Complete IRB protocol
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Title of the study: Implementation of Trauma-informed HIV Care in Memphis, TN
Meharry Medical College
Clinical Trials registry: 22-08-1234
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The Human Subjects protocol for St. Jude was amended in response to requests from St. Jude's IRB administrators. Primarily, they requested greater details

ABSTRACT:
We will accelerate health equity among underserved Black youth in Shelby County, Tennessee (Memphis)—a region with the fourth highest HIV incidence nationally, where half of Black youth with HIV (BYWH) are appointment non-adherent. Psychological trauma is a critical and understudied mechanism driving appointment non-adherence and HIV-related health disparities: YWH endure high levels of post-traumatic stress disorder; repeated trauma exposures associated with HIV care provision contribute to degradations in personnel professional quality of life; these trauma sequelae thwart patient-provider relationships and trust, contributing to treatment fatigue, disengagement, and viral failure. Trauma-Informed HIV care (TIHC) improves multi-level outcomes by ensuring institutional health practices adequately Recognize and Respond to trauma and Resist Re-traumatization for all. Our research will support TIHC implementation for youth receiving care in St. Jude Children's Research Hospital's HIV clinic. Through this exploratory, sequential mixed methods study we will: 1) Convene and engage a steering committee to co-produce TIHC implementation throughout all research activity; evaluate steering committee member experiences of adapting TIHC to enhance access to care for BYWH and professional quality of life for HIV care providers; collect baseline patient experiences of clinic and perceived safety. 2) Implement and evaluate adapted TIHC with HIV clinic personnel. 3) Conduct a pilot of adapted TIHC with patients. There is strong rationale to support the TIHC and proposed research as meaningful approaches to improve HIV outcomes among BYWH.

SIGNIFICANCE:
Scope of the Problem: HIV disproportionately impacts Black youth in the Southern United States.
The Southern United States (U.S.) suffers a disproportionate HIV disease burden, with prevalence rates seven times higher among Black persons than white and youth (aged <24 years old) representing a third of all new infections.[1-3] With a steadily accelerating HIV epidemic, Shelby County, Tennessee (TN), ranks fourth in the country for new infections and is an Ending the HIV Epidemic (EHE) Phase I priority jurisdiction.[4-5] The HIV clinic at St. Jude Children's Research Hospital (St. Jude) in Memphis provides HIV care for the majority of local youth with HIV (YWH)[5] and recognizes an urgent need for enhanced intervention to mitigate HIV health disparities for Black youth. EHE plans in the U.S. and Memphis[4-5] and NIH high priority areas highlight the need to *reduce health disparities among people with HIV* and *train the workforce conducting high priority HIV research*.[6]

Improving HIV appointment adherence is an actionable way to prevent poor downstream outcomes.
HIV appointment non-adherence poses a major threat for consequent disease transmission and morbidity that must be addressed to enhance health equity.[7-11] Compared to all people living with HIV (PWH), *youth are more likely to miss HIV appointments*,[1] with 36% having missed two or more in the last year.[7] Compared with white YWH, *Black YWH [BYWH] are >70% more likely to miss HIV appointments*,[7] contributing to downstream disparities such as a >two-fold decrease in viral suppression.[8] Efforts to improve HIV appointment adherence are particularly exigent at St. Jude, where 97% of youth HIV patients are Black and "no show" rates have climbed to almost 50% (M. Wilkins, unpublished data, 2021). However, HIV appointment non-adherence is modifiable through co-interventions that effectively address drivers of missed appointments.

Psychological trauma is an under-addressed driver of HIV appointment non-adherence in BYWH. Trauma refers to lasting effects of adverse events,[9-14] and childhood trauma is associated with elevated risks[15] for psychological unwellness and non-adherence to HIV care. [15-19] YWH report an average of six traumatic events, with 47% meeting the criteria for posttraumatic stress disorder (PTSD) and HIV diagnosis[14] and racial discrimination intensifying experiences[12,20] (e.g., Black youth generally endure more trauma than white youth, with ~6 racial trauma events annually).[21] Tennesseans with HIV have high levels of childhood trauma (~80% with $\geq$4 exposures),[22-23] contributing to an eight-fold increase in missed HIV appointments[15] and the HIV-trauma syndemic.[9-11] Among Memphis youth, trauma exposure is 9x that of national rates,[24-26] and Black youth, comprising 88% of all YWH in the area, have an HIV appointment adherence rate of 50% (M. Wilkins, unpublished data, 2021). Yet, HIV-trauma co-interventions to modify appointment adherence among BYWH are lacking and have yet to address racial trauma, representing major equity gaps in HIV care.

Trauma produces multi-level consequences, negatively impacting HIV care providers.
HIV care providers are repeatedly exposed to patient trauma, presenting a commonly unrecognized occupational hazard.[11,27-28] These exposures cumulatively lead to vicarious trauma,[29] causing decrements in professional

quality of life, including chronic exhaustion, lack of empathy, hypervigilance, minimization, sense of persecution, guilt, anger/cynicism, addictions, and feelings of hopelessness.[28] Without institutional mitigation efforts, providers experience burnout[30] (e.g., depersonalization, apathy, and disengagement from patients),[11] which is high among HIV care providers nationally (66%-77%),[11] and poses significant threats to patient retraumatization[31-32] and appointment non-adherence.[27] However, multi-level trauma interventions offer high impact potential to improve professional quality of life and appointment adherence in high priority regions.[33]

Trauma-informed HIV Care (TIHC) improves patient and provider outcomes but requires refinements. Trauma-related patient and personnel outcomes are modifiable[9,27-28,31-35] via *multi-level TIHC interventions.*[36-40] TIHC, an evidence-based intervention in which health system practices are intentionally designed to *Recognize* and *Respond* to trauma to *Resist re-traumatization* on multiple levels,[40] has been effective with numerous populations: youth in general,[41] PWH in TN, and HIV care providers[22,33] in the South.[27,42] However, TIHC has yet to be tested with BYWH,[11,16] and further research is needed to address critical gaps. First, TIHC efforts require stronger integration of *Cultural Responsiveness* to enhance provider understanding that racial/cultural background affects relationships and trauma response.[43] Recently a community-created anti-racism intervention for medical providers, *Presence 5 for Racial Justice*, was feasibility implemented in a pediatric setting and clinic in Memphis, underscoring its potential as an adjunctive to TIHC.[44] Second, building from our past TIHC research, which shows personnel-level intervention components were feasibly implemented,[45] personnel components now require rigorous effectiveness testing. Finally, patient-level TIHC intervention components require refinements; building on our past *Stage I Trauma Therapy*[46] research in TN, which primarily focused on patients establishing neurophysiological *safety* to remain adherent to HIV treatment (via *Motivational Interviewing*, *Stress Inoculation training*, and *Resilience-focused care*),[38,46-48] research is needed that explores the benefits of advanced trauma therapy (i.e., Stage II) in which traumatic experiences are more deeply processed and overcome. As Memphis' local EHE plan cites implementation of TIHC as a priority for the region, efforts are urgently needed to implement TIHC in Memphis to improve HIV health equity. Though Shelby County's End HIV 901 plan identifies TIC as critical to local EHE goals, the primary care provider for BYWH in the region, St. Jude Children's Research Hospital's (SJCRH) HIV Clinic, has not yet implemented TIC. Our past EHE supplement research with SJCRH shows the HIV clinic has the following gaps in care: 1) no routine personnel training on trauma; 2) no systematic patient trauma screening, assessment, or treatment; and 3) no clinic-based systematic efforts to enhance patients and provider cultural responsiveness or elicit and integrate stakeholder experiences to improve practices. Following this research, as part of our overall Community-Based Participatory Research partnership with SJCRH, we will work with a TIC steering committee (TSC) to engage patients, providers, and ancillary staff to co-produce multi-level TIC implementation. However, strategies for promoting CBPR-focused implementation are lacking, despite collective action being critical to TIC.

Research Quality Plus for Co-Production (RQ+ 4 Co-Pro) is an IS approach to defining and evaluating the quality of co-production. It allows implementation strategies to be tailored to context, values, and purpose and can support planning, management, and learning across the lifecycle of an implementation effort.

DATA COLLECTION:

We will conduct an exploratory, sequential mixed methods design study[52] through three aims**.**

Aim 1a: Adapt our TIHC-Y to enhance access to care for BYWH and PQOL for HIV care providers. Approach: We will follow principles of community-based participatory research (CBPR) to apply the Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, and Testing (ADAPT-ITT) framework to adapt our TIHC intervention for youth (TIHC-Y) through iterative stakeholder engagement (patients, providers, and experts) and integrated qualitative data derived from semi-structured Focus Group Discussions (FGD). Hypothesis 1: Stakeholder consensus, reached via application of CBPR and ADAPT-ITT phases, will result in a contextually appropriate, multi-level, and culturally responsive TIHC-Y.

Aim 1b: TIHC Steering Committee (TSC) will assess contextual support for co-production and develop an implementation plan. Approach: We will explore TSC member's (n=18) perceptions of institutional/clinic support for co-production. The RQ+ 4 Co-Pro rubric will be used to assess three contextual factors: Knowledge

Use Environment, Research Environment, and Capacities for Co-Production. The TSC will be asked to rate each area on a four-point scale and provide qualitative explanations to support their ratings. The group will then review the three quality dimensions for co-production—rigor, legitimacy, and positioning for use—and develop a plan for implementation. We will do this through both qualitative and quantitative mechanisms. The RQ+ 4 Co-Pro rubric includes Likert items to assess participant's perceptions on a scale and to elicit their qualitative descriptions of their responses. We will also conduct one-on-one interviews with steering committee members and any other clinic staff who have had significant engagement with this study to elicit these responses. Interviews will occur two times throughout the duration of the project. Once at the end of year one and once at the end of year two. Responses will be recorded and transcribed verbatim with quantitative results documented in REDCap.

Aim 1c: We will collect quantitative data with patients during the first year of the study to ensure we have a baseline understanding of patients' needs and perceptions of the clinic. Patient experiences will be assessed primarily using the Organizational Trauma Resilience - Patient Reported Experience Measure (OTR-PREM). We will include additional scales at the same time to establish discriminant validity with the OTR-PREM as explore associations with ART adherence, Social Determinants of Health, probable Post-Traumatic Stress Disorder (which is assessed via brief, 8-item symptom inventory), discrimination, and multi-level resilience. See appendices for measures to be used. St. Jude personnel (Research Associate) will help recruit patients to complete baseline assessments. This will entail that St. Jude personnel will briefly inform patients about the study verbally and give them a flyer with a QR code. Patients will then go through a process of electronic consent via REDCap and those consenting will complete the self-administered survey.

Aim 2: Implement and evaluate adapted TIHC-Y with HIV clinic personnel. Approach: Trainings will include traditional TIHC components (Trauma Resilience trainings and Trauma Exposure Response workshops via Sandra Bloom model Creating Presence), with one-on-one coaching, and be augmented for the first time with an anti-racism group intervention (Presence 5 for Racial Justice) designed to promote health equity via the training of medical workforce. Mixed method assessments (via surveys and FGD) will be conducted prior to beginning the personnel intervention: surveys will be administered around year one of the total study and again at six and twelve months after the intervention begins to show multi-dimensional impacts on organizational trauma resilience and personnel PQOL. We will use the TICOmeter, OTRA, and TICS to assess clinic practices, climate, and culture. See appendices for measures to be used. FGD will be conducted with both personnel and patients after the personnel intervention period ends. Patients will also complete the OTR-PREM at three time points throughout this study (to assess their perceptions of the clinic culture): during Aim 1b (baseline), after Aim 3 is complete (time 1), and again after Aim 2 is complete (final follow-up). Additionally, we will conduct evaluations immediately before and after personnel workshops to assess changes in attitudes and knowledge (via the ARTIC tool). Hypothesis 2: Improvements, from pre-post training, will be observed for organizational trauma resilience and PQOL. Outcomes will have a dose-response relationship with intervention engagement. We will file an amendment during year 2 to reflect specifically which instruments and procedures will be used with the personnel intervention (based on the feedback from the TSC; see Aims 1a and 1b).

Aim 3: Conduct pilot study of adapted TIHC-Y with St. Jude patients. Approach: Occurring over ~1.5 years, consenting YWH will receive the Screening, Brief Intervention, and Referral to Treatment (SBIRT) intervention or TIHC-Y. Primary outcomes (and assessment modalities) for this study include: 1) Effectiveness: Rate of missed HIV appointments and trauma response (via medical records/validated scales) and 2) Implementation: acceptability, feasibility, and appropriateness (via interviews/short surveys). Hypothesis 3: Intervention will be: 1) associated with significant improvements in appointment adherence and trauma response and 2) found to be acceptable, feasible, and appropriate. We will file an amendment during year 2 to reflect which instruments and procedures will be used with the SBIRT process (based on the feedback from the TSC; see Aims 1a and 1b).

Timeline for recruitment:

Year 1: Adapt intervention with stakeholders. Conduct focus groups with patients and personnel. Conduct baseline surveys with patients 18+ to gauge baseline levels of trauma and resilience. Conduct interviews with steering committee members to assess experiences of research. Clean and analyze data and use findings to inform Aims 2-3.

Year 2: Conduct focus group discussions and surveys with personnel; begin recruitment for personnel intervention and clean and analyze data to inform Aim 3. Conduct FGD and surveys with patients to assess if perception of clinic has changed. Develop patient intervention based on Aim 1a and 1b results.

Years 3-5: Begin recruitment for patient screening and intervention; clean and analyze data and share de-

identified findings.

This is a multi-level study that will occur in three phases, with some overlap in the phases, spanning 5+ years in time.

For Aims 1a,b,c, we will convene a group of stakeholders to help us adapt the trauma-informed HIV care (TIHC) for youth (TIHC-Y). Meharry will recruit personnel, patients, and community members who have interaction with St. Jude's HIV clinic to act as stakeholders for this group. Methods for this group engagement will follow the principles of Community-Based Participatory Research by applying a co-production approach, and will entail that this steering committee will remain intact (with rotating members) over the span of the five years if not longer).

We will conduct surveys and focus groups with personnel and patients to discuss 1) the best methods for adapting the intervention to the St. Jude HIV clinic setting and to include racial trauma and 2) their perception of participating in the co-produced research to guide TIHC implementation. The intervention will primarily be adapted during year 1, and developed in year 2-3, but the steering committee will meet throughout the duration of the total project and will engage in quarterly evaluations to ensure research is being conducted in an equitable and inclusive way. Steering committee members will complete these evaluations as part of overall quality improvement. Interviews and FGD will primarily be held in-person on campus at St. Jude, with virtual administration as a backup should virtual be more convenient in an extenuating circumstance. Dr. Brown, Jamie Stewart, or St. Jude RA, will be responsible for conducting the FGD and interviews.

There are four topical experts who will be involved in our work and intermittently participate in steering committee meetings as well as FGD. Those include: Dr. Samantha Hill (Emory University) as a pediatric infectious disease doctor; Ms. Tami Walker (University of TN) who is a TIC expert and Licensed Master Social Worker/LMSW; Dr. Baraka Floyd (Stanford) who is a pediatrician who helped create the Presence 5 for Racial Justice (which we will use as part of Aim 2); and Dr. Robert McLean (Ottawa Hospital and International Research Development Center) who developed the RQ+ 4Co-Pro, which we will use to evaluate the steering committee member experiences. These topical experts may either administer or participate in FGD or interviews, as deemed by the steering committee and the topical expert per the topic at hand. For steering committee meetings, all members attending the meetings will receive gift cards for participating. Each meeting attended will return a $50 gift card. Meharry will be responsible for administering these gift cards electronically. FGD will be conducted to validate suggested adaptations for both patient and personnel intervention components, which will entail that both patients and personnel may be asked to participate in FGD, which will include a $50 gift card as participation compensation.

For the patient survey portion, we will recruit patients (18 and older) via routine care (via QR codes) to complete a brief, self-administered electronic survey. We have already received IRB approval at Meharry for this phase of the research but are including it here so that it can become part of St. Jude's overall protocol for this study. This aim will help us learn baseline levels of trauma exposure and resilience among patients as well as patient experiences of their care at the HIV clinic. The intent behind this research activity is to estimate prevalence of trauma among youth with HIV as well as perceptions of HIV clinic care environment. Recruitment will be conducted by St. Jude Research Assistant (RA) during routine medical appointments. Those interested will have access to link to an electronic consent process via REDCap. Those consenting will complete the survey through self-administration also via REDCap. Survey administration will be overseen by Dr. Brown and Meharry Program Manager Jamie Stewart. Survey participants will be compensated $25 for completion of surveys.

For Aim 2, we will recruit all personnel of the St. Jude HIV clinic to participate in surveys and focus group discussions (FGD). We will then invite all to participate in various psychoeducational interventions. Surveys, FGD, and intervention activities will continue for those consented for one year. We will also conduct surveys before and after all psycho-educational intervention workshops, and we will conduct one FGD with patients as well as assess perceptions of their care environment via a brief survey (OTR-PREM). All FGD and surveys are voluntary and participants will consent to their participation prior to engaging in FGD, survey responses, or intervention activities. We will submit an amendment prior to engagement in this aim to clarify research activities and timeline for this portion (which will be adapted by prior portions of this multi-phase study).

Finally, for Aim 3, we will recruit 100 patients (of ~250 patient census in SJ HIV clinic) to complete trauma

screenings. We anticipate 70 will meet the threshold for trauma exposure/effects and will agree to receive an experimental Screening, Brief Intervention, and Referral to Treatment (SBIRT) TIHC-Y intervention. Patients will be also asked to participate in FGD and surveys to assess changes in health outcomes and perceptions of care. All interventions, surveys, and FGD are voluntary. We will submit an amendment prior to engagement in this aim to clarify research activities and timeline for this portion (which will be adapted by prior portions of this multi-phase study).

Recruitment:
Potential subjects will be recruited based on the aims.
For aims 1-2, we will use purposive sampling/targeted recruitment to gather together a steering committee based on either membership as St. Jude personnel involved in patient care and/or development of site procedures; membership as a patient who is 18 years or older; or the four topical experts who have already committed to participating. The above sampling (with personnel) will be used to recruit for FGD, surveys, and interviews associated with Aims 1-2. We will also recruit a small sample of patients to participate in adaptation and evaluation of adaptation via FGD and interviews in the first two years of the project. For the patient surveys, we will recruit patients via routine care appointments. Research Assistant will recruit patients via verbal engagement and presentation of a QR code to the study link to those who show interest. The RA will not engage in consenting the patients but will focus on verbally telling them about the study for recruitment purposes. Patients will then follow the link and complete a written electronic consent process. Once consented, they will complete a brief, self-administered electronic survey.

For Aim 3, all HIV clinic personnel and ancillary staff members will be invited to participate in surveys and FGD. All patients will be invited to participate in clinic culture surveys and will be invited during routine appointments by the RA. For patients, we will use a mix between purposive and snowball sampling, depending on how successful we are with patients engaging in the study. All patients participating in the intervention will be invited to complete surveys and brief interviews.

Inclusion:
For Aims 1-2:
Inclusion: St. Jude HIV Clinic stakeholders (Patients 18-<24 years old; clinic personnel and ancillary staff >18 years old). Exclusion: Individuals not interfacing with St. Jude ID clinic or patients <18->24 years old.
Aim 3:
Personnel inclusion: Current St. Jude personnel, >18 years old.
Patient inclusion: Patients of St. Jude, aged 18-24, living with HIV, who are trauma-affected (Score >1 on both Trauma History Questionnaire, and the PTSD Primary Care-5 for effects). Exclusion: Patients aged <18, >24, or not trauma-affected.

Compensation:
For Aims 1-2, all steering committee members (except study PI) will be compensated for each meeting and focus group discussion (FGD), and each activity is listed below by year.
TIHC Steering Committee (N=19 – excludes PI): Quarterly evaluations ($50 x 19 x 4 meetings)= $3800
Six Focus Groups ($50 each participant X 8 participants each)= $2400
One-on-one interviews for RQ+ 4 Co-Pro annually (up to 20 personnel and patients): 20x $50 ($1,000)
4 topical experts – draft review ($250 x 4 Topical Experts) (excludes PI) = $1,000
Meeting for TSC to review draft ($50 x 10 members of TSC) = $500 TSC Meetings – incentivize patients ($50 x 6 patients x 4 meetings) = $1,200
Patient baseline surveys= 75 x $25 ($1,875)
Total Year 1 Incentive Cost = $11,275

<u>Year 2 Incentives:</u>
TIHC Steering Committee Quarterly evaluations ($50 x 19 x 4 meetings)= $3800
Personnel surveys - baseline and survey 1 ($25 x 70 Personnel x 2 surveys) = $3,500
Participation for personnel trainings:
Trauma Stewardship for all providers ($25 x 27 Providers x 6 sessions) (27) = $4,050
Basic Trauma Resilience trainings: ($25 x 70 Personnel x 6 trainings) = $10,500
Post training focus groups (3 per year) – 2 with staff ($50 x 10 personnel x 2 focus groups) = $1,000 and 1 with patients: ($50 x 10 patients x 1 focus group) = $500. Total = $1,000
TSC Meetings – incentivize patients ($50 x 6 patients x 4 meetings) = $1,200

One-on-one interviews for RQ+ 4 Co-Pro annually (up to 20 personnel and patients): 20x $50 ($1,000)
Total Year 2 Incentive Cost =$26,050

Year 3 Incentives:
TIHC Steering Committee Quarterly evaluations ($50 x 19 x 4 meetings)= $3800
Personnel surveys – survey 2 and 3 ($25 x 70 Personnel x 2 surveys) = $3,500
Patient screenings ($25 x 50 patients) = $1,250
Baseline patient assessment ($50 x 35 patients) = $1,750
Intervention session/SBIRT ($25 x 35 patients) = $875
3 month follow up ($25 x 35)= $875
TSC Meetings – incentivize patients ($50 x 6 patients x 4 meetings) = $1,200
Personnel surveys – final survey (occurs just before end of grant year) ($25 x 70 Personnel) = $1,750
6 month follow up: 15 x $25= $375
Total Year 3 Incentives Cost: $14,245

Year 4 Incentives:
TIHC Steering Committee Quarterly evaluations ($25 x 19 x 4 meetings)= $3800
Patient screenings ($25 x 50 patients) = $1,250
Baseline patient assessment ($50 x 35 patients) = $1,750
3 month follow up patient assessment ($25 x 35 patients) = $875
patient assessment ($50 x 35) = $1,750
Intervention session/SBIRT ($25 x 35 patients) = $875
6 month follow up patient assessment ($50 x 20)= $1,750
TSC Meetings – incentivize patients ($50 x 6 patients x 4 meetings) = $1,200
Total Year 4 Incentives Cost: $13,250

Year 5 Incentives:
TIHC Steering Committee Quarterly evaluations ($25 x 19 x 4 meetings)= $3800
6 month follow up patient assessment ($50 x 35) = $1,750
TSC Meetings – incentivize patients ($50 x 6 patients x 4 meetings) = $1,200
Total Year 5 Incentives Cost: $6,750

Potential Risks
The research protocol calls for people living with HIV who have been exposed to trauma and have current trauma response. We are adapting an intervention that has already been studied for effectiveness and safety, however, given the nature of the intervention (e.g., discussing the impact of past difficulties), there are potential for risks. We believe these risks will be minimal and mild. There are potential risks for personnel participating in that they may feel uncomfortable answering honestly about the culture of their work space; however, we will keep all responses confidential and not allow any staff members of the clinic to see any identifiable results. It is also a risk for patients or personnel to participate in focus group discussions as total confidentiality cannot be guaranteed. Consent forms will reflect this reality so that it is part of the informed consent processes per participant. Additionally, personnel will be recruited for participation by research staff who are not their direct supervisor to enhance autonomy in informed consent.

Special Precautions:
Protection against risk of patient subjects: Steps taken to minimize any risk include: 1) all staff will be trained to collect information using study protocol to ensure confidentiality and anonymity, and 2) participants will be reminded that their participation is voluntary, and they have the right to withdraw from the study or refuse to answer any questions. The protocol for the proposed project will be approved by the institutional review board of Meharry Medical College as well as St. Jude. Study participants will be recruited from St. Jude the local community thru flyers, electronic communication (for those consenting to this) and one-on-one verbal invitation by the Research Assistant. Potential participants who respond to study advertisements will be screened for inclusion over the telephone by personnel who have been trained on study procedures and who have active CITI Certification for Protection of Human Subjects. Key study personnel will obtain informed consent electronically prior to participant participation in Aim 1 research activities. Participants will sign informed consent forms that have been IRB-approved once the study has been explained to them in full, and they have stated that they understand what is being asked of them. We view informed consent as an ongoing process, so participants will be given the opportunity to ask questions about their participation throughout the course of the study. A copy of the informed consent will be kept centrally at our study

office within locked filing cabinets, and a copy will be given to each study participant as well. Participants will be given a toll-free number to call for questions.

Protections Against Risk:
The primary concern for participants is a sense of discomfort in surveys, interviews, and intervention discussion material, and participants will continue to be informed participation is voluntary and they may abstain from answering any questions or engaging in any discussions for which they may feel discomfort. We will have a Data and Safety Monitoring Plan that includes monitoring of adverse events.

Should a participant become distressed during surveys, interviews, or sessions, our team will respond according to sections 1-2 below: 1) If the participant is in-session with their interventionist/trained mental health professional (Licensed Clinical Social Worker), and the interventionist clinically deems the participant is having a negative abreaction (signs of distress, including person's behavioral, affective, or verbal cues indicate a response more exaggerated than expected by someone who is discussing a past painful memory/experience [e.g., appears dissociative, reports suicidal/homicidal ideation, experiences panic, etc.]), the interventionist will cease discussing routine protocol material and will assess the person for acute mental health needs. If the person is deemed to be a harm to themselves or someone else, the LCSW will follow state laws for Duty to Warn or Protect. If the person appears dissociative or as though they are overwhelmed (panic), the LCSW will remain with the person and administer grounding exercises to help them return to the here and now. They will then re-assess the person's state and safety plan with them how to care for themselves or seek help outside of the session if any of the symptoms return after the session. Part of the safety plan will include contacting friends/family/clinic or emergency mental health support staff when needed and reporting experience to clinic staff and research staff as soon as possible so this may be documented as an Adverse Event. 2) If the participant appears distressed during surveys and/or one-on-one interviews with the Research Assistant (RA), the RA will do the following: First, the RA will be trained in basic mental health response via discussions with the study PI prior to interfacing with patients. Through this training, the RA will learn the signs of participant distress (e.g., on-going confusion that is not person's previous demeanor, coupled with glazed stare, etc. [signs of dissociation]). Should the RA become concerned the participant is distressed or have the participant report they are having difficulties getting through the material, the RA will stop the survey/interview an instead as the participant if they would be comfortable with our team contacting a social worker, psychiatrist, or psychologist with St. Jude to assist them for acute support. If the person says yes, then the participant will keep the person either with them in person or on the phone (if the follow-up is virtual). Once the on-call mental health support has been engaged with St. Jude, the person will follow the procedures outlined above under section 1. If the person does not wish to contact any at St. Jude for acute support, then the RA will remind the person of the informed consent process, which outlines that key study personnel will be notified of the person's experience, and it will be deemed an adverse event, and the KSP will follow-up with the person to discuss their experience.
We anticipate very few AEs. AE's will be discussed with Drs. Pettit, Audet, and on-site collaborator, Dr. Wilkins and, if necessary, consultation with a physician (Dr. Gaur; see letter of support) will be encouraged to contact the study PI as soon as possible for serious AEs. We will withdraw participants who have a serious AE. For other AEs, if either study investigators or the participant wishes it, the participant will be withdrawn from the study. We will also form a Data Safety and Monitoring Board (DSMB). If the percent of serious or severe AEs appears to be greater than 5% the DSMB will be notified to decide on early termination of the study.

Recruitment and Informed Consent:
Study participants will be recruited from St. Jude Infectious Diseases clinic using various methods (flyers, emails if consented, verbal invitation). Participants will sign informed consent forms that have been IRB-approved once the study has been explained to them in full, and they have stated that they understand what is being asked of them. We view informed consent as an ongoing process, so participants will be given the opportunity to ask questions about their participation throughout the course of the study. A copy of the informed consent will be kept centrally at our locked study office within locked filing cabinets, and a copy will be given to each study participant as well. Participants will be given a toll-free number to call for questions.

Protections Against Risk:
The primary concern for participants is a sense of discomfort in surveys, interviews, and intervention discussion material, and participants will continue to be informed participation is voluntary and they may abstain from answering any questions or engaging in any discussions for which they may feel discomfort. We will have a Data and Safety Monitoring Plan that includes monitoring of adverse events.

All patient participants in this study will be provided standard care, current basic mental health screening and

access to a social worker, psychiatrist, and psychologist, as well as the brief intervention. The risks of the intervention are very small and relate to sense of discomfort in discussing intervention adaptations; however, increased access to mental health professionals is expected to minimize risk potential. Thus, the risk-benefit balance seems reasonable, and participants expressing any discomfort in participating will be invited to consider if they would like to roll off the TSC.

Potential Benefits:
Patients and personnel may benefit as we expect the refined intervention to lead to improvements in patients and personnel (e.g., professional quality of life related to compassion satisfaction, compassion fatigue, and burnout). They will also receive the potential benefit of altruism, knowing they contributed to this refinement of an intervention that will be used throughout the clinic. Further, the HIV-trauma scientific and practice communities may benefit from any insight into engaging patients and personnel in a trauma-informed intervention as a replicable model to be scaled out in other clinics.
This study has the potential to add to our understanding of the mechanisms that may promote uptake of a trauma intervention among a population that is disproportionately impacted by trauma. This could have a positive impact on public health and on reducing the burden of HIV-related health disparities. Additionally, HIV providers are shown to have higher level of burnout than other providers, and thus an intervention targeting improvements in this area could be replicated to help other HIV providers improve their quality o life which could create greater retention in provider employment and greater continuity of care for patients.

Human Subjects Protection for specifically targeted populations (personnel):
We will be recruiting personnel of St. Jude HIV clinic for Aims 1-3. Our primary methods for ensuring we minimize risk for personnel is that we will ensure all personnel are aware participation is voluntary (they may cease participating at any time); they will be recruited by study personnel who is not in a supervisory role; and we will ensure that no personnel from St. Jude who are also Key Study Personnel have access to identifiable data. We will do this by excluding KSP from having access to REDCap (where data will be stored) and then removing any identifiers from data sets prior to sharing with personnel KSP during analysis stages.

Stopping rules:
Should a participant become distressed during surveys, interviews, or sessions, our team will respond according to sections 1-2 below 1) If the participant is in-session with their interventionist/trained mental health professional (Clinical Social Worker or trained Research Assistant), and the interventionist clinically deem the participant is having a negative abreaction (signs of distress, including person's behavioral, affective, or verbal cues indicate a response more exaggerated than expected by someone who is discussing a past painful memory/experience [e.g., appears dissociative, reports suicidal/homicidal ideation, experiences panic, etc.]), the interventionist will cease discussing routine protocol material and will either themselves assess the person for acute mental health needs or engage another clinic mental health professional to do so (e.g., an LCSW, psychologist, or psychiatrist). If the person is deemed to be a harm to themselves or someone else, the mental health professional will follow state laws for Duty to Warn or Protect. If the person appears dissociative or as though they are overwhelmed (panic), the practitioner will remain with the person and administer grounding exercises to help them return to the here and now. They will then re-assess the person's state and safety plan with them how to care for themselves or seek help outside of the session if any of the symptoms return after the session. Part of the safety plan will include contacting friends/family/clinic or emergency mental health support staff when needed and reporting experience to clinic staff and research staff as soon as possible so this may be documented as an Adverse Event.

2) If the participant appears distressed during surveys and/or one-on-one interviews with the Research Assistant (RA), the RA will do the following: First, the RA will be trained in basic mental health response via discussions with the study PI prior to interfacing with patients. Through this training, the RA will learn the signs of participant distress (e.g., on-going confusion that is not person's previous demeanor, coupled with glazed stare, etc. [signs of dissociation]). Should the RA become concerned the participant is distressed or have the participant report they are having difficulties getting through the material, the RA will stop the survey/interview an instead as the participant if they would be comfortable with our team contacting a social worker, psychiatrist, or psychologist with St. Jude to assist them for acute support. If the person says yes, then the participant will keep the person either with them in person or on the phone (if the follow-up is virtual). Once the on-call mental health support has been engaged with St. Jude, the person will follow the procedures outlined above under section 1. If the person does not wish to contact any at St. Jude for acute support, then the RA will remind the person of the informed consent process, which outlines that key study personnel will be notified of the person's experience, and it will be deemed an adverse event, and the KSP will follow-up with the person to discuss their experience. We anticipate very few

AEs. AE's will be discussed with Drs. Pettit, Audet, and on-site collaborator, Dr. Wilkins and, if necessary, consultation with a physician (Dr. Gaur; see letter of support) will be encouraged to contact the study PI as soon as possible for serious AEs. We will withdraw participants who have a serious AE. For other AEs, if either study investigators or the participant wishes it, the participant will be withdrawn from the study. We will also form a Data Safety and Monitoring Board (DSMB). If the percent of serious or severe AEs appears to be greater than 5% the DSMB will be notified to decide on early termination of the study.

All serious AEs will be reported to the MCC Institutional Review Board within 48 hrs. Follow-up of all unexpected and serious AEs will also be reported. All AEs will be reviewed weekly by the PI and yearly by the IRB. Any significant actions taken by the local IRB, and protocol changes will be relayed to the funding agency. We estimate the significant AE rate to be 5% or less. If the monthly monitoring indicates the rate is above this, we will convene a meeting of the DSMB.

Should a personnel member become distressed, site PI (Megan Wilkins) and study PI (Brown) will meet with this personnel member to assess their experience. PI Brown will then call an ad hoc meeting with co-primary K01 mentors Drs. April Pettit and Carolyn Audet to determine next best steps and if changes to protocol are warranted.

Trial Safety.
AEs will be tracked to determine if any AEs result in dropouts. The research staff will report any unexpected AEs to the PI within 24 hours so that the PI can decide on the appropriate action. All unexpected AEs will be monitored while they are active to determine if treatment is needed. For each weekly study meeting, the research assistants will prepare a summary of all AEs, if they caused a dropout, required treatment and presumed relation to intervention. The PI will review this at the weekly study meeting (or before if more urgent). At the weekly meeting (or before if urgent), research assistants will report any premonitory symptoms to suggest emergence of a psychiatric condition (e.g., depression, alcohol dependence). Dr. Wilkins, a licensed psychologist, will be available on ad-hoc basis for on-site clinical supervision for any issues that cannot be resolved with Dr. Brown.

Study procedures will follow as much as possible the FDA's Good Clinical Practice Guidelines. By nature of the study protocol, all participants will have multiple opportunities to address any concerns, questions, or possible contraindications for the intervention.

The research assistant will be instructed not to reveal whether a person is a participant in the study and will report to the PI any outside requests for information about a participant or any breaches in confidentiality. All requests by participant's providers and other medical providers will be referred directly to the PI.

Data Safety Monitoring Board:
This section is based on the recommendations in "Guidance for Developing a Data and Safety Monitoring Plan for Clinical Trials Sponsored by NIMH."
Summary of the Protocol. We will adapt an evidence-based trauma-informed HIV care (TIHC) intervention to the St. Jude youth-focused infection disease (ID) clinic. We apply community based participatory research and implementation science methods to adapt the intervention via stakeholder engagement to ensure the adapted intervention is contextually appropriate, multi-level, and culturally responsive. This study will determine the feasibility, appropriateness, and effect sizes for a future grant application.

Trial Management. The study will be managed from the Center for the Study of Social Determinants of Health within the Department of Psychiatry and Behavioral Sciences at the Meharry Medical College (MMC). Recruitment, data collection, data management, and treatment provision will be coordinated and centrally managed at our research lab at MMC and will work with an on-site Research Assistant located at St. Jude Infectious Disease (ID) clinic.

Data Management, Quality Assurance, and Analysis. Data will be collected by the appropriate individual (Research Assistant; PI) and will only be identified with the study's ID of the participant. The codes linking the name of the participant to the participant ID will be kept confidential in a secured cabinet by the PI or password-protected data file. Participants will enter data in REDCap, a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields. These

procedures are effective in minimizing data entry errors (e.g., missing or errant data). Server maintenance will be conducted by Information Technology Specialists at Vanderbilt University. Once data have been entered into REDCap, participants may not re-enter REDCap to view their data.

Regulatory Issues. The study does not require an IND from the FDA. All serious AEs will be reported to the MCC Institutional Review Board within 48 hrs. Follow-up of all unexpected and serious AEs will also be reported. All AEs will be reviewed weekly by the PI and yearly by the IRB. Any significant actions taken by the local IRB, and protocol changes will be relayed to the funding agency. We estimate the significant AE rate to be 5% or less. If the monthly monitoring indicates the rate is above this, we will convene a meeting of the DSMB. DSM Plan Administration. The PI will be responsible for monitoring the trial, with oversight provided by the primary mentor. The PI will examine monthly the outcomes database for missing data, unexpected distributions or responses, and outliers. The PI will check weekly the AE database prepared by the research assistants prior to weekly lab meetings to determine if any trauma response symptoms scores are higher than expected. A DSM report will be filed with the IRB and funding agency on a yearly basis, unless greater than expected problems occur. The report will include participant characteristics, retention and disposition of study participants, quality assurance issues and reports of AEs, significant/unexpected AEs and serious AEs. We will report efficacy at the end of the trial.
Data Safety and Monitoring Board (DSMB). We will create a DSMB to monitor both the rate and severity of AEs, and any unexpected increase in trauma symptoms. This panel will include 3 clinicians with expertise in mental health, and an administrator. The DSMB will meet annually to review any AEs related to the study, as well as review any data management related errors. The board may be called at any point if needed for unexpected AEs, etc. Modification will be made in the procedures and/or the protocol if necessary, based on the findings of the board.

Analysis Plan for Aim 1 a & b:
We will use the Research Quality Plus+ for Co-Production (RQ+ 4 Co-Pro) framework to guide our evaluation with the steering committee. This framework provides a rubric in which contextual items are scored on a four point scale and quality dimensions are scored on an eight point scale. We will also elicit qualitative discussions that will be analyzed with thematic content analysis. Finally, we will analyze patient baseline surveys according to mixed effects models. To analyze FGD and interviews, Dr. Brown (PI) and Research Assistant (RA) will create a codebook by each independently coding data. Themes will be reviewed with mentors Drs. Audet, Pettit, Pichon, and Sales to reach a 95% theme agreement and consensus, with final review to be conducted with the TSC. Framework Method58 and NVivo software 12 (QSR International) will be used to determine themes according to the ADAPT-ITT framework, eight elements for measuring intervention contextual fit,59 and the cultural responsiveness sub-scale of the Organizational Trauma Resilience Assessment,60 while allowing others to emerge. We will also generate code reports and summary tables from “thick descriptions” 61-63 of activities associated with phases 1-6.

Analysis Plan for Aims 1c & 2: Primary- and secondary- outcomes will be assessed using mixed effects models. Linear mixed effects models72 will be used for measures with a continuous outcome (e.g., TIHC attitudes)73 and ordinal mixed effects models will be used for measures with Likert scales (e.g., professional quality of life74). Mixed effects models will include a random effect per person to account for the correlation between observations taken from the same individuals over time. Our primary analyses will look at effect of time comparing baseline (time 0) with postintervention time periods (times 1-3: baseline, at 6-months, and again at 12-months months). Covariates included in these models are job position, age, sex, and race. Additional analyses include level of intervention engagement (proportion of attendance in required trainings) as an exposure variable. FGD will be analyzed through the creation of a codebook by study PI (Dr. Brown) and RA, with each coding and then reviewing with mentors for consensus and the steering committee, using framework methods with the Organizational Trauma Resilience Assessment and other TIC instruments to code data and inform the next phase of TIC implementation as data-driven, based on site findings (e.g., if item in dimension of trauma responsive services shows personnel do not report an increase in certain TIC attitudes or in practices related to trauma screening, next phase of training will respond to areas needing further improvement).
Sample Size and Power Calculations: With a two-sided type I error rate of $\alpha=0.05$, n=70 personnel, we have 80% power to detect a small-to-medium standardized mean difference (of 0.34) between pre- and post-intervention measurements for trauma resilience (primary measures 1-4 are based on findings from a past study [N=150] showing significant increase between pre: Mean=58.0 and post: Mean=61.7 measures, with medium effect size, via the validated tool we will use)64,73 and professional quality of life (with secondary measures 1-2 based on a past study [N=50] showing significant decrease in burnout between baseline and six month follow-up, from pre: Mean=24.5 to post: Mean=20.9.74 Past research with St. Jude personnel found an 85%

participation rate,75 indicating the invited 117 personnel as more than sufficient to reach the needed sample size of 70.

Data analysis for Aim 3:
We will compute summary statistics and plots to inspect data for missingness and distribution normalcy, including a scatter plot of the time series and bivariate comparisons between pre/post intervention periods to assess outcomes. For appointment adherence, we will use a Poisson regression model to conduct an interrupted time series (ITS) analysis91-92 with level change (levels of engagement with mental health providers) to detect associations between the patient-level intervention (primary exposure) and changes in appointment adherence, with up to 12 time points possible, with only three points on either side (pre and post intervention) needed for the ITS design.91 Models will adjust for covariates, including gender, age, race, and ethnicity. For trauma response, we will use linear mixed effects models to investigate impact of the primary exposure on trauma response over time. To ensure rigor and reproducibility, we will only conduct post-intervention adherence after the intervention is complete, in case participants engage with intervention during routine appointment times. We will conduct exploratory analyses to explore dose-response effects of the number of mental health appointment patients have completed following SBIRT TIHC-Y and impact on missed HIV appointments and trauma response as a time-varying covariate in the Poisson regression model; sensitivity analyses may be needed to account for missingness in trauma response (time-varying covariate) when participants miss visits (primary outcome) and fail to complete remote assessments. Qualitative interviews will be analyzed through the creation of a codebook by study PI (Dr. Brown) and RA, with each coding and then reviewing with mentors for consensus and the steering committee, using Trauma Symptoms of Discrimination67 and Multilevel Resilience Scale83 will be used to determine themes, while allowing others to emerge. Sample Size and Power Calculations: The current missed visit rate is ~50%. With a pooled sample size of the total 70 participants, we anticipate having 80% power to statistically detect a change in the missed visit rate from 50% in the pre-intervention period to at least 28% in the post-intervention period, corresponding with a nearly 2.6x increased odds of appointment adherence. This calculation was based on a two-sided type I error rate of 0.05. Our preliminary work shows adults receiving a trauma intervention had 4x increased odds of appointment adherence,28 indicating this intervention effect on missed visits is plausible.