epidemic changes, at some point in their lifetime, an estimated 1 in 16 black men will be diagnosed with HIV infection. They have other serious co-morbidities such as hepatitis C or cancer; mental health issues including substance abuse, a range of mood disorders, violence in the home and a syndrome of grief and multiple losses with an insubstantial social support network.

Human Immunodeficiency Virus (HIV disease) is now recognized as a manageable chronic illness for persons able to access and adhere with treatment. (25) Patient-identified outcomes focused upon quality of life (QOL) are preferred to simple tracking of viral response and prolonged survival. Patient's engagement in care is critical to the clinical management of HIV infection. Patients who missed visits within the first year of initiating outpatient treatment had more than twice the long-term mortality than those who remained in care. (104) A systematic review of multidimensional needs of HIV positive persons with early disease, within 6 months of diagnosis, identified persistent factors: a) having physical and psychological symptoms; b) impaired well-being; c) decreased peace and calm and increased thoughts of suicide; d) practical problems; e) lack of emotional support; and, f) fear of being rejected by families. (142) Those with chronic health needs are at higher risk for psychosocial and physical sequelae (8,86,112) and staff caring for them may suffer levels of stress in engaging and retaining these patients in care. (89,157)

The Affordable Care Act (ACA) and the National HIV/AIDS Strategy call for the patient-centered medical home (PCMH) as health reform progresses in the US. Currently coordination of care and the team approach are central to this model. (169) Team-based health care is recommended by the Institute of Medicine as the optimal approach for care delivery in a complex health system. (101) Randomized controlled trials have documented that implementation of palliative care (PC), a discipline

grounded in effective functioning of an interdisciplinary team, improves survival and quality of life in both cancer and HIV patients.(46,150) This type of care is based upon an appreciation for patient-family values and beliefs and enhances communication with clinicians and integrates positive attitudes and skills with disease-specific delivery models.(103,139) A survey of HIV patients not taking combination antiretrovirals (ART) indicated that overall QOL could be improved by targeting depressive symptoms, physical activity, and coping strategies as part of comprehensive treatment protocols. (84) Use of a multidisciplinary team approach is known to benefit HIV patients in the domains of symptom control, pain, anxiety, insight, and spiritual well-being.(36,37,66) A systematic review of successful engagement and retention activities documents that strengths-based case management, patient navigation, and recognition of system-level barriers are effective but not adequate alone. YMSM have voiced a need to "feel respected" by clinic staff.(79) Clinicians relying solely on laboratory and clinical indicators may perceive patient-centered activities to be time-consuming(33) and not acknowledge patient preferences for more individualized care or the suffering from physical or mental symptoms that patients can experience. (12) Persons with a history of abuse are known to have difficulties with trust and relationship building and actual "time spent with clients" was significantly associated with retention in care over a 6-month period.(95)

The early implementation of a palliative approach is a complex interdisciplinary approach that enhances communication at the point of care and requires integration of attitudes and skills with comprehension of the underlying illness, in addition to operative disease-specific delivery models.(103,139) In this study, the experience from implementation of the CASA curriculum in HIV care and treatment in international settings is evidence of its value as a management model for chronic illness.(6,43,47) This approach encourages effective engagement in care and goal setting with patients and with family carers.(48) The proposed study is in line with the need for research to document the process of forming and training interprofessional care teams and represents an important advance in the field.(9) Large-scale studies of the early integration of a palliative approach have been impeded by multiple factors related to size and organization of services.(1) With greater than 50% of clinical events and deaths experienced by PLWH despite their use of ART, clinicians must be more attentive to symptom management; evidence of effectiveness of PC exists for other chronic illnesses.(5,50,71) Only 18-28% of ALL HIV positive individuals in the US have documented viral control.(148) with Baltimore ranking among the cities with the lowest percentage with viral control, with only 14% of HIV infected adults having documented viral control.(53) Chronic disease impacts the well being of patients, their families/informal support systems and professional caregivers(74) and the World Health Organization cited "patient-centered care" as one of four necessary health reforms.(165) Emphasis is placed upon the need for full integration of broader health and social needs to avoid neglecting holistic health promotion activities.(26) Symptom burden alone has been correlated with quality of life.(42) An international HIV review noted the need for integrated: 1) pain and symptom management; 2) advance care planning; 3) psychosocial support; and 4) delineated patient, clinician, and service delivery care barriers regardless of antiretroviral (ART) usage.(66) Regardless of whether a prior history of substance abuse exists, pain, a symptom commonly experienced with HIV, causes disability, suffering, and impaired QOL is poorly addressed.(37,38,55)

To effect behavioral change and improve clinically meaningful patient-centered outcomes, we must consider a range of strategies at the patient, provider and system level. CASA specifically targets the first two levels and with successful demonstration may provide sustainable effects system-wide. Patient populations that are difficult to engage and retain in care impact the overall health of both individuals and the health delivery system. YMSM living in the inner city face multiple personal and health system barriers to achieving desirable control of HIV disease. These barriers may be generalizable to other hard to engage populations. Specifically in HIV disease, a lack of adherence with keeping outpatient appointments has a known association with lack of adherence to ART itself and failure to achieve viral suppression. Missed appointments increase overall health costs, resulting in lack of control of the epidemic and increasing healthcare stigma against the population of YMSM. Modifications in health delivery methods are needed for clinicians as well as for the delivery system. Findings from this study will improve patient mental health and QOL outcomes that can decrease the spread of HIV; improve staff stress related to working with hard-to-engage populations; and reduce waste of healthcare resources.

Successful integration of new care approaches is known to be enhanced by the use of cross-training and team-building for interdisciplinary teams; in-house training for staff; emphasis on continuity of care; and data-driven patient-level management(160) where the underlined activities are all elements of the CASA curriculum.(73) HIV care(161) delivery has long relied upon a multidisciplinary approach but the compassion seen in the early epidemic must now be re-directed toward YMSM who remain at risk for poor outcomes despite effective disease management strategies.(105) The CASA approach will enable HIV staff to modify ART management approaches in a manner that may improve early antiretroviral control of difficult to reach populations. Early integration of the palliative approach (EIPA) is desired for both cancer (46,99,15) and HIV care where recent studies have demonstrated improved QOL and prolonged survival.(92,150) In-depth understanding of the underlying illness is necessary to identify clinically appropriate timing of interventions as well as specific skills for reaching patients. Educational initiatives using EIPA for a variety of health conditions (e.g. congestive heart failure,(71) end stage renal disease,(12) ALS and chronic neurologic disorders, general surgery and intensive care units (3,35) have been effective. In HIV disease the challenge remains to identify initiation strategies and appropriate timing for discussions with YMSM, their carers, and for clinicians to achieve improved outcomes.(143)

YMSM may demand more time during an appointment if clinicians are not skilled in effective care provision or they may create missed appointment resulting in inefficiency for the health delivery system. In current economic conditions, clinicians are challenged to provide extensive care in limited visit time. For clinicians faced with non-adherent patients in the era of effective antiretroviral therapy this presents multiple dilemmas. In the pre-ART era work overload and stress derived from social relationships at work were the main predictors of psychological distress, emotional exhaustion and depersonalization on the part of clinicians.(89) Patients requiring attention beyond that encountered in usual care delivery are likely to impact the workload in the ART era. The YMSM may have low self-esteem and a fear of failure or other individual barriers to engagement. Use of self-care strategies is one activity used in the CASA teaching that can benefit both persons hard to engage in care and the cadre of clinicians who care for them. Sharing one's story is one effective mechanism. Appreciation for the linkage between personhood and body image – important in this population – can be key toward promoting self-esteem.(23) Building in motivational activity to accompany routine medical care is another mechanism for engagement that can also respond to the call for patient-centered care.(94)

Self-care for clinicians is documented as a method for prevention of compassion fatigue in nursing, social work and medicine. Profound emotional disturbances can occur in clinicians exposed to cancer, chronic illnesses and end-of-life care(139) and unexamined emotions can lead to provider burn-out and depression, thus compromising patient care.(41,100,138) Self-care for clinicians, an integral part of the CASA curriculum, must be included during a change in care delivery strategies by improving the ability of clinicians to cope with frustrations inherent in engagement of YMSM in care.(30) Repeated exposure to emotionally sensitive issues can lead to symptoms consistent with post-traumatic stress syndrome in the clinician. Clinicians caring for persons with HIV disease before the use of ART experienced psychological difficulties likely to respond to interventions to improve work-related stress.(14) Confronting the emotional under-pinning of interactions with patients, family and staff; naming and recognizing emotions that threaten the individual, e.g. need to rescue; frustration and sense of failure at progressive illness; fear of becoming ill; grief and loss; powerlessness and being overwhelmed; and desire to avoid and escape are incumbent for successful management in emotional situations.(100) Without specific skills-building related to self-care, it is not likely that post-graduate clinicians will incorporate behaviors that might limit the occurrence of compassion fatigue, burn-out, or even suicide.(149) Given the emotionally charged backgrounds of many inner city YMSM, clinicians may be stressed when patients are hard to engage in care.

A 2009 Commonwealth survey of US healthcare showed that 42% of chronically ill Americans surveyed reported inefficient, poorly coordinated, or unsafe care. The CASA curriculum, consisting of multidimensional assessments accomplished by an interdisciplinary team documenting physical, psycho-emotional, social, and spiritual domains, integrated with planned goal-setting; and augmented by support efforts for both caregivers and health providers, can inform an effective care plan with regular review of care goals that reflect patient-centered outcomes specific for HIV, the underlying illness.(54) In the CASA study, the curriculum is tailored to existing ART delivery models and, with an emphasis on communication, problem-solving skills and symptom management, will be appropriate for interface with difficult-to-reach populations, such as HIV positive YMSM.(135) Pain, a symptom that causes disability, suffering, and impaired quality of life, is particularly poorly addressed in patients with a history of substance abuse, representing a significant sub-population of the HIV epidemic.(78) Through enhancing HIV clinicians' communication with these patients and their own support system, therapeutic decisions that are patient-centered and accommodate patient values will be promoted.(131) The same approach can be applied to other problems that negatively impact QOL in the patient. Harding et al noted a persistent need for integrated care in the ART era related to: a) pain and symptom management; b) advance care planning; c) psychosocial support; and, d) terminal care(66) and delineated care barriers related to the patient, clinicians, service delivery and disease despite the availability of ART.(66)

Behaviorally-infected individuals(130) cared for in adult clinics resemble the young adult or adolescent populations. Characteristics unique to this group include psycho-social issues, neurocognitive disorders, barriers to care related to stigma and disclosure, lack of health insurance, poverty, changing sexual health and identity, and HIV prevention.(39,156) Adherence with HIV management in these age groups is known to be poor.(120,151,154) Factors associated with better retention at 12 months include discontinuing substance use, decreased structural barriers, decreased unmet needs, and no negative beliefs about HIV.(15,128,155) Known barriers reflect the demographic group targeted.(24,102) Multidimensional assessment and management of YMSM includes: a) recognition and management of mental health issues e.g. depression or PTSD;(152) b) clarification and improved communication with existing social supports; c) attention to symptom management in the setting of substance use and effective referrals; d) recognition of impact of changes in physical appearance;(129) e) serious loss issues e.g. childhood sexual abuse or death of important

support persons;(64) and, f) assessing issues of HIV-related stigma and disclosure. Mental health issues facing the outpatient with HIV and chronic pain range from individual coping capacity through severe mental illness(32,49,153,164) and affective mental health issues may be correlated with missed visits and earlier mortality. (104) While the majority of HIV outpatients do not suffer from severe mental illness, the stress of HIV illness alone may exacerbate problems ranging from altered self esteem, unresolved sexual identity, and early experience of abuse or other loss. CASA is designed to address the following PCORI questions: "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?" and "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

2 If available, upload your applicable literature search:

Name	Created	Modified Date
African RCT Use of PC in HIV_1471-2334-12-288.pdf	4/7/2014 1:07 PM	4/7/2014 1:07 PM
TZ Study.pdf	4/7/2014 12:40 PM	4/7/2014 12:40 PM
REFERENCES CITED.docx	12/16/2013 9:22 PM	12/16/2013 9:22 PM

3 * Provide a list of 3 keywords or search terms (1 per line) relevant to your research that would help potential participants find your study using search engines:

Keyword 1: HIV/AIDS

Keyword 2: palliative care

Keyword 3: interprofessional education

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

View: v2_Study Procedures

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. If some of the questions below are not applicable to the research (i.e., chart review), enter "N/A."

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

There are 2 research populations targeted: a) STAFF (2 groups: 1) CASA Team (Trainers being trained) and All-STAFF asked to complete 2 surveys about work-related stress approximately 18 months apart. There are no invasive procedures involved in this protocol; PATIENTS complete 3 surveys over 18 months to describe YMSM in 2014-2016. There is an educational intervention for STAFF only not for PATIENTS.

OVERVIEW of PROCEDURES:

STAFF: This is a 3-part inter-professional experiential educational (IPE) intervention for a selected multidisciplinary team of staff members from one outpatient HIV clinic. Staff will complete 2 surveys over 12-18 months regarding their response to the educational intervention and their own work-related stress.

The CASA Team (receiver of intervention) is a selected multidisciplinary team to be trained at the experimental site. This team will attend an initial palliative training (timing to be determined with input from the site Directors) followed by on-site clinical coaching (1.25 hours every other week for up to 18 months) to review progress of patients enrolled in the study and how the team is effecting use of the palliative skills. The CASA Team and the Expert Coaching Team members will identify content for quarterly in-service education for all staff members to share learning. This sequence simulates usual continuing education for outpatient clinics in chronic care. Evaluation forms will be developed after the curriculum content is finalized and submitted to the IRB.

In response to changes in the administration of the intervention site the Delivery Schedule for the intervention was adapted but content was retained: The Educational intervention was a) initiated with an all-staff in-service to introduce aims of the study and one content area; followed by b) 2-hour sessions for the selected CASA Team 1-2 times per month through May, 2015. On-site coaching was reduced to 1 to 2 times per month for 1.25 hours per session. Content was delivered as planned. Because of changes within the intervention clinic itself and lack of space, the "on-site" coaching was held in a familiar space easily accessible by members of the CASA Team. Six quarterly in-services were offered on schedule for all staff.

PATIENTS: There is no intervention for this group but they do complete surveys. Survey responses will be compared between the 2 clinic sites before and after the training intervention. Data is collected at both sites for 9 months prior to the intervention to describe the current YMSM population in Baltimore. Each participant will give informed consent and 1) complete a Baseline Visit at the University of Maryland, Baltimore (UMB) Institute of Human Virology Jacques Initiative Clinic or at the UMB Evelyn Jordan Center where he receives HIV care. Participants will be asked to complete a survey on a password protected touch-pad that will take 45-60 minutes at first completion. The questions are about current health and medical history. This data is encrypted and de-identified before being sent via a secure internet site to our data center at New York University.

Members of the Study Team will review selected data elements from the electronic medical record (laboratory results and diagnoses) that will be compared with survey responses. Personal health information (data) will be extracted, or taken, from the clinical record of enrolled patients to document HIV status relative to clinical management including time in care, medications taken, laboratory results and attendance at clinic visits. 2) Surveys will be questions about health status and symptoms. Participants will be able to listen to the questions read aloud through earphones and a study team member will be present to answer questions.

The SURVEY CONTENT asks about symptoms such as pain, tiredness, depression (sad mood), anxiety, or sleep problems; current daily activity level; and sexual history. 3) Follow-up Visits: participants will complete the same survey 2 more times over an 18-month period about 6 months apart at regularly scheduled clinic visits or at a time that is convenient for them. The Study Team will review the clinic records following the visit to obtain laboratory results and medications to compare survey responses. Contact information will be up-dated at each visit including the name of someone to call if the patient does not keep an appointment. Total time for each of the 2 follow-up visits is approximately 30-60 minutes. Time for any patient participant is up to 18 months to achieve 2 visits following the Baseline. Questions will not be duplicated in the electronic survey. Questionnaires being used for the survey have been up-loaded individually.

The CASA CURRICULUM and EDUCATIONAL MANUAL will be generated during the study period and will be available in final format by the end of the study. It will include domains specific to integration of palliative care strategies with on-going HIV management specifically to include (but not limited to): (1) engagement principles based upon respect for the individual including cultural context and life transitions; (2) multidimensional assessment and management of symptoms and other issues faced by HIV positive young men who have sex with men (YMSM); (3) goal-setting and problem-solving; (4) use of self-care strategies for the staff team and (5) use of

quality improvement methods to integrate new skills with usual care. The curriculum will be submitted to the IRB for review during the Fall of 2014 and offered to the clinic team in 1-2/2015. The final curriculum will be posted with study results at the end of the study period to facilitate replication of the process. The curriculum will be completed during the second phase of the study while the YMSM population in Baltimore is being described. The Research Team will use feedback from the staff team to further refine the curriculum that can be shared with the second study site staff following the study if it appears to be beneficial in the US setting. All curricular materials will be submitted to the IRB prior to their being given to staff participants.

POTENTIAL RISKS to PARTICIPANTS:

STAFF:

- 1) There is a risk that staff members will not be interested, become bored, or feel overwhelmed by participating in the study. They will be reminded that they have the option of leaving the study at any time without concern for their employment status. They will also be referred for counseling with the Employee Assistance Program or another program of their choice should they wish.
- 2) The inter-professional palliative education is delivered in the manner that most health professionals receive on-going continuing education: 1) attend a didactic/iterative session (training for trainers); followed by 2) on-site clinical coaching; and 3) quarterly in-service education for all staff members of the clinic to share results of implementation of new approaches to care delivery. Attendees will complete evaluation forms based upon session content for each session.

PATIENTS:

- 1) SURVEYS: Questions on the surveys may be boring to participants or during the interviews could raise psychological or emotional issues for any of the participants and there is a protocol in place for assessing their need for de-briefing or further counseling including referrals for appropriate follow-up.
- 2) EXTRACTION of electronic medical records (EMR) for purposes of comparison with outcome data (elements describe above). Confidentiality is always a concern with HIV patients and staff are trained in methods for protecting the confidentiality of patients at all times in addition to having all survey documents de-identified and encrypted.

3) QUALITATIVE INTERVIEWS:

The second half of the study will add a qualitative component using structured interviews. These will be approximately 1 hour and selected participants from both staff and patients will sign another consent form for this process. These interviews will be structured during the study to reflect findings regarding description of the study population. Any participant will be offered a small compensation for his/her effort. A separate consent form will be submitted prior to this activity reflecting findings from earlier phase of the study.

CURRICULUM REFINEMENT: This involves the review, presentation, refinement and final presentation of teaching materials used in international HIV teaching settings to teach clinic staff members palliative skills for populations known to be difficult to engage and retain in outpatient HIV care. Evaluation forms for feedback are identified by a unique code for each participant. The Research Team is aware that there will be only 1 representative of each discipline and, for the most-part, responses will not have identifying mechanisms. No responses will be linked externally in an identifiable manner in dissemination efforts. Feedback from each discipline will be useful in refinement of the curriculum.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

N/A This is an educational intervention and there are no procedures being performed.

Point of Information:

PATIENTS - Standard OUTPATIENT HIV CARE:

HIV patients are routinely monitored as outpatients every 3-6 months with laboratory testing specifically CD4 cell count and HIV PCR (viral Load) measurements as well as electrolytes and liver panels with yearly screening for co-occurring illness. At each visit a history and physical is documented along with current medications and management strategies. We will review this information from the electronic medical record (EMR) to be correlated with patient survey responses.

3 * Describe the duration of an individual participant's participation in the study:

Following the informed consent process:

1) INTERVENTION RECIPIENT - STAFF:

- a) Members of the HIV clinic STAFF Team (CASA Team) will participate in the training that has 3 parts and takes place over about 18 - 24 months. At this time the initial training time has not been determined with the clinic administration. It will be submitted to the IRB before staff participate in the study.
- b) Selected clinic staff will participate in Baseline and 1 follow-up survey. Questions on this survey are related to work-related stress and response to the educational intervention.
- c) Clinic staff participating in 1-time qualitative interviews will be consented prior to the interview

LONGITUDINAL DATA COLLECTION:

- 2) PATIENTS: Enrolled HIV positive young men who have sex with men (YMSM) will complete a baseline survey and the same set of questions at 2 subsequent visits approximately four to six months apart making the overall participation of each enrolled patient about 12 or up to 18 months as they will be seen at regularly scheduled clinic visits or at a time that is convenient for them.

4 * Describe the duration of the entire study:

The study is funded to take place over 3.5 years (10/9/2013 - 3/30/2017). The study was not actually funded at the documented start date. Data collection was anticipated to begin in April, 2014 and the intervention to take place in January, 2015. The curriculum is to be refined prior to use with the Expert Coaching Team, who will be trained in coaching skills prior to the intervention. All materials will be submitted to the IRB before use with participants.

Modification #16:

The study is extended 6 months until March 2017.

5 * Describe any additional participant requirements:

There are no additional procedures.

ID: VIEW4E0280585B400
Name: v2_Study Procedures

View: v2_Sample Size and Data Analysis

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

RATIONALE: This is a proof of concept study in a US population. It is an educational intervention for outpatient clinic staff. The study provides a longitudinal, behavioral description of how staff are impacted by the educational intervention. The patient population being cared for by these trained staff in the intervention clinic are compared

to patients attending a second (control) clinic with similar care delivery but no educational intervention to observe for changes in mental health and quality of life of patients being cared for at the clinic.. The analyses will allow for comparisons of both staff (related to work-related stress, or burn-out) and patient outcomes between these clinics.

The patient population being addressed is HIV positive young men who have sex with men (YMSM) at high risk of short-term poor health and early mortality because they do not engage well and remain in care. Black and African American YMSM are among the fastest growing sub-population of newly reported HIV infections accounting for 55% of new HIV infections among YMSM.(21) High rates of HIV among YMSM were reported in a locally-conducted 2009 survey, which found that 30% of (135) YMSM (ages 16-24, mean age 21; >95% Black or African American) tested HIV-positive. This study will characterize this population in Baltimore in 2014-2015 and clarify the impact of training staff in palliative skills for care-management.

The SAMPLE SIZE CALCULATION is described below:

Aim 1: STAFF - RECIPIENTS of the INTERVENTION: Statistical comparisons will be made to analyze the impact of the training on staff work-related stress and burnout. We will use single case or small group comparisons of qualitative data augmented by insights provided in the qualitative interviews. Our sample is large enough to assure a sample representative across subgroups of interest (e.g. CASA Team member) or clinic role, as well as exhaustive of different perspectives among roles for which there is more than one staff member.

We will enroll up to 80 staff members between the 2 study sites.

1) INTERVENTION RECIPIENTS: STAFF of HIV clinic:

a) The 5-7 member CASA Team is multidisciplinary (selected by clinic administrator with the Research Team) SEE Documents Section.

b) up to 40 from each of 2 clinics (80 total) - adults over 18 years; male or female; who speak English. These staff members will represent a broad cross-section of staff, be consented separately to participate in qualitative interviews regarding their response to the educational intervention or to the study if no intervention took place.

For Aim 2: PATIENTS - AFFECTED POPULATION: The sample size selection for longitudinal analyses of patient data represents a balance between having enough people entered to assure that data interpretation is reasonable and true and the availability of cases and resources exist..

For Aim 3: CURRICULUM Refinement: There is no power calculation warranted for the Intervention which is a usual train-the-trainer model.

SAMPLE SIZE: (Based upon the numbers needed to evaluate the PATIENT population of YMSM)

Sample size calculations were made for logistic regressions predicting the likelihood of patients reporting viral suppression which indicates control of their disease (meaning that the patient is actually taking ART as prescribed). This is based upon the following assumptions: (1) improvement of 10% in patients reporting viral suppression by Follow-up #2 Survey among patients at Site 1 (experimental); (2) $1 - \beta = 0.8$; (3) $\alpha = 0.05$; and (4) $d_{eff} = 2.2$.

These analyses estimate the need for a total sample size of 170 (85 per site) at study end. Allowing for 20% attrition from Baseline to Follow-up 2 it will be necessary for us to accrue a total of 204 patients (102 at each site) in order to have a sufficient number of patients completing all 3 Patient Surveys. This number is higher than the number of patients we estimated to be required for the two-sample comparison of survivor functions using Cox Proportional Hazard regressions ($n=140$), (176) allowing for attrition. This sample size provides adequate power for the proposed longitudinal regression models. Based upon analyses made with N-Query Advisor 7.0 software 44 assuming $\alpha = 0.05$ and power $(1-\beta) = 0.8$, the 170 cases completing Baseline, Follow-up1 & Follow-up 2 will allow us to identify "small to medium" effects for the total model ($R^2 = 0.063$) and individual coefficients as well as a "medium" effect for up to each of 15 co-variables on R^2 (as small as 0.055) as outlined in Cohen (29).

The proposed sample size will allow us to estimate models including: a) a dummy variable noting the intervention arm, b) a term to correct for attrition bias, c) the baseline counterpart of the dependent (patient outcome) variable, and, d) a set of up to 12 relevant co-variables.

ENSURING ELIGIBLE PATIENTS:

To assure that there would be a sufficient pool of potentially eligible patients at each of the study clinics to accrue the needed number of patients, we had each clinic review their clinic enrollment data to identify current clients who were potentially eligible for participation. We also identified patients at the UMB adolescent HIV clinic who are 16-17 years old but will be 18 by the end of study accrual and may move to one of the adult clinics. Based upon these reviews we estimate there will be an initial total of 135 potentially eligible patients at Site 1 and 185 at Site 2. Assuming participation rates of 75% at Site 1 and 55% at Site 2, we should easily be able to accrue the 204 patient participants required.

SAMPLE ATTRITION: This is a critical issue in longitudinal studies since there are numerous reasons participants may drop out. In YMSM, if attrition occurs non-randomly it can pose a threat to the ability to interpret the data. We address this by offering an honorarium at each survey and scheduling follow-up surveys at the next regular clinic appointment. We will also offer patients the option to complete follow-up surveys at a time that is most convenient for them. To further prevent loss to follow-up, following informed consent, we request names, addresses, and telephone numbers of up to 3 friends, neighbors, or relatives who will know how to contact them if we are unable to reach them in the future. We have extensive experience identifying and enrolling PLWH into observational and interventional research studies. Since clinics in this study have outreach workers, we are projecting a 20% loss to follow-up. If attrition is substantial, reasons for "drop out" will be analyzed for future implementation.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

DATA ANALYSIS:

This is a longitudinal, descriptive study evaluating the impact of an educational training for outpatient clinic staff on patient outcomes cared for by the trained staff members. The analyses are complex: 1) there are 2 target groups (staff and patients); and 2) the intervention is offered in 3 stages (teaching; coaching; all-staff education); and it is a pre-post comparison of the impact of a training intervention upon patients cared for by trained staff using 1 site as the control for the other.

The data collected is psycho-social, meaning both psychological and sociological, reflecting graded rather than dichotomous, or Yes-No responses. This means that multiple comparisons are being made. This large array of data requires mathematical modeling to describe true associations and accurate interpretation of the data. This is explained in detail below.

For PATIENTS quantitative results (survey responses) are supplemented by data extracted from the clinical electronic medical record (EMR) and by qualitative interviews with selected participants from each of the 2 target groups.

Addressing AIM 1: STAFF:

QUANTITATIVE: We will use data from Staff-Baseline and Staff-Follow-up surveys at both sites. We will enroll up to 80 STAFF members between the 2 sites. An array of descriptive and graphical techniques will be performed to characterize the distribution of the variables at each point in time as well as aggregate change in work-related stress, or burnout from Baseline (B) to Follow-up (F). Point estimates with confidence intervals will be used to estimate population values. Comparisons of data from participants in the Intervention and Control groups at Baseline (B) will identify potential heterogeneities between sites with regard to the distribution of staff background characteristics that might be related to stress or burnout (e.g., staff's clinic role/position -- physician, nurse, outreach worker, substance abuse counselor, etc.).

Between-group comparisons at B and F will be made with chi-square, t-tests (Fisher's exact as appropriate) and comparisons of change across time will be assessed by paired Student's t-test or paired Wilcoxon test. Post-hoc power calculations will be performed to determine if we have adequate statistical power for further testing.

Of particular interest would be comparisons between B and F reports of staff burnout (this is a contingency analysis) and HIV-carer stress (paired t-tests). Although some between group comparisons will be made to assess whether the program appeared to impact staff reports of work-related stress, or burnout, analyses of training effect must rely primarily on analysis of individual or subgroup data augmented with insights provided from the qualitative interviews with the Intervention group staff.

The nonrandom assignment of staff, the limited number at each clinic, the nature of CASA training delivery (CASA team receives hands-on training, while remaining staff learn from the CASA team using a train-the-trainer model), and the differential distributions of staff with regard to clinic roles preclude accrual of a sufficient sample size for multivariate analyses to simultaneously control Site and relevant between-group heterogeneities.

Comparisons between sites will be limited to descriptions of findings for two subgroups determined by: 1) whether or not the staff member was part of the CASA Team (Y/N) and, 2) staff's clinic role/position (Physician, Nurse, Outreach, Counselor, etc.). CASA Team members differ from other staff not only because they received hands-

on training in the integration of palliative skills into their role at the clinic, but because they also hold a dual role both as both trainees and trainers. Similarly, the nature and level of potential impact that integrating palliative care precepts into their work is likely to have will vary by the staff member's role at the clinic; not only due to the work they do but on the basis of the clients they serve.

Addressing Aim 2: PATIENTS: Data is collected at baseline (B) and at 2 follow-ups (F) from enrolled patients.

QUANTITATIVE ANALYSIS:

First, descriptive analysis of all data from baseline and 2 follow-ups from each site will be conducted and between-arm comparisons made to understand all study outcomes (clinic attendance, medication adherence, viral suppression, self-esteem, mental health and QOL) and other measures of patients': demographic and psychological characteristics, disease/treatment and health status, psychological history, and goal setting and care planning. These analyses will identify potential heterogeneities of the sample (both within and between arms) that might require statistical redress.

Second, through comparison of longitudinal data points, we will describe "change in time-varying patient characteristics", "stressors", "modifiers" and "outcomes". "Attrition and balance" in key characteristics of the pre- and post-test groups will be assessed by comparing data from those completing: only baseline surveys; baseline and one follow-up; and baseline plus 2 follow-ups.

LOGISTIC REGRESSIONS: For viral suppression and other dichotomous potential correlates of study outcomes we will estimate several logistic regression models. Given the longitudinal data collection with respondents repeatedly completing the same measures, patient reports for all measures are likely to be correlated. This violates the assumption of independence underlying logistic regression because it results in underestimates of standard error and therefore inaccurately increases the likelihood of rejecting the null hypothesis (Type-I error). To take into account higher intra-class correlation in the nested observations, we will use several generalized estimating equation (GEE) models with logit link.(167) The GEE model relates the marginal response $\mu_i = E(y_i)$ to a linear combination of covariates by: $g(\mu_i) = x_i\beta$ and under logit link, $g(\mu_i) = \log(\mu_i/1-\mu_i)$, where y_i is the indicator of viral status of the individual i at time t partner, and β 's are the estimated parameters. In this model specification, the covariance structure is treated as nuisance parameter. We will be using STATA 12, statistical software (147) for data cleaning and data analysis.

SURVIVAL ANALYSIS:

Several unadjusted and adjusted Cox Proportional Hazard regression models will be estimated for comparing survival curves between Site 1 and Site 2 including models that allow for time-varying correlates [e.g., Cox-Aalen (97). Evidence of a short-term intervention effect on attendance (retention in care) will be made by comparing survival curves at both sites from 8 months (prior to the baseline assessment) to 16 months following the initiation of the intervention training at Site 1. Descriptive analyses and identification of sample heterogeneities and potential sources of bias. Summary statistics and graphical displays will present characteristics of study participants in each intervention arm as reported at B, F1, and F2, as well as to describe aggregate change of time-varying measures over three time periods: B to F1 (short-term gains), B to F2 (longer-term), F1 to F3 (maintenance).

BIAS: Analyses will be conducted to identify potential sources of bias that may require statistical redress in multivariate analyses. Characteristics of participants in the experimental arm at B will be compared to those of patients in the Control group to identify potential heterogeneities between samples. Given the nonrandom assignment of patients to study arm, it will be necessary to compare characteristics of participants in the study arms at B to identify potential heterogeneities between sites with regard to the distributions of patient or other background characteristics that research suggests might be related to patient outcome(s). Characteristics of participants at B will be compared on the basis of their level of study completion (only B, B+F1, or B+F1+F2) to assess attrition and identify its potential correlates. Between-group comparisons within a single interview will be made with chi-square, t-tests (Fisher's exact as appropriate) or one-way ANOVA with F-tests of significance; and comparisons of change across time assessed by paired Student's t-test or paired Wilcoxon test. Concordance between measures at different times will be assessed using correlation coefficients: Pearson or Kendal tau/Spearman. Probit modeling will be used to determine whether specific patient characteristics, stressors, and/or modifiers are associated with attrition.(119) Propensity analyses (93) will be conducted to calculate terms to control for potential unbalance between intervention arms (see "Propensity Scores" below) will be used.

Addressing Aim 3. CURRICULUM:

Descriptive analyses of the training evaluation forms (to be developed following refinement of the curriculum and submitted to the IRB before being used with STAFF) completed by the teaching team or instructors, expert coaches, and HIV clinic staff including administrative staff during all 3 levels of the CASA training including quarterly all-staff educational sessions will be used to evaluate the training. This analysis will 1) confirm that topics and issues intended to be taught were presented including cultural issues; 2) document both consistency and completeness of the training; 3) identify unanticipated issues raised during the training; and 4) identify aspects of the training that need revision or expansion. These descriptive analyses represent what Cook, Cook and Mark (26) refer to as the "take" of the intervention, or how successful the training is at accomplishing what it intends. Participant insights will be used to suggest training revisions to improve the "reach", or scope of the training, success of implementation and overall effectiveness of the training for other settings. The "reach" describes both breadth and depth of the impact of the training. Attendance logs will document that all members of the team received the training. We will use the RE-AIM framework [62] in analyzing the acceptability, feasibility, and impact of the CASA intervention. The RE-AIM framework focuses on the content and outcome of a training and guides examination of the clinics including the social, cultural, and care needs of the YMSM. The analysis focuses on essential training elements that foster implementation and sustainability of the training incorporating staff and patient perspectives.

LONGITUDINAL DATA ANALYSIS:

The third analysis is longitudinal and will examine trends of change in study outcomes that will describe potential correlates/mediators of change, as well as comparisons of change in study outcomes for both populations (STAFF and PATIENTS) and potential correlates between study arms. Thus we are able to determine training effect and analyze maintenance and sustainability of intervention effects. Assumptions will be checked with non-parametric alternatives. Appropriate multiple testing techniques (i.e., Bonferroni) will be applied as needed. Analyses will be conducted using SAS 9.3 or IBM SPSS Statistics v20.

Longitudinal analysis of the training effect and its long-term maintenance/sustainability. We will describe trends over time (short-term [baseline to first follow-up], longer-term [baseline to second follow-up], and maintenance [follow-up 1 to follow-up 2]) in the remaining study outcomes and potential correlates, using Laird and Ware's longitudinal analysis techniques.(162) This involves model choice and potentially model averaging. A best model will be chosen based on the Akaike information criterion.(34) Model averaging techniques might prove useful given "a priori" information is available about factors likely to be associated with improved outcome. Longitudinal techniques will be used to identify relationships among changes over time, baseline characteristics and behaviors at follow-ups 1 and 2.

Multiple regressions will be used to estimate models predicting residualized change (short-and long-term) scores (27) for study outcomes, including potentially relevant covariates (characteristics and stressors) plus a term noting the intervention arm in which the patient participated. Next, to test if an effect noted for the Intervention Arm from the 1st model is accounted for by the impact of the intervention on the mediators, these models for outcomes will be re-estimated including residualized change scores for the mediators.

For both sets of analyses:

- a) a term will be included to balance the arms (based on propensity score matching);
- b) assumptions will be checked; non-parametric alternatives and transformations considered; and, if needed, appropriate terms added to control for biases associated with failures of randomization and/or attrition;
- c) heterogeneity of intervention effect will be examined using statistical modeling to determine the interaction between the intervention and other covariates. [Examining relationships between changes in outcomes and various factors (e.g. demographics, SES, social support) will determine factors that define heterogeneities of intervention effects. Statistical interactions will be examined using graphical displays and statistical tests of interaction]
- d) missing data will be investigated by inferring a relationship between variables (socio-demographics, outcomes) and 0-1 indicator that defines whether or not a measure is observed.(132) This analysis will identify factors likely to cause measurements to be missing. Should a substantial proportion of cases (> 10%) be missing for a critical independent variable and evidence found of non-randomness, missing data will be handled using multiple imputation methods (61) and
- e) Internal Validation will use re-sampling techniques (permutation and bootstrap). (59) Based on our experience in statistical modeling, we will balance model richness against danger to over-fit. However, we expect estimates and inferences made will be robust.

Propensity Scores for multivariate analyses (144): A primary project goal is to accurately measure the intervention effect. Caution will be employed to recognize and protect from sources. To achieve balance between arms for the purposes of the proposed regression analyses, we will perform propensity score matching. Because of potential informative patient drop out, protocol violations, missing data, practice effect, carryover effect, order effect, etc. the characteristics of participants in the two intervention arms may not be balanced.

We will describe the impact of the CASA training on study outcomes. Groups of patients with similar propensity scores are expected to have similar values for all the background information. Propensity scores provide a means of summarizing all of this background information into a single value. The propensity score method is based on a logistic regression model that involves the conditional probability of being in the intervention arm given background information.(145) Specifically, the logistic model constructs a relationship between a dummy variable for intervention arm) and predictor variables that include all covariates that extant research or patient reports have described to be associated with the center site plus all of the covariates to be included in the final model. The propensity score analysis will involve a large number of covariates. An adjustment for hidden covariates may be less crucial in this setting, given the anticipated high level of overlap between arms in populations being served, and because it is likely that an unmeasured confounder can be described as a combination of the measured variables.

Modeling will potentially involve dimensionality reduction techniques (principal components, multidimensional scaling, etc.) and/or model selection (based on Bayesian Information Criteria). However, with propensity score modeling there is generally not as much of a concern about over-fitting (since the outcome is not involved) or degrees of freedom. To assess the viability of the propensity score for use in the regression analyses we will stratify participants based on quintiles of the propensity score.(34) Within each stratum, we will check whether each co-variate has achieved the desired balance. Sensitivity analyses will be conducted to determine possible effect of missing co-variables on propensity scores and study findings.

QUALITATIVE ANALYSIS: (Addressing Aims 1 and 2)

We will use content/thematic analysis to characterize the qualitative data(113) that will be obtained with open-ended interviews of STAFF and PATIENTS to understand their insights regarding care experiences and needs that facilitated or impeded their engagement and retention in care.

We will analyze experiences and feedback from patients at both sites regarding their HIV care in general as it relates to their accounts of the factors which contribute to/impede their engagement in care; and, for patients from Site 1, the value of the CASA training in general (Aim 2). Similarly, we will analyze Site 1 staff reports of their education/training experience in enabling implementing the CASA approach with ongoing HIV care (Aim 1) and examine their description of the impact of the CASA training on their work-related stress, or burn-out and perceptions of ongoing management, and ability to engage and retain YMSM in care (Aim 3). These analyses will be guided by the RE-AIM framework.(58) Specific attention will be focused on deriving insights from the patient and staff interviews on the context of the service environments and the social circumstances, culture, and care needs of the diverse communities affected.

These analyses will describe essential training elements that will foster sustainable adoption and implementation of the program as both patient and staff perspectives will be available. Dr. Raveis working collaboratively with Karus and Carrero will read and re-read the qualitative transcripts, revising and expanding upon a coding manual for the patient and staff interviews, defining the common terminology to describe the themes, and a common set of criteria by which to identify and code them. Coding discrepancies will be discussed and resolved, then the process is repeated with a new set of transcripts until an acceptable level of inter-coder reliability is achieved, estimated using an appropriate chance-corrected statistic (e.g., kappa for nominal data and T-index for ordinal data), (140) 20% of each coder's cases will be double-coded by another coder for continued inter-coder reliability. We will use NVivo for qualitative data analysis.(122) Variables from the patient and staff surveys, medical records, and clinic records will be imported into the qualitative files to contextualize the analyses.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

View: v2_Sharing of Results

Sharing of Results

- 1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

This study collects psychosocial, or behavioral, information and all lab-work is part of routine clinical care.
Information on individual patients is de-identified at the time of collection. There is no diagnostic testing or imaging.
No individual results will be shared outside of the study reports or publications that will refer to aggregated data.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

View: v2_Psychological/Behavioral/Educational Methods and Procedures

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

- 1 * Select all behavioral methods and procedures which apply to this study:
Surveys/questionnaires
Key informant or semi-structured individual interviews
Audio or video recording/photographing
Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

View: v2_Surveys/Questionnaires

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

- 1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
CASA STUDY: data collection tools - Please note that these are listed in reverse order below as the first tool collects demographics.

Demographic and Psychosocial characteristics: Age, race, ethnicity, marital/partner status, education, occupational status, household income and composition, homelessness, age at first incarceration, and religious identification.

QUESTIONS included in patient survey (note that the electronic versions will be prepared prior to any consenting or enrollment and once these have been tested we will revise the exact time needed to collect the data. There are similar questions used on some of the questionnaires and we will omit repetitive questions.

Relative to HIV disease:

- self-report measure of adherence to ART developed and validated by the Adult AIDS Clinical Trials Group (AACTG)22;
- HIV Symptom Index, elicits impact of symptoms on daily life in past month, demonstrated construct validity in samples of HIV clinic patients,77 and
- Eastern Cooperative Oncology Group measure of Performance Status.108

Psycho-social history:

- 3-item alcohol/drug use and treatment history and a 3-item mental illness and treatment history; both developed for use with PLWH from vulnerable populations at 5 PC sites serving similar populations;79,117
- Life Events Checklist 62 widely used to identify events associated with PTSD, Sexual Behavior Questionnaire (NHANES 2009-2010)16 plus one item describing Sexual identity, sexual activity (5 items) and sexually transmitted diseases other than HIV (5 items) will document prevention behavior reflecting engagement in care, and we will add one tested question related to having sex for money.

Mental Health and Quality of Life:

- Patient self-esteem, important in YMSM, assessed with Rosenberg Self-Esteem Scale126 [SO], a 10-item, well validated scale, used with PLWH;159 ;
- McGill QOL Questionnaire (MQOL)31 [SO], a 16-item measure of QOL for persons with advanced/serious illness with demonstrated validity with PC populations,4
- the Palliative Outcome Scale (POS)70 [SO], a 10-item multidimensional well-being tool well validated for use in PC settings, we modified wording and response categories in prior work for use with US respondents from vulnerable populations from UK version in consultation with the measure's developer (Higginson)87 and will also incorporate 2 additional items from the African POS, a shortened version of the POS developed in 8 African countries and validated at 5 sites among 682 patients and 437 family caregivers.67,114

Goal Setting and Care Planning:

- Patients will be asked if they have identified someone who might serve as their health power of attorney;
- patients' perceived satisfaction with treatment/care will be assessed using a modified FAMCARE Scale,85 a 20-item measure we have successfully modified in previous studies to elicit patient's perceptions of the quality of their own care.

Electronic medical record (EMR) reviews and abstraction.

- EMR will be the most valid source of information regarding patients' attendance, adherence, and viral suppression (as a validating indicator of successful adherence).
- Clinic appointment files and electronic medical records of each study patient will be reviewed to extract monthly information on:

- o appointments scheduled;
- o date /results of relevant laboratory test (CD4, HIV PCR, Hemoglobin, Albumin);
- o date of symptom or opportunistic infection diagnoses,
- o functional status,
- o opportunistic infection reported within 12 months of study entry;
- o all ART prescribed and any changes made during study period (date prescribed;
- o reason discontinued, i.e.inability to tolerate; began more appropriate or efficacious therapy; no reason).
- o Based on these data staff will also code each patient's documented adherence rate [SO];
- o HIV Disease Control Status (unable to initiate therapy; on therapy-HIV controlled; on therapy-HIV not controlled; documented treatment failure; other), viral load suppression (Y/N) [SO]; a dummy variable noting whether the patient was defined as lost-to-follow-up (no contact w/patient > 2 months); and a variable noting persistence of attendance (# of appointments attended in each quarter of the prior year) [SO].

Family History of Substance Abuse 3 questions

- o Monthly clinic data for patients will be coded from 6 months prior to accrual into the study until 18 months follow-up.

STAFF Questionnaires are given to the staff who receive the teaching intervention in 2015. There are 2 instruments to measure staff stress related to caring for persons with HIV disease.

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
ADDITIONAL questions STAFF.docx	7/21/2016 12:13 PM	7/21/2016 12:13 PM
Staff Questionnaire_v8.26.15. clean copy.doc	8/26/2015 10:18 AM	8/26/2015 10:35 AM
Patient Follow-upSurvey1_v7.7.15	7/7/2015 4:44 PM	7/7/2015 4:44 PM
Patient Total Survey v7.7.15	7/7/2015 4:43 PM	7/7/2015 4:43 PM
Patient Total Survey v5.5.15	5/11/2015 1:27 PM	5/19/2015 11:31 AM
Staff Questionnaire_v11.2014-2.doc	12/1/2014 1:26 PM	12/1/2014 1:26 PM
FINAL_Family History of Substance Abuse (2).docx	10/14/2014 6:57 PM	10/14/2014 6:57 PM
Patient's Total Survey_v6.27.14	7/2/2014 1:02 PM	7/2/2014 1:02 PM
POS_Touch Pad	7/2/2014 1:01 PM	7/2/2014 1:01 PM
Burnout inventory	5/16/2014 1:11 PM	5/16/2014 1:11 PM
AIDS Stress Scale	5/16/2014 1:11 PM	5/16/2014 1:11 PM
FAMCARE Scale.pdf	12/19/2013 4:40 PM	12/19/2013 4:40 PM
Sexual-Behaviors.pdf	12/19/2013 4:39 PM	12/19/2013 4:39 PM
Health Care Power of Attorney.pdf	12/19/2013 4:34 PM	12/19/2013 4:34 PM
POS.pdf	12/19/2013 4:34 PM	12/19/2013 4:34 PM
McGill-QOL.pdf	12/19/2013 4:34 PM	12/19/2013 4:34 PM
Rosenberg Self-Esteem Scale.pdf	12/19/2013 4:34 PM	12/19/2013 4:34 PM
Alcohol-Drug-Use_Mental-Illness.pdf	12/19/2013 4:34 PM	12/19/2013 4:34 PM
Life-Events-Checklist.pdf	12/19/2013 4:33 PM	12/19/2013 4:33 PM
AACTG_Adherence.pdf	12/19/2013 4:33 PM	12/19/2013 4:33 PM
HIV Symptom Index.pdf	12/19/2013 4:33 PM	12/19/2013 4:33 PM
ECOG Performance Status.pdf	12/19/2013 4:32 PM	12/19/2013 4:32 PM
Demographics.pdf	12/19/2013 4:32 PM	12/19/2013 4:32 PM

3 * What is the total length of time that each survey is expected to take?

The STAFF Questionnaires take less than 5 minutes to complete.

The PATIENT questionnaires initially take 45-60 minutes to complete but the same questions will be repeated at 2 subsequent data collection times and, in our

experience, responders take about half this time to complete the questions in future surveys.

- 4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

☒ Yes ☐ No

- 5 * Do any questions elicit information related to the potential for harm to self or others?

☒ Yes ☐ No

5.1 If Yes, what procedures are in place to assure safety?

Data collection staff will be trained in methods for noticing discomfort caused to participants by answering questions. Participants will be offered either individual supportive counseling by trained staff or referral for on-going needs. Both sites where these questionnaires are completed currently provide outpatient HIV care and have mental health and or social workers on site. They are both 1-2 blocks from the primary hospital with full psychiatric back-up as needed. Part of the initial training emphasizes the need for staff to be aware of these reactions in patients. The electronic tablets used to collect data will be password protected.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

View: v2_Interviews

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

- 1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

☐ Yes ☒ No

- 2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
STAFF-TopicGuide.docx	1/4/2017 10:23 AM	1/4/2017 10:23 AM
Patient-TopicGuide.docx	1/4/2017 3:20 AM	1/4/2017 3:20 AM

- 3 * What is the individual duration of each interview and what is the entire duration of the interviews?

The content of the interviews asks about their experience of the educational intervention and how it may have impacted care delivery. There are no questions about protected health information.

- 4 * How will the interview responses be recorded and by whom?

Trained interviewers knowledgeable about confidentiality and safety of participants will conduct the interview.

- 5 * Do any questions elicit information related to the potential for harm to self or others?

☐ Yes ☒ No

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0947A633C00
Name: v2_Interviews

View: v2_Audio or Video Recording / Photographs

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1

* Indicate the type of recording (check all that apply):

Audio

1.1

If Other, specify:

2

* What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)

The audio recordings are meant to establish reliability of the interview content; these will be transcribed for use in data analysis of interview content. They will not have PHI information and will be destroyed after use.

3

* Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?

☒ Yes ☐ No

4

*** How will individuals' identities be protected?**

The identity of the individual is not documented within the recording. The questions related to experience of participating in the study and are not meant to cause discomfort or harm. Questions are not personal so much as to better understand the experience. There will be a study number only to identify the content. The actual recordings will be destroyed after the abstracted data has been reviewed and there is no further need to view content. The recordings will be kept in a locked file cabinet in the study office of the PI until they are wiped clean.

ID: VIEW4E094C128C800

Name: v2_Audio or Video Recording / Photographs

View: v2_Educational Tests/Practices

Educational Tests/Practices

You indicated that this study involves educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods).

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

*** List all educational tests to be used in the study and/or the the normal educational practices that are being studied:**

This study involves normal educational practices (instructional strategy, iterative techniques, and classroom methods to encourage adult learners to participate including experiential exercises, case-based learning, and media discussions). It does not involve educational tests beyond simple pre and post educational surveys that will be developed after the curriculum is refined. This training is directed to the staff, no training is given directly to enrolled patients. The full curriculum is to be refined up to month 14 of the study. All materials will be provided to the IRB before they are offered to staff participants. There is no specific curriculum at this time.

2 If the study involves normal educational practices, provide information as to how the educational practices are "normal" and not considered experimental:

Overview of training intervention. The training intervention is drawn from a conceptual model for implementation of guidelines (166) and successful palliative teaching models implemented across the US using train-the-trainer methods.(51,96,123,163) These teaching methods have been used by the PI and augmented with implementation science approaches for mixed health professionals.(52,138) The intervention is grounded in constructivist learning theory, meaning that learners participate in a learning process whereby new experience is added to, and modifies, previous understanding, (110) as opposed to lower educational levels where didactic information alone is imparted. CASA intends to enable staff to pursue active problem solving. The training intervention follows a typical implementation science approach being introduced in phases with monitoring of outcomes.(52)

Training Content. Domains addressed are fundamental to a palliative approach. Training goals are not meant to create PC specialists but, rather, to improve care of individuals. These include: a) respect for racial, ethnic and cultural aspects;(33) b) recognition of the impact of life transitions on individuals; and c) acknowledging the life-threatening aspects of chronic illness despite therapeutic advances. The intervention is expected to improve the illness experience for each patient by enhancing the relationship between patient and clinician where the interdisciplinary team itself is the clinician. An extensive scientific evidence base exists for each of these concepts, (51) but early integration has not been tested in the HIV population in the US. These methods have been successfully implemented for HIV patients in Africa. The curriculum refinement for this study allows these concepts to be re-adapted to a US population.

The conceptual framework guiding the educational intervention is Johnson's self-regulation theory.(75,76) This theory has been used for developing interventions to assist individuals to face uncertainties and stress of threatening events.(69,82,98) The theory focuses upon both informational and psychological interventions. Self-regulation theory proposes that patients (or others) respond in ways consistent with their understanding of the experience.(75) Content in the representation of an event is key as individuals can be influenced by information.(75) In the context of the proposed research, HIV staff can learn to understand threatening events and their own responses through provision of information and support. Interventions are based on self-regulation theory to assist individuals to direct their attention to objective features of the threatening event (in this case, health workers have difficulty accepting that YMSM may choose not to remain in care).

3 Upload any educational testing materials:

Name	Created	Modified Date
There are no items to display		

4 * Are any of the test questions or educational practices likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e. illegal activities)

☒ Yes ☐ No

5 * Do any questions elicit information related to the potential for harm to self or others?

☒ Yes ☐ No

5.1 If Yes to either question 4 or 5, please explain what procedures are in place to assure safety?

Routine screening for depression is contained in this educational intervention. Both members of the study staff and of the Expert Coaching Team are experienced in dealing with this situation clinically and part of the instruction is to assist adult learners (HIV clinic staff) to become more comfortable in executing appropriate responses to patients who may express these topics. Any evidence of psychological concern or suicidal ideation will be addressed immediately including appropriate referrals. Staff involved in this study are experienced in working with patients with these concerns. Both clinics are located near mental health services that can provide additional back-up.

ID: VIEW4E095334BF800

Name: v2_Educational Tests/Practices

View: v2_Data Collection / Record Review

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

Prospective (data is not yet in existence and/or collected)

2 * Will this study involve adding data to a registry or database for future use?

☐ Yes ☒ No

3 * Will the data be released to anyone not listed as an investigator on the protocol?

☐ Yes ☒ No

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

View: v2_Pro Prospective Data

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

Medical records

Other

1.1 If Other, please specify:

Patient surveys, staff educational evaluation forms to be created, selected interviews with each target population

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

From the electronic medical record (EMR):

1) Personal and demographic information: name; address; telephone number; contact person; date of birth; HIV treatment and response with specific laboratory markers of disease

2) Medical information: date of diagnosis; weight and height; diagnoses especially HIV-defining illness and specific symptoms such as pain with severity score if documented; medications including antiretrovirals, antidepressants, anxiolytics, antipsychotics, antiemetics, antiarrhythmals, statins, proton pump inhibitors, sleep medications, pain medications including opioids and anticonvulsants; laboratory results - specifically hemoglobin and platelet count; HIV PCR (viral load measurement); CD4 cell count (used for monitoring immune response); documentation of antiretroviral drug resistance; creatinine; liver function studies (ALT; AST; Alk Phos; Bilirubin; albumin); urine drug screens.

You can also upload a copy of the data fields/variables to be collected for the study:

Name

Data Collection from YMSM.docx

Created

12/17/2013 3:40 PM

Modified Date

12/17/2013 3:40 PM

ID: VIEW4E0E25B643800
Name: v2_Pro Prospective Data

View: v2_Clinical Trial Registration

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

☒ Yes ☐ No

2 * Has this trial been registered?

☒ Yes ☐ NoID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

View: v2_Clinical Trial Registration Information

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?

☒ Yes ☐ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?

☐ Yes ☐ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

- 3 * Registration Number
NCT02136680

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

View: v2_Participant Selection

Participant Selection

- 1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? **Screening includes determining potential participants' initial eligibility for and/or interest in a study.**
300

- 2 * How many participants (or specimens, or charts) will be enrolled/used for this study? **A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.**

Local - the number being enrolled at this site:
284

Worldwide - the number being enrolled total at all sites (including local enrollment):
284

- 3 * Gender:
Male
Female

- 4 * Age(s):
18 years and older (Adult)

- 5 * Race/Ethnicity:
All Races Included

- 6 * Language(s):
English

6.1 Specify Other:

- 7 * Are you excluding a specific population, sub-group, or class?
☒ Yes ☐ No

- 7.1 If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:
There are 2 populations enrolled in this study: (80 STAFF and 204 PATIENTS for total 284.)

LONGITUDINAL SURVEYS: PATIENTS (YMSM 18 - 35 yrs)
- 204 at 2 HIV clinics. Females are excluded as this is a study to describe the Baltimore population of HIV positive young men who have sex with men. It should be noted that some of these youth live and self-identify as "female" without truly being transgender and this population will be included in this study. The CICERO application does not allow for the answer of Transgender or cross-dressing.

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

View: v2_Vulnerable Populations

Vulnerable Populations

- 1 * Will you be including ANY of the following Vulnerable Populations? (Select all that apply)
Employees or Lab Personnel
Students

You may not include any members of the above populations as subjects in your research unless you indicate this here.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

View: v2_Vulnerable Populations - Employees or Lab Personnel

Vulnerable Populations - Employees or Lab Personnel

You indicated that employees or lab personnel are included in this study.

- 1 * Describe how you will ensure participation in this research will not affect employment and prevent undue influence:
We will explain to all participants that participation is voluntary and that they do not have to take part in this study. If they choose not to participate or withdraw participation, there will be no adverse consequences. It will not affect their employment or care.

Enrollment in this study is voluntary and each participant will sign a consent form that documents his/her right to withdraw at any time and stating that participation in this study or not will not impact their rights, care or employment status.

ID: VIEW4E0E5192BA800

Name: v2_Vulnerable Populations - Employees or Lab Personnel

View: v2_Vulnerable Populations - Students

Vulnerable Populations - Students

You indicated that students are included in this study.

- 1 * Describe the types of students that are included in this study:
We will not actively target students for this study, but will allow them to participate if they meet the eligibility criteria.
- 2 * Describe how you will prevent undue influence.
As previously stated for employees, we will inform them that participation is voluntary and that they do not have to participate. If they choose not to participate or decide to withdraw from the study, there will not be any adverse affects.

ID: VIEW4E0E519F32000

Name: v2_Vulnerable Populations - Students

View: v2_Eligibility

Eligibility

- 1 * Do you have an existing Eligibility checklist(s) for this study?

☐ Yes ☒ No

- 1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

- 1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

Number	Criteria
View	PATIENT Inclusion Criteria (See Attachments for STAFF Eligibility)
View 1	1) HIV positive
View 2	2) Male
View 3	3) Male who has sex with men
View 4	4) Age 18 - 35 years
View 5	5) Attend either of the 2 University of Maryland clinics (Jacques Initiative or Evelyn Jordan Center)
View 6	HIV Clinical Staff (CASA TEAM) Inclusion Criteria
View 7	1. Currently working as either a physician, nurse practitioner or PA, nurse, social worker or counselor, outreach worker or administrative in the HIV outpatient clinic.
View 8	2. Interest in learning and teaching new approaches for care management
View 9	3. Operational understanding of how the clinic functions.
View 10	4. Selected by clinic administrative staff and Research Team.
View 11	All Staff Inclusion Criteria
View 12	1) Staff Member of Clinic
View 13	2) Adult 18 years or older
View 14	3) Agreed to participate in study

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

Number	Criteria
View 1	Cognitively impaired and unable to answer questions
View 2	Not willing or unable to sign consent
View 3	Medically Unstable (require medical stabilization); this person may be re-evaluated for inclusion following medical stabilization.

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00058180_7 v2-4-2015-1423076465668(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

View: v2_Recruitment

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them:

We will solicit referrals of eligible patients from primary care providers or designated clinic staff able to review appointment schedules at the JI and the Evelyn Jordan Clinic of UMMS. Note: these clinics were combine to be the Center for Infectious Diseases. The initial contact will be made by the participant's Primary Care Provider (PCP) who will explain that the study exists. The PCP or designated clinic representative will give contact information to the CASA Study Program Manager or Dr. Alexander, and if the subject is interested in participating in the study, the subject will contact us.

The PCP can also ask the subject if the research staff may contact them to discuss the research study. If the subject has agreed to be contacted we will do so. Our introductory remarks may be "Your PCP has told us that you might be interested in participating in this research study, we have reviewed your chart and find that you may qualify to join this study if you are interested." If interested we would have the subject come to the clinic and go through the informed consent process.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

We will inform the participant during the initial contact, the consenting process, and at study visits that the study is voluntary participation and that they can withdraw at any time without any loss of care or benefits that they are otherwise entitled to.

In the secondary qualitative interviews, individuals will complete a separate consent document. They will be advised that participation is voluntary.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

PI
Study Staff

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

View: v2_Advertising

Advertising

1 * Will you be using advertisements to recruit potential participants?

☐ Yes ☒ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

View: v2_Research Related Risks

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

Potential Research related Risks:

1) Potential risks to STAFF who consent to participate in the study are minimal but if a staff member decides not to participate after initial involvement in the study there will be no ramifications and another staff member will be substituted. The risk is of personal stress at expanding ones' activities. One of the primary aims of this study is to assist staff in self-care strategies that may address such stress and to document clearly for the literature what magnitude of impact may exist.

2) PATIENTS: There exists a potential for unintended HIV disclosure with concern for psychological or other impact on participants. Despite improvement since the early HIV epidemic, stigma remains and can result in consequences in personal and public relationships. There are legal protections but these may not address issues faced by the individual. Therefore, the seriousness of the risk must be individualized.

PROTECTIONS AGAINST RISK: For both STAFF and PATIENTS: We will obtain direct informed consent that is voluntary, and can be rescinded at any time without prejudice. After discussion of the study and review of the consent form, they will sign the form and be given a copy that includes the PI's and Project Manager's phone number as well as the contact number for the UMD Institutional Review Board office at the UMD. Consent will be sought only by research staff who have received training for this process and will be working under the direct supervision of the PI.

PATIENTS: The risks to participants are not different from usual clinical care. However, because there is always a risk of unintended disclosure for YMSM who have not yet disclosed their own status there will be study procedures for monitoring, detecting, and managing such side effects occurrences. Confidentiality is always a concern. Therefore data collection forms will contain only the unique study ID#s, with the master list kept in a locked file cabinet in a locked project office. When the study is completed, the list will be destroyed and all data will be identified only by ID#s. Only the PI and Project Manager will have access to these lists during the study.

To further deal with this concern, all procedures will be strictly proscribed and all attempts to maintain confidentiality will be addressed with predictable procedures for managing unintended disclosure. There are no alternative methods for addressing this topic.

There is always a potential for the loss of confidentiality. The risk of the loss of confidentiality will be minimized by following HIPAA guidelines, obtaining a Certificate of Confidentiality and, as required, keeping research records in a secure area and participants will be provided privacy during their research interactions (i.e. private exam room, or area for consent).

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

View: v2_Potential Benefits and Alternatives

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

- 1 *** Describe the potential direct benefit(s) to participants:**
Potential Benefits of the Proposed Research to Human Subjects and Others.
This study responds to a request from the Patient-Centered Outcomes Research Institute in relationship to the Affordable Care Act recognizing the need to explore and document factors that might be targeted for improving engagement and retention in care of HIV positive YMSM who are at high risk for morbidity and early death if they are not able to begin and maintain appropriate HIV treatment. The study has the potential to provide direct clinical benefit to participating YMSM and clinicians of the HIV clinic by providing an opportunity to address multidimensional factors not a part of routine HIV care and treatment in that an intended outcome is that YMSM will become more adherent with their own healthcare. Patients and clinicians may find the discussions of benefit personally. Patients who remain actively enrolled in their own HIV care are known to have prolonged life and improved outcomes.
- 2 *** Describe the importance of the knowledge expected to result from the study:**
The study could have implications for development of future care strategies for difficult to engage populations and in development of policy related to need for multidisciplinary teams to care for YMSM who are HIV positive.
- 3 *** Describe how the potential risks to participants are reasonable in relationship to the potential benefits:**
The anticipated benefits outweigh the minimal risks of the study in that an individual patient may be encouraged to remain adherent with antiretroviral therapy that is known to prolong life expectancy.
- 4 *** Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.**
This is not an intervention study, the alternative is not to participate. Participation is voluntary and enrollees are free to leave the study at any time.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

View: v2_Withdrawal of Participants

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

- 1 *** Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:**
Participants may be withdrawn from the study without their agreement if the PI feels that the participant is not following the study instructions or procedures as required. or if the PI for some reason feels that it would be in the best interest of the participant to stop.
- 2 *** Describe procedures for orderly termination:**
Orderly termination would include a final study visit in which the participant would be given a chance to ask questions and informed of how they can get the final results.
- 3 *** Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:**
Participants can notify the study team at anytime that they wish to withdraw. As explained in the consent form any data already collected will continue to be used. Any participant questions or concerns can be addressed at that time.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

View: v2_Privacy of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

- 1 *** Describe how you will ensure the privacy of potential participants throughout the study (*privacy refers to persons and their interest in controlling access to themselves*):**
Study interactions will be accomplished in private rooms (consenting, discussions and interactions). There are 4 types of data collected in this study: 1) survey input from enrolled patients will be de-identified at the time of collection, encrypted and recorded electronically on a password protected Touchpad; 2) educational evaluation forms from staff coded with a unique identifier; 3) surveys from staff members that will be protected in the same manner as #1 and #2; 4) interviews from selected participants where a coding system is used and no identifying data will be connected with interview materials. The key for the unique identifiers will be kept in a locked cabinet of the locked offices of the PI. Electronic data and tablets will be password protected.
- 2 *** Describe the location where potential participants will receive research information and detail the specific actions the study**

team will take to ensure adequate privacy areas:

As stated above, the research interactions will be conducted in private rooms. This will allow the participant and the study staff to freely speak and interact without concern of others intruding or listening to the conversation that is private.

3 * Describe potential environmental stressors that may be associated with the research:

All HIV patients remain at high risk relative to general stigma regarding the disease. This is not research related but it remains a reason why anyone working with this population must adhere to good confidentiality and privacy practices.

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

View: v2_Confidentiality of Data

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

Yes

2 * Where will research data be kept (address electronic and paper data as applicable)?

Research data will be kept at the offices of the NYU PI in a locked office. The PI at 29 S Greene St Suite 300, Baltimore, MD 21201 will maintain the key to unique identifiers in a locked cabinet in the locked office. Electronic data will be encrypted after collection, de-identified before transmission and stored on a secure network system with firewall protection. Data will be coded with a unique identifier at the time of collection. Any paper or computer information related to the study will only use coded data.

3 * How will such data be secured?

Research data will be coded and kept in a locked office. Electronic data will be password protected and stored on a secure network. Only the research team will have access to this data.

4 * Who will have access to research data?

The PI and her research team only.

5 * Will study data or test results be recorded in the participant's medical records?

☐ Yes ☒ No

6 * Will any data be destroyed? (*Please note that data for FDA regulated research and VA research cannot be deleted*)

☐ Yes ☒ No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 * Do you plan to obtain a Certificate of Confidentiality?

☒ Yes ☐ No

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date
COC	7/17/2014 12:06 PM	7/17/2014 12:06 PM

8 * Discuss any other potential confidentiality issues related to this study:

Stigma still exists relative to HIV disease. Also the topic of homosexuality requires confidentiality. The target population of patients represents these issues. Study staff have been accustomed to the importance of protecting the privacy and confidentiality of these patients since the early epidemic in 1980's. It is still critical to pay strict attention to these issues. All staff and participants will be reminded of this at each educational session.

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

View: v2_Monitoring Plan Selection

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

Data Safety Monitoring by a Committee

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

View: v2_Monitoring Plan - Committee

Monitoring Plan - Committee

You indicated that the monitoring will be done by a Committee.

1 * Will the Committee be Internal or External?

Internal DSMB

2 * What data will be reviewed?

Adverse Events
Enrollment Numbers
Outcomes (Primary, Secondary)
Preliminary Analyses

2.1 If Other, specify:**3 * What will be the frequency of the review?**

Other

3.1 If Other, specify:

Data and Safety Monitoring Plan.

The proposed research, as defined by NIH criteria, is a clinical trial to gain culturally appropriate concepts and factors that might be used to develop future interventions for care and treatment of HIV positive young men who have sex with men (YMSM). There is no pharmaceutical intervention. The PI and research team will review monthly for safety in addition to monitoring study progress and all events will be reported to the IRB using a graded reporting criteria. There is a need to continuously monitor safety of patients enrolled in the study, patient representatives participating in the study and clinicians at the study sites. On a quarterly basis, the PI and NYU study team will review all data collected to ensure that it was done in compliance with study procedures. Sources of data for this review will include all participant data, whether collected from the medical record or self-report.

4 * Safety monitoring results will be reported to:

IRB

4.1 If Other, specify:

ID: VIEW4E1B025761800
Name: v2_Monitoring Plan - Committee

View: v2_Monitoring Plan - Internal DSMB

Monitoring Plan - Internal DSMB

You indicated that the monitoring committee will be an internal DSMB.

1 * List Internal DSMB Members:

Name

View [Carla S Alexander MD](#)

View [Victoria Raveis PhD](#)

View [Peter Selwyn MD](#)

2 * Confirm that no financial or other conflicts of interest exists for the above individuals.

☐ Yes ☒ No

3 * Will there be an interim efficacy analysis?

☐ Yes ☒ No

3.1 If Yes, when?**4 * Briefly describe the DSM review process itself. Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?**

Data and Safety Monitoring Plan.

The proposed research, as defined by NIH criteria, is a clinical trial to gain culturally appropriate concepts and factors that might be used to develop future interventions for care and treatment of HIV positive young men who have sex with men (YMSM). There is no pharmaceutical or imaging intervention. The PI and research team will review data and study procedures monthly for safety in addition to monitoring study progress and all events will be reported to the IRB using a graded reporting criteria. There is a need to continuously monitor safety of patients enrolled in the study, patient representatives participating in the study and clinicians at the study sites.

On a quarterly basis, the PI and NYU study team will review all data collected to ensure that it was done in compliance with study procedures. Sources of data for this review will include all participant data, whether collected from the medical record or self-report.

5 * What are the criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study?

This is an educational study and there are not anticipated adverse events that would result in termination of the study. The procedures are well described and there is a plan for addressing psychosocial responses on the part of all participants. Any adverse events would be reported to the IRB and reviewed by the Research Team. The study population of patients is one that is known to be difficult to engage and retain in care and the goal of this study is to contribute to the improvement this condition. We are realistic that we may not succeed in keeping all patients engaged in their own clinical adherence and that this might result in negative outcomes for the patient. We are attempting to teach the clinical team new approaches for addressing these negative outcomes as they are known to negatively impact staff as well. We would document these responses with the intent that our documentation may be of assistance in the future.

ID: VIEW4E1B0261D9400
Name: v2_Monitoring Plan - Internal DSMB

View: v2_Research Related Costs

Research-Related Costs

- 1 *** Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?**
Yes
- 1.1 **If Yes, check all that apply:**
Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)
- 1.2 **If No, who is responsible for payment?**
- 2 *** Who is responsible for the uncovered research-related costs?**
There will be no uncovered research-related costs
- 2.1 **If Other, specify:**
- 3 **If the participant is responsible for any research-related costs, identify and estimate the dollar amount:**

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

View: v2_Compensation for Research-Related Injury

Compensation for Research-Related Injury

- 1 *** Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?**
☐ Yes ☒ No
- 1.1 **If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:**

Name	Created	Modified Date
There are no items to display		
- 1.2 **If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?**
☐ Yes ☒ No
- 1.2.1 **If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:**
- 1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

View: v2_Payment to Participants

Payment to Participants

- 1 *** Will participants receive payment (money, gift certificates, coupons, etc.) for their participation in this research?**
☒ Yes ☐ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

View: v2_Payment Detail

Payment Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) for their participation in this research.

- 1 *** Payment to participants will be for: (check all that apply)**
Parking
Time and effort
- 1.1 **If Other, specify:**

2 * What is the total dollar value of the payments over the duration of the study? *Total payment(s) for participation in research of \$600 or more is required to be reported on an IRS Form 1099.*
\$85

3 * Describe the timing and distribution plan for the payment (schedule, means, etc.)?
Patient will receive cash at each completed survey or interview.
\$20 for completion of each patient survey; \$25 for completion of each interview for both selected patients and staff.

4 * Method(s) of payment to be Used:
Cash

4.1 If Other, specify:

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

View: v2_HIPAA

HIPAA (Health Insurance Portability and Accountability Act)

- 1 * HIPAA applies to the University of Maryland School of Medicine, the University of Maryland School of Dentistry and the VA. Are you affiliated with, or will be accessing data from, any of these places? ☒ Yes ☐ No
- 2 If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA? ☒ Yes ☐ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

View: v2_Protected Health Information

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

- 1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)
Name
Address (if more specific than Zip Code)
Dates
Telephone numbers
Email addresses
Medical record numbers
- 2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
The PHI is necessary for documenting the clinical status of the patient to be compared with study related questionnaire information.
- 3 * What is the source(s) of the PHI?
Electronic Medical Record (EPIC)
- 4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
Protected Health Information will not be reused. PHI will only be extracted for study purposes and will be de-identified. It will not be shared with anyone else outside the study team.
- 5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)
Obtain written authorization (*upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms"*)
Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)
- 5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):
Name Created Modified Date
There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

View: v2_Waiver/Alteration of Authorization

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

- 1 * **Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:**
This is not an interventional study and no drugs will be used, the research will present no more than minimal risk to the privacy of the participants because data will only be used by those authorized to have it, it will be coded in a way that the participant is not identifiable and all collected information will be secured by being in locked cabinets in locked rooms and electronic data will be password protected in secure systems.
 - 2 * **Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:**
PHI collected during the study will be protected from improper use and disclosure by being deidentified with coded numbers. Data will be stored in locked cabinets in locked rooms that are accessible only to study personnel. Electronic data will be password protected.
 - 3 * **Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:**
When subject's charts are reviewed for recruitment purposes, and, when it is determined that a subject would not qualify for this study we will destroy/shred any written information we may have collected. If the subject qualifies for the study we will use their initials as an identifier until we can approach them regarding their participation in the study. If they agree to participate we will use the study coded identifier and if they decide they do not want to participate we will destroy/shred their information immediately.
 - 4 * **Why could the research not practicably be done without access to and use of this PHI?**
Subjects for this research have HIV that needs to meet a set of inclusion and exclusion criteria in order to be eligible for the project. Consequently, conducting a brief screen of PHI is the most viable way for us to identify an adequate sample of candidates who have a high likelihood of being eligible.
 - 5 * **Why could the research not practicably be done without the waiver or alteration?**
If we recruited unscreened volunteers a high percentage would prove to be ineligible after participating in an extensive assessment. This would subject many people to unnecessary interviews and stress, and would be prohibitively costly for the project.
 - 6 * **Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?**
☐ Yes ☒ No
- 6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

View: v2_Informed Consent Process

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

- 1 * **Indicate the type(s) of consent that will be involved in this study: (check all that apply)**
Written Consent Form
- 2 * **Describe the Informed Consent process in detail:**
There are 2 POPULATIONS being consented for this study - STAFF and PATIENTS. Of the STAFF POPULATION there are 2 unique GROUPS described below:
1) STAFF members from outpatient HIV clinics on the UMB-UMMC campus. As a vulnerable population, staff members will be assured that their decision to participate or not participate in this study will not affect their employment status.
The consent process begins with appropriate training for those involved in research who will be trained to assist the Principal Investigators in screening for eligibility and conducting the consent process for staff members of HIV clinics identified above who are eligible for this study.

GROUP 1 of STAFF = Staff members who will participate in the CASA team will be selected by the Site Director and the PI of the CASA study based upon pre-described criteria including willingness to participate, working knowledge of clinic operations, and possible previous teaching or supervisory experience. Once site staff are identified, and asked about their willingness to be screened a member of the Research Team will meet with the staff member to describe the study and to answer questions. The staff member will be given the opportunity to take the consent form home to review with someone else. When all of his or her questions have been addressed he/she will be asked to sign the consent form and will be given a copy for himself or herself. The study staff will review with the enrollee procedures for contacting study staff outside of usual clinic hours including the name and number for Dr. Alexander.

GROUP 2 of STAFF = All STAFF at each of 2 HIV sites will be asked to complete a BASELINE and FOLLOW-UP survey. The STAFF will be asked to complete a survey about work-related stress BEFORE and AFTER the teaching intervention. This process was previously approved by the IRB but only partial survey content was up-loaded. This survey will be completed following a consent process and before 1/30/2015.
The CONTENT of the survey includes the AIDS Stress scale and the Burn-out Inventory previously up-loaded in CICERO. The survey consists of 12 items plus the Professional Quality of Life* instrument. The latter is a measure of compassion satisfaction, secondary traumatic stress and burn-out. The other 12 items ask for demographic and educational background as well as time in HIV care delivery and the Burn-out Inventory. The total time to complete this survey would be a maximum of 15 minutes and each staff person at the intervention site would be asked to complete it 2 times (Baseline - January or February, 2015 and Follow-up – April or May, 2016).

2) PATIENTS: HIV positive young men who have sex with men (YMSM) ages 18-35 year who attend either of 2 outpatient HIV clinics on the UMB-UMMC campus. The consent process begins with appropriate training for those involved in research who will be trained to assist the Principal Investigators in screening for eligibility and conducting the consent process for patients identified above who are eligible for this study.
Once PATIENTS are identified by staff of the clinic and the patients primary care provider has indicated that it is appropriate to contact the patient, a member of the Research Team will meet with the patient to describe the study and to answer questions. The patient will be given the opportunity to take the consent form home to review with someone else and when all of his questions have been addressed he will be asked to sign the consent form and will be given a copy for himself. The study staff will review with the enrollee procedures for contacting study staff and will obtain from him mechanisms for making contact should the telephone number given not be functional.

For STAFF to be enrolled, the same attention to privacy and confidentiality will be maintained. This is an in-service educational intervention for staff where the INTERVENTION begins 1/2015 and is completed approximately 18 months later. The reason for completing the Informed Consent Process is that STAFF are being asked to complete a de-identified pre- and post-educational survey related to work-related stress in caring for persons living with HIV disease. All STAFF have already been aware of the CASA study being conducted at the site and have attended an introductory lecture about the study. The site management staff will alert them about the survey and they will have the opportunity to refuse to complete the survey without having any impact on their employment or in their attendance at the all staff training sessions.

The selected PATIENTS or STAFF who will be asked to participate in qualitative interviews will complete a separate complete process with regard to these interviews and their questions will be answered. They will be advised again that their participation is voluntary.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

☒ Yes ☐ No

4 * Describe who will obtain Informed Consent:

A trained member of the Research Team or the UMB Principle Investigator will obtain the consent for each enrollee in the study. Members of the Research Team will be coordinated and supervised by the Program Manager and will have direct access to Dr. Alexander.

In this case the training includes CITI training, HIPAA training, training by Dr. Raveis the Co-Principle Investigator for this study and supervision by Dr. Alexander and the Program Manager. There will be direct on-site observation of the consent process until we are assured that members of the Research Team are comfortable and competent in this role.

Research Team members trained to enroll PATIENTS will receive further training in enrollment of STAFF and the need to assure that their participation is voluntary.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. (Answer "N/A" if not obtaining consent from LARs)

N/A

6 * Describe the setting for consent:

Each participant in the study will have the consent form discussed with them in a private room with confidentiality.

The two initial clinics are now combined in to one UMMC CID on the MTC and there are examination or meeting rooms available for private and confidential discussions. Persons completing qualitative interviews will also be able to complete these interviews in private offices where confidentiality can be maintained.

7 * Describe the provisions for assessing participant understanding:

Each participant will be asked to repeat back to the study team member his/her understanding of the goals of the interview. We will discuss that if questions make them feel uncomfortable they will be able to speak with a counselor if needed.

8 * Describe the consideration for ongoing consent:

We will advise the PATIENT that they have the right to withdraw from the study at any time.

For STAFF enrollees, we will remind participants that this is a study and that they have the right to withdraw at any time without recrimination.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

View: v2_Consent Forms - Draft

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
Qualitative Consent - STAFF.docx	1/4/2017 3:46 AM	1/4/2017 3:46 AM
Qualitative Consent - PATIENT.docx	1/4/2017 3:46 AM	1/4/2017 3:46 AM
Patient Consent Form3.16.16cleancopy	3/16/2016 4:38 PM	3/16/2016 4:38 PM
Patient Consent Form3.16.16redlinecopy	3/16/2016 4:36 PM	3/16/2016 4:36 PM
STAFF CONSENT FORM11.25.15redlinecopy.docx	11/25/2015 1:36 PM	11/25/2015 1:36 PM
STAFF CONSENT FORM11.25.15.docx	11/25/2015 1:35 PM	11/25/2015 1:35 PM
Patient Consent11.25.15.docx	11/25/2015 1:33 PM	11/25/2015 1:33 PM
Patient Consent11.25.15redlinecopy.docx	11/25/2015 1:33 PM	11/25/2015 1:33 PM
Patient Consent Form_redlinecopy 9/3/15	9/3/2015 2:01 PM	9/3/2015 2:08 PM
Patient Consent Form 9/3/15	9/3/2015 1:57 PM	9/3/2015 2:06 PM
All STAFF CONSENT_1-27-Track changes	2/11/2015 2:36 PM	2/11/2015 2:36 PM
rAll STAFF CONSENT_1_27.docx	1/27/2015 5:52 PM	2/11/2015 2:34 PM
All STAFF CONSENT_11_262.30pm.docx	12/1/2014 1:16 PM	12/1/2014 1:16 PM
Patient Consent Form 4/15/14	4/28/2014 4:05 PM	4/28/2014 4:05 PM
Staff Consent Form 4/15/14	4/28/2014 4:05 PM	4/28/2014 4:05 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

2 Upload any HIPAA authorization forms here:

HIPAA 7-1-14
HIPAA Authorization Form

7/1/2014 4:06 PM
12/11/2013 1:39 PM

7/1/2014 4:06 PM
12/12/2013 9:41 AM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates:
<http://hrpo.umaryland.edu/researchers/consents.html>

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

View: v2_Organization Review Requirements (other than IRB)

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

- 1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

IHV Clinical Division

If this information is incorrect, please notify the HRPO office.

- 2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation?

☐ Yes ☒ No

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

- 3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer?

☐ Yes ☒ No

-OR-

Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

- 4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases?

☐ Yes ☒ No

- 5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity?

☐ Yes ☒ No

- 6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)?

☐ Yes ☒ No

- * 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)?

☐ Yes☒ No
- * 6.3 - Will the research be conducted on VA property, including space leased to and used by VA?

☐ Yes☒ No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

View: v2_Summary of Required Reviews (other than IRB)

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Summary of Required Reviews (other than IRB)

- 1
- Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission
This protocol has no related submissions (RSC, GCRC, IBC, etc)

- 2
- Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization
IHV Clinical Division

Review Status
Complete

View: v2_Additional Documents

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

Additional Documents

1

Upload all additional documents here:	Created	Modified Date
Name	1/4/2017 3:47 AM	1/4/2017 3:47 AM
CORRECTED STAFF SURVEY - Merger Questions (Boxes included).docx	5/11/2015 1:34 PM	5/19/2015 11:33 AM
Patient Total Survey v5.5.15-Redlined Copy	5/11/2015 1:35 PM	5/11/2015 1:35 PM
Staff Questionnaire- Redlined Copy	4/2/2014 5:35 PM	2/5/2015 12:15 PM
HIV Clinical Staff (CASA TEAM) Inclusion Criteriae	2/4/2015 2:09 PM	2/4/2015 2:09 PM
All Staff Eligibility Criteria Form	1/27/2015 5:59 PM	1/27/2015 5:59 PM
CASA Team Introduction 2.0.pptx	1/27/2015 5:59 PM	1/27/2015 5:59 PM
Content of CASA	12/1/2014 1:56 PM	12/1/2014 1:56 PM
Rev_MODIFICATION 6 Summary.docx	12/1/2014 1:19 PM	12/1/2014 1:19 PM
MODIFICATION #6 Contents of Educational Intervention12.1.docx	6/27/2014 5:23 PM	6/27/2014 5:23 PM
Interviewer Comments Items.pdf	4/3/2014 7:03 PM	4/3/2014 7:03 PM
Pictoral Timeline.docx	12/16/2013 9:19 PM	12/16/2013 9:19 PM
PCORI RESEARCH PLAN.docx		

View: v2_Final Page of Application

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization
IHV Clinical Division

Review Status
Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission
This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation

By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- Obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C50000
Name: v2_Final Page of Application

View: IRB - Add a Team Member

Add a Team Member

- * Select Team Member:**
Patrick Ryscavage
- Research Role:**
Sub-Investigator
- * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☐ Yes ☒ No
- * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☐ Yes ☒ No
- * Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Dr Ryscavage joined the UMB-IHV in 2011 and is active in on-going research with the clinical division of the Institute of Human Virology. Prior to that he accomplished research relative to the care and treatment of young adults with HIV disease making the transition from adolescent to adult health care. He is currently an HIV care provider at the UMB-IHV working with both adolescent and adult patients.

View: IRB - Add a Team Member

Add a Team Member

- * Select Team Member:**
Catherine Kelleher
- Research Role:**
Research Team Member
- * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☐ Yes ☒ No
- * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☐ Yes ☒ No
- * Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Dr Kelleher has a long history of conducting and participating in research. In this study she will be a member of the Educational Team responsible for oversight of the curriculum and for teaching Mindfulness and Self-Compassion both self-care strategies addressed by the palliative approach being taught for HIV outpatient staff members.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Mary Lynn McPherson
- 2 **Research Role:**
Research Team Member
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☐ Yes ☒ No
- 4 *** CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☒ Yes ☐ No
- 5 *** Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- 6 *** Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Dr. McPherson is a Professor in the UMB School of Pharmacy where she serves as Vice Chair for Education. She has extensive educational experience in education of interprofessional teams. Her research experience is related to development of educational materials for pain and symptom management and she directs the Residency in Palliative Care for PharmD's.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Debra Wiegand
- 2 **Research Role:**
Research Team Member
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☐ Yes ☒ No
- 4 *** CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☐ Yes ☒ No
- 5 *** Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- 6 *** Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Dr. Wiegand is Assistant Professor & Research Scholar in the Department of Organizational Systems and Adult Health at the UMB School of Nursing. Her research has focused upon palliative issues near the end of life and the impact of clinical work upon nurses and other clinicians. She is also accomplished in collection and analysis of qualitative and quantitative data relative to palliative care.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Yvonne Henley
- 2 **Research Role:**
Technician or Assistant
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Ms. Henley is an RN with broad experience including chart abstraction for studies. She is well grounded in management of HIV disease and is able to abstract from EHR. She will abstract and assist in management of PHI for input to study analysis. She has completed CITI and HIPAA training.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:

Sabrina N'Diaye

- 2 Research Role:

Research Team Member

- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

She is a licensed social worker and teacher completing a PhD in Mind-Body Medicine with a focus on self-care strategies of health workers. She will lecture in the educational intervention and serve as a member of the Educational Team for this study.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:

Fiyinfolu Adetunji

- 2 Research Role:

Research Team Member

- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

She is a recent graduate of the University of Maryland - College Park in Biological Sciences where she has prior experience as a research scholar.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Linda Otieno
- 2 **Research Role:**
Research Team Member
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☒ Yes ☐ No
- 4 *** CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☒ Yes ☐ No
- 5 *** Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- 6 *** Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Linda Otieno is a student research assistant enrolled in the UMB Public Health Masters program. She has completed HIPAA and CITI training and will participate in all relevant training regarding execution of this study. She will be responsible for several aspects of the study under direct supervision of the PI.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Vera Carter
- 2 **Research Role:**
Research Team Member
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☒ Yes ☐ No
- 4 *** CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☒ Yes ☐ No
- 5 *** Does this study team member have a financial interest related to this research?**
☐ Yes ☒ No
- 6 *** Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:**
Ms. Carter is Administrative Staff in the Institute of Human Virology. She is responsible for the coordination of research team meetings and support for data collection and accessing medical records.

View: IRB - Add a Team Member

Add a Team Member

- 1 *** Select Team Member:**
Rebecca Brotemarkle
- 2 **Research Role:**
Research Team Member
- 3 *** Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.**
☐ Yes ☒ No
- 4 *** CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:**
☐ Yes ☒ No

5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Dr. Brotemarkle is Assistant Professor in the UMB School of Nursing where she has taught research methods. She is a certified trainer in palliative nursing and will serve on the educational team for this study. She and Dr. Alexander have worked together in caring for persons with HIV for over 20 years. She currently is responsible for quality improvement and implementation for a community hospital in Baltimore as part of her SON activities.

View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:

Dawn Lockman

2 Research Role:

Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Dr. Lockman is a palliative care and instructional design fellow in the School of Pharmacy. She has worked in multiple palliative and HIV settings and brings this expertise to the educational team for this study.

View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:

Sylvia Huntley

2 Research Role:

Technician or Assistant

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Ms. Huntly is currently a PhD candidate in mental health and will participate in qualitative interviews to be conducted for the study regarding the experience of previously enrolled participants from both PATIENT and STAFF cohorts who will be re-consented for purposes of this interview. She will be trained with other interviewers and has completed HIPAA and CITI training.

View: IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:

Christopher Welsh

- 2 **Research Role:**
Research Team Member
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Welsh is Associate Professor of Psychiatry and Medical Director for the UMMC Comprehensive Recovery Program. He is a member of the educational team and provides expertise in the areas of addictions and mental health issues facing persons with HIV disease. He has provided care delivery for patients attending the local study sites and is actively involved in other research protocols.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Sean Williams
- 2 **Research Role:**
Other
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Sean Williams will work as a Data Collector and Interviewer on this study. He has completed CITI and HIPAA training as well as introduction to good research practices by members of our Research Team.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Mei Ching Lee
- 2 **Research Role:**
Research Team Member
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Lee is on the faculty of the University of Maryland Baltimore School of Nursing. She is an experienced investigator in Palliative Care.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Arin Judith Chwalow
- 2 Research Role:
Research Team Member
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
☐ Yes ☒ No
- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
A. Judith Chwalow is a nurse by basic training with a DrPH degree. She has in-depth experience in curriculum development and working with HIV patients in African settings. She will be an active member of the curriculum refinement team and will assist in meeting Milestones as described by the sponsor.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Renard Murray
- 2 Research Role:
Research Team Member
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
☐ Yes ☒ No
- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Mr. Murray is a data collector. He has experience as an HIV peer mentor and experience with interviewing HIV patients.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Peter Memiah
- 2 Research Role:
Sub-Investigator
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Dr. Memiah is currently Director of Outcomes and Evaluations for the International Programs of the UMB-IHV Clinical Research Program. In that capacity he worked with the PI in multiple African settings to implement and measure HIV care and treatment activities in 12 countries. He is experienced with adapting implementation strategies to local care delivery sites and will be active in design and completion of the implementation aspect of this study.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:

Debra Elfenbein

- 2 Research Role:

Research Team Member

- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☐ Yes ☒ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Ms. Elfenbein is an editor and is involved in refinement of the curriculum from the study.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:

Ila Mulasi

- 2 Research Role:

Sub-Investigator

- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

☐ Yes ☒ No

- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

☒ Yes ☐ No

- 5 * Does this study team member have a financial interest related to this research?

☐ Yes ☒ No

- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

Ila Mulasi MD who currently cares for outpatients with HIV disease and has graduate training in palliative care and experience with palliative care research for persons with HIV disease. She will serve on the Intervention teaching team in this study. CITI Refresher is completed.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Vicki Tepper
- 2 Research Role:
Research Team Member
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
☐ Yes ☒ No
- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Tepper is an Associate Professor of Pediatrics and Division Head of Pediatric Immunology. She has served as principal investigator for 3 studies relative to HIV-infected children and adolescents and adherence. She is an international adviser on HIV pediatric research regarding psychological and social challenges of caring for HIV positive children.

View: IRB - Add a Team Member

Add a Team Member

- 1 * Select Team Member:
Frank Oldham, Jr.
- 2 Research Role:
Other
- 3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
☐ Yes ☒ No
- 4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ Yes ☒ No
- 5 * Does this study team member have a financial interest related to this research?
☐ Yes ☒ No
- 6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Frank Oldham is a consultant to the study who has served as a manager of large HIV-related organizations; he has also served as an interviewer for focus groups relative to HIV disease. He will be coordinating various meetings that must take place to complete study close-out activities and he will be trained and supervised as an interviewer for qualitative interviews to understand the perspective and experience of young men living with HIV participating in the current study.