Study Title: Social Networks and Methadone Maintenance Treatment Retention and Antiretroviral Therapy Retention in Tanzania

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JHSPH IRB Research Plan for New Data Collection

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For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.

PI Name: Haneefa Saleem

Study Title: Adaptation and Pilot of a Social Network Intervention to Improve Retention in Medication-Assisted Treatment for Opioid Use Disorder in Tanzania

IRB No.: IRB00019420

PI Version No. / Date: Version 3.0/04.4.2023

I. Aims of the Study: *Describe the aims/objectives of the research and/or the project's research questions or hypotheses.*

The primary aim of this study is to adapt, pilot, and assess the acceptability and feasibility of a social network intervention intended to improve retention in medication-assisted treatment for opioid use disorder. A secondary aim is to assess the potential effect of the intervention on antiretroviral adherence among individuals enrolled in medications for opioid use disorder who are also living with HIV.

II. Background and Rationale: *Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.*

People who inject (PWID) drugs in Tanzania have high rates of HIV. The elevated HIV risks associated with injection drug use have been well documented (41). Globally, PWID have 28 times higher HIV prevalence than the general adult population (42). In Tanzania, estimates of HIV prevalence among PWID, have ranged from 35% to 50% (9-11) compared to 5.1% in the general population (12). HIV rates are even higher among women, with prevalence estimates among women who use drugs reaching upwards of 66% (10, 13).

Medication-assisted treatment (MAT) for opioid use disorder is recommended as part of a comprehensive package of interventions for the prevention, treatment, and care of HIV infection among PWID (14). People retained in MAT have lower HIV risk (15, 16), reduced rates of overdose and mortality (17), greater access to other services (18), and greater likelihood of positive treatment outcomes (43-46). Among HIV-positive (HIV+) PWID, retention in MAT is associated with antiretroviral (ART) adherence and HIV viral suppression (8).

Tanzania delivers a good quality MAT program, but retention in treatment continues to be a challenge. To date, over 1,150 men and women have been enrolled in the MAT program at the Muhimbili National Hospital, with about 600 currently active—that is, they attend the clinic on a daily basis for methadone dosing. MMT retention at the Muhimbili MAT clinic is comparable to estimates reported in North America (47, 48), Europe (49, 50), and Asia (51, 52). However, there is ample room for improvement–only 57% of people who enroll in the MAT program at the clinic are retained at 12 months (19). Leaving MAT against medical advice is associated with increase drug use, including injection drug use, and risk behaviors, legal problems, community harms, overdose risk and mortality, and disengagement from other treatment, such as HIV and mental health treatment (8, 17). To date, research on MAT retention in Tanzania has focused mainly on individual factors, identifying treatment dose, age, gender, and history of sexual abuse as predictors of attrition (19), with less attention to social or structure factors.

Social network interventions can potentially harness the power of social ties to improve MAT retention and ART adherence for PWID. Social network interventions have been used in various models to improve health. Peer-based interventions, such as peer navigators living with HIV, treatment supporters, and adherence clubs, focused on improving retention in HIV care, have been implemented with positive results (57). There is also a growing body of evidence of sustained positive influence of social networks and social network interventions on HIV prevention and treatment, including among PWID (58). However, there have been few studies of social network interventions to support people receiving MAT or people receiving MAT who are also living with HIV (59-61). In preliminary qualitative research that we conducted in Tanzania, we found that the social environment, particularly family and peer support, are essential for MAT retention and recovery. Our findings indicate that restoring social ties outside of other people who use drugs may aid in MAT retention and ART adherence.

One social network intervention that can support MAT retention is the Brief Social Behaviour and Network Therapy (B-SBNT) intervention developed to facilitate recovery among people receiving medication-assisted treatment for opioid use disorder in the United Kingdom. The B-SBNT involves families and the wider social networks of people receiving medications for opioid use disorder to support recovery. Key components of the intervention include: mapping the social networks of clients; inviting others identified through the mapping to participate in the intervention; building communication strategies with network members; and developing joint activities with network members. In the original B-SBNT, the intervention is delivered by therapists/clinicians who undergo training.

III. Study Design:

A. *Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).*

We will carry out this research study in two stages. In stage 1, we will adapt the B-SBNT intervention to the Tanzania context. We will apply the ADAPT-ITT framework (34), which provides a guide for systematically adapting interventions to new target audiences and new settings in seven phases: 1) Assessment, 2) Decision, 3) Administration, 4) Production, 5) Topical experts, 6) Integration, and 7) Training. Table 1 outlines the methodology, including data collection methods, that we will adopt for each phase of the ADAPT-ITT framework. For Phase 1, we will conduct key informant interviews with providers at the Muhimbili MAT clinic and community outreach workers and other staff of community-based organizations operating in Dar es Salaam that provide outreach and/or services to people who use drugs. For Phase 2, we will use findings from Phase 1 to decide on which components of the original B-SBNT intervention should be selected for adaptation. For Phase 3, we will conduct focus groups with current clients enrolled in the Muhimbili MAT clinic, individuals identified by current Muhimbili MAT clients as providing them social support, and community outreach workers. The focus groups will allow us to obtain feedback from intended audiences on the components, content, and delivery approach for the intervention to help inform adaptation. For Phase 4, we will use findings from Phase 3 to revise and development any new intervention materials and procedures. Phase 5, we will hold key stakeholder workshops with topical experts, MAT clinic providers, key government officials involved in decision-making on opioid use disorder treatment programs, and other key stakeholders from civil society focused on outreach and other programming for people who use drugs to present and

solicit feedback on the adapted intervention. For Phase 6, we will integrate feedback from Phase 5 into intervention materials. For phase 7 , we will train intervention facilitators in the adapted intervention manual, and other materials and procedures. Only Phases 1, 3, and 5 of Stage 1 involve human subjects research, so the plan outlined throughout this research plan will focus on these three phases for Stage 1.

Table 1. Phases of adaptation and associated methodology based on the ADAPT-ITT framework.

	Description	**Methodology**
Phase 1: Assessment	Assess capacity of CBOs/clinics to adapt and implement the social network intervention	Key informant interviews with MAT clinic providers (n=6) and CBO staff (n=4)
Phase 2: Decision	Decide which components of the original B-SBNT intervention should be selected for adaptation	Literature review; Analysis of Assessment data from Phase 1; Selection of intervention components
Phase 3: Administration	Pre-test intervention content/ implementation strategies using theater tests	Theater tests of intervention through focus groups with current MAT clients (n=2), social supporters identified by current MAT clients (n=1), and community outreach workers (n=1)
Phase 4: Production	Revise and develop any new intervention materials and procedures	Develop adaptation plan based on findings from Phases 1-3; Adapt existing and develop any new intervention materials and procedures
Phase 5: Topical experts	Solicit feedback from topical experts on revised/new materials and procedures	Identification of experts; Key stakeholder workshops with topical experts and government officials
Phase 6: Integration	Integrate feedback from Phase 5 into an adapted social network intervention	Revise intervention materials and procedures based on findings from Phase 5
Phase 7: Training	Train intervention facilitators	Train intervention facilitators to administer the intervention using adapted intervention materials resulting from Phase 6

In Stage 2, we will conduct a small pilot of the adapted B-SBNT intervention to assess its acceptability and feasibility. Facilitators will be trained on the content and implementation of the adapted intervention and will deliver the intervention to a small sample of current MAT clients at the Muhimbili MAT Clinic and their identified social support persons.

B. *Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.*

Stage 1:

Phase 1: 6 MAT clinic providers based on number and roles of providers at the Muhimbili MAT clinic and 4 CBO staff based on interviewing one person from each of the four CBOs currently referring potential clients to the Muhimbili MAT clinic.

Phase 3: To obtain diverse perspectives on the proposed intervention components and strategies, we will hold 2 focus groups with MAT clients with 8-10 people per focus group for a total of up to 20 MAT clients; 1 focus group with 8-10 community outreach workers. This will allow us to reach data saturation and get essential feedback on the intervention to incorporate in the intervention manual and protocol.

Phase 5: We will hold key stakeholder workshops with up to 20 representatives from the Ministry of Health, Drug Control and Enforcement Agency, and select community-based organizations that provide services to people who use drugs.

Stage 2: We will pilot the intervention adapted in Stage 1 with up to 80 people: 20 current MAT clients at the Muhimbili MAT Clinic and 20-60 social support persons identified by recruited MAT clients (MAT clients will be able to invite up to 3 social support persons to participate in the intervention). The main purpose of this pilot is to assess the feasibility and acceptability of conducting a social network intervention among MAT clients and individuals identified by them as social support persons. The pilot study is not powered to assess statistical significance. With a sample size of 20 current MAT clients and up to 60 social support persons, we will be able to estimate the proportion of people who will attend at least 80% of the intervention sessions with some precision.

C. *Does your study meet the NIH definition of "clinical trial": "***A research study in which one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

Yes.

IV. Participants:

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care or who are wards of the State. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

A. **Inclusion Criteria:**

Stage 1: Inclusion criteria for key informant interviews will be: 1) at least 18 years old, 2) current provider or staff person at the Muhimbili MAT clinic OR current community outreach workers/staff person at a Dar es Salaam-operating CBO providing outreach to people who use drugs.

Inclusion criteria for focus group discussions will be: 1) at least 18 years old, 2) a current Muhimbili MAT client OR a person identified by a current Muhimbili MAT clients as a social support person OR

current community outreach workers/staff person at a Dar es Salaam-operating CBO providing outreach to people who use drugs.

Inclusion criteria for the key stakeholder meeting will be: 1) at least 18 years old, 2) a government representative involved in decision-making on opioid use disorder treatment programs in Tanzania OR a key stakeholder from civil society organizations focused on outreach and other programming for people who use drugs OR a MAT clinic provider OR a topical expert relevant to the adapted intervention (e.g., social support interventions or economic strengthening interventions).

Stage 2: Inclusion criteria for MAT client participants in the intervention pilot will be: 1) 18 years old or older, 2) currently enrolled in the MAT program at the Muhimbili MAT clinic, 3) prescribed methadone for the past 3 months, 4) received a positive test result for heroin, cannabis or alcohol use in the past 3 months, 5) provide consent for trial participation.

Inclusion criteria for social support persons in the intervention pilot will be: 1) 18 years old or older, 2) identified as a social support person of a MAT client participating in the pilot trial, 3) lives in Dar es Salaam, 4) provide consent for trial participation.

B. **Exclusion Criteria:**

Stage 1: none.

Stage 2: none.

NOTE*: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.*

V. Study Procedures:

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If you will collaborate with other institutions or organizations, or plan to subcontract JHSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA) , which is a promise to comply with human subjects research regulations.

*If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section.*

If your study will develop in phases, address each item below by phase.

A. **Recruitment Process:**

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and their qualifications.*

   Stage 1: For Phase 1, we will recruit key informants through the Muhimbili MAT clinic, CBOs, and snowball sampling. MAT clinic providers and CBO staff will be approached directly by the study team and purposively sampled based on job function (e.g., clinicians, social workers, occupational therapist).

For Phase 3, clinic staff will announce to MAT clients that focus groups will be held at certain dates and times and to reach out to the study team if interested. MAT clients will be given the opportunity to sign up to attend a focus group. We will hold two focus groups with 8-10 MAT clients in each. One focus group will be with clients who have been enrolled in MAT for more than 5 years. The other focus group will be with clients who have been enrolled in MAT for less than 5 years. We will attempt to have equal numbers of male and female clients in each focus group. At the end of each focus group, the study team will provide each person with a recruitment card with study team information to give to a person who they consider a positive support person (i.e., family member, partner, or friend) and who is not a current MAT client so that they can reach out directly to the study team if they are interested in participating in a focus group. One focus group will be held with 8-10 identified social supporters. For focus group with community outreach workers (8-10 community outreach workers), the study team will reach out directly to the directors of CBOs involved in outreach work for people who use drugs in Dar es Salaam and the MAT clinic and provide information on the study. The study team will ask CBO and MAT directors to refer any community outreach workers to the study team if they are interested in learning more about participating in a focus group. A study team member will provide all potential participants with an overview of the purpose of focus groups and assess his/her interest in participating. If the person is interested in participating, we will provide them with the date, time, and location of the focus group.

For Phase 5, we will identify and recruit topical experts based on recommendations from the local study team. The local co-PI will reach out directly to potential topical experts and other key stakeholders to invite them to a key stakeholder workshop.

Stage 2: We will pilot the intervention with a maximum of 80 people: 20 current MAT clients at the Muhimbili MAT Clinic and up to 60 social support persons identified by recruited MAT clients. Muhimbili MAT clinic staff will compile a list of clients who have tested positive for heroin, cannabis, and alcohol based on monthly urine screen in the past 3 months or random alcohol breathalyzer test in the past 3 months. The list will be stratified by HIV status to obtain equal number of MAT clients with and without HIV. From the list, the research team will randomly select 10 clients with HIV and 10 clients without HIV. MNH MAT clinic staff will introduce the study to the selected MAT clients who meet study eligibility and refer those interested in participating to the study team.

During the social mapping session of the intervention, MAT client participants will be asked to identify up to three people who provide them with support to invite them to participate in the intervention. MAT clients will be provided a letter to give to each of the social support persons identified and will provide the study team with the phone numbers of the social support persons, if available. The recruitment letter will include the contact information for the local co-PI. If a phone number for a social support person is provided, the study team will attempt to contact the identified social support person up to three times. The study team will only contact social support persons identified by participating MAT clients after the MAT client has informed the social support person of the study and the social support person is expecting to hear from study staff. The study team will confirm with the MAT client that social support persons have been informed of the study through the recruitment letter and/or vocally. Once contact with the identified social support person is made, a member of the study team will introduce the study to the social support person and invite them to participate in the study.

2. *Address any <u>privacy</u> issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks*.

   To protect privacy and minimize the risk of a breach of confidentiality, all recruitment conversations between the study team and potential participants will take place in a quiet and private location.

B. **Consent Process**:

1. *Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening*.

   a. *Who will obtain informed consent, and their qualifications*:

      Local interviewers trained in the responsible conduct of research, including ethical conduct of research, informed consent, and confidentiality, and sensitivities in working with vulnerable women and men, will obtain informed consent from study participants.

   b. *How, where, and when the consent discussion(s) will occur*:

      Consent discussions will occur verbally between the local study team member and the participant prior to their participation, preferably immediately preceding the interview or focus group, in a quiet and private location. The study team member will read through the consent form and will use probes to assess whether the participant understands what is being asked of him/her. The study team member will give the participant the opportunity to ask questions about the study before asking for her/his consent to participate. The study team member will offer a copy of the consent script which will include information on how to contact the study staff and IRBs to ask for further information or to report adverse events associated with his or participation in the research.

   c. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:
      We will recruit clients and providers directly from the MAT clinic, so any client enrolled in the clinic will be eligible. CBO staff will be recruited directly from CBOs, so any staff will be eligible. Social support persons will undergo screening to determine their eligibility for pilot trial participation.

   d. *Whether you will obtain a signature from the participant or will use an oral consent process*:

      For Stage 1 activities: We will use an oral consent process since this study present no more than minimal risk to participants. A written, signed consent form would be the only document linking the participants' names to the study and would increase the potential risk of breach of confidentiality.
      For Stage 2 pilot intervention: We will obtain a signature from participants.

   e. *Whether you will obtain a legally authorized representative's signature for adults lacking capacity*:
      N/A

   f. *If children are included in the study, if and how you will obtain assent from them*:

      N/A

   g. *If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision). If any of the children are "wards of the state", additional regulatory requirements will apply:*
      N/A

   h. *If you are seeking a waiver of informed consent or assent, the justification for this request*:

We request a waiver of informed consent for participants of the key stakeholder workshop as we will only disseminate findings and get their feedback on the intervention in their official job capacities. These workshops will not include any personal questions.

i. *Whether you will include a witness to the consent process and why*:

We will not include a witness to the consent process to better protect participant privacy.

j. *If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials*:

N/A

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	**Consent Document(s)** **(Adult Consent, Parental Permission, Youth Assent, etc.)**	**Languages**
Tanzania	Adult Consent	Swahili

C. **<u>Study Implementation</u>**:

1. *Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate*.

Stage 1: For Phase 1 of the ADAPT-ITT approach that we are adopting for this study, we will conduct key informant interviews with providers at the Muhimbili MAT clinic and community outreach workers and other staff at community-based organizations operating in Dar es Salaam that provide outreach to people who use drugs. Local Interviewers, who will be fluent in English and Swahili and have previous experience conducting qualitative interviews and/or focus groups, will be trained in ethics and the specific interview data collection approach that will be used in the study. After obtaining informed consent, the Interviewers will conduct interviews with key informants in a private location using semi-structured interview guides. Interview guides will include questions on intervention content/components, implementation approaches, duration, and training needs. Key informant interviews are expected to last between 45m and 1h and will audio recorded with participant permission. Interviews will be transcribed in Swahili and translated to English.

For Phase 3, we will conduct focus groups with current clients enrolled in the Muhimbili MAT clinic, individuals identified by current Muhimbili MAT clients as providing them social support, and community outreach workers. Focus groups will be moderated by a member of research team and a notetaker from the research team will also be present. The moderator will use a semi-structured focus group discussion guide. The guide will include questions on content/components, implementation approaches, duration, potential economic strengthening activities. Focus groups are expected to last between 1.5 and 2h. Discussions will be audio recorded with participants' permission and audio recordings transcribed in Swahili and translated to English.

For Phase 5, we will hold up to two half-day, key stakeholder workshops with topical experts, including MAT clinic providers, key government officials involved in decision-making on opioid use disorder treatment programs, and other key stakeholders from civil society focused on outreach and other programming for people who use drugs. Workshops will be structured around presenting key findings and materials produced from phases 1-4 and eliciting feedback on intervention content and implementation strategies. Members of the research team will facilitate the workshops. Each workshop will last 4-5 hours and notes will be taken throughout the workshop to document discussions.

Stage 2: After obtaining informed consent, MAT clients and their identified social support person(s) will complete a pre-intervention survey. The survey with MAT clients will include questions on socio-demographics, substance use behaviors, methadone treatment, stigma experiences, coping skills, and social support. For questions on social network members, MAT clients will be asked not to specify names of family, friends, other MAT clients, or other important people in their lives. Rather, they will be asked to use nicknames, initials, or relationships (e.g., "mother," "sister," "uncle," etc.) to identify important people. The survey with social support persons will include socio-demographic questions as well as questions on interactions with the MAT client who identified them as a social support person, substance use behaviors, methadone treatment, and knowledge and attitudes towards substance use disorders and people with a substance use disorder. The pre-intervention survey is expected to last approximately 15 minutes (for social support persons) and 20 minutes (for MAT clients). MAT client participants will then attend seven sessions over the course of six weeks. Social support persons will attend up to five sessions over the course of six weeks. The sessions are outlined in the following table:

Table 2. Description of intervention sessions

Session #	Session name	Session description	Social support person invited to session?
1	Introduction	• Aim: Present information on the intervention program (duration, content, expectations) • Separate, 50-min group sessions will be held with participating MAT clients and social support persons identified. The social support person introduction session will be held two weeks after the MAT client session.	Yes
2	Working in a social network-based context	• Aim: Identify, recruit, and maintain a network supportive of positive change • In this 50-min session, the counselor will explain the importance of social support in achieving positive outcomes, identify the primary goals for which the client will focus on in the program, identify people who can provide the client with positive support using social network mapping, plan and rehearse contacting potential social	No

		support persons, plan for activities with social support persons and maintenance of social network support.	
3	Setting drinking and drug use goals	• Aim: Understand the client's current substance use, establish substance use harms, and agree on where the client would like to be in relation to their substance use • In this 50-min session, the counselor will get an account of recent substance use behavior, elicit concerns about the behavior and its consequences (change talk), explore motivation to change and self-efficacy for achieving a change plan, agree on a change plan (commitment talk)	Yes
4	Coping skills 1	• Aim: Identify high-risk situation for drinking and drug use and agree on a coping strategy for each situation • In this 50-min group session with other MAT clients, the counselor will provide information on the nature of high-risk situations, help the clients to brainstorm potential coping strategies, and interactively practice coping in high-risk situations	No
5	Coping skills 2	• Aim: Identify high-risk situation for drinking and drug use and agree on a coping strategy for each situation • In this second 50-min session on coping skills, the counselor will work with clients and their social support persons to discuss to create an individualized network-based coping strategy	Yes
6	Making lifestyle changes	• Aim: Establish a lifestyle, free of alcohol and drug problems, with network support • In this 50-min session, the counselor will establish an understanding of an alcohol/drug problem-free lifestyle based on the vision of the MAT client and their social support persons, identify roles in achieving new routines and activities, create an action plan (with weekly schedule for routine activities, including income generation), and use problem-solving to address challenges to the plan	Yes
7	Generating income	• Aim: Build income-generating skills • In this 3-hour group session with other MAT clients and social support persons, the facilitator(s) will lead hands-on training on income-generating skills, including construction, carpentry, cooking, and jewelry-making.	Yes

Participant attendance will be recorded for each session. Members of the study team will observe sessions and take notes on intervention fidelity and delivery using a semi-structured form. After each session, participants will be asked to complete a brief exit survey to assess satisfaction with the session. The exit survey will be administered by the intervention counselor. At the end of the pilot, the study team will conduct a post-intervention survey with MAT client participants and their participating social support persons. The post-intervention survey will include similar questions to the baseline survey but will also include questions to gauge acceptability and satisfaction with the intervention, experiences with social and income-generating activities, and suggestions for changes to the intervention. The post-intervention survey is expected to last between 15 minutes (for social support persons) and 20 minutes (for MAT clients).

We will also conduct 25 follow-up qualitative, in-depth interviews with 10 MAT client participants, 10 social support person participants, and all 5 intervention counselors, about one month after the trial. We will purposively sample participant based on their attendance in sessions and based on responses to survey questions, so that we can obtain a sample of individuals with various experiences with the program. Study interviewers will use a semi-structured interview guide to facilitate the discussion. The

guide will include questions on experiences with the program (what worked and what could be improved), how well counselors followed the intervention manual, what clients learned, how clients incorporated lessons learned in their daily lives, and changes in the quality of relationships with social support persons and other people in their lives. Interviews are expected to last about 45 minutes and will be audio-recorded with participant permission.

2. *Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place*.

   Stage 1: All participants will be in contact with the study team for recruitment purposes. For Phase 1, key informant interviews are expected to last between 45m and 1h. Phase 1 participants will participate in a single key informant interview. It is possible that health providers or CBO staff who are interviewed for Phase 1 will be invited to the key stakeholder workshop for Phase 5. For Phase 3, focus groups are expected to last 1.5 to 2h. Each focus group participant will participate in just one focus group discussion. The informed consent process for key informant interviews and focus groups will take place before the interview or the focus group and is expected to last no more than 10m. Key stakeholder workshops will last 4 to 5h.

   Key informant interviews will take place in a private and quiet location, either at the study office, the CBO office, or the provider office at the MAT clinic. Focus groups will take place in the conference room of the building that houses the study office located near the Muhimbili MAT clinic on the grounds of the Muhimbili National Hospital. The key stakeholder workshops will take place in rented venues (conference rooms) in either Dodoma (where many government offices are located, including the Ministry of Health) or Dar es Salaam.

   Stage 2: All pilot participants will be in contact with the study team for recruitment purposes, for pre- and post-intervention surveys, and through the pilot intervention. Upon enrollment, the pre-intervention survey is expected to take 20m to complete for enrolled MAT clients and 15m for enrolled social support persons. MAT clients will participate in six 50-min sessions and one 3h session over the course of six weeks. Social support persons will participate in four 50-min sessions and one 3h session over the course of six weeks. After each intervention session, participants will complete a 5m exit survey. The post-intervention survey is expected to take 20 minutes and 15 minutes for MAT clients and social support persons to complete, respectively, and will be conducted a week after the intervention ends. A select number of pilot participants will also be in contact with the study team for an approximately 45m follow-up, in-depth interview one month after their last intervention session.

3. *Describe the expected duration of the study from the perspective of the individual participant and duration overall*.

   Stage 1:
   Phase 1: Key informant interviews are expected to last 45m to 1h.
   Phase 3: Focus group discussions are expected to last 1.5 to 2h.
   Phase 5: Key stakeholder meetings are expected to last 4 to 5h.

   Stage 2:
   MAT client participants: Six weeks, as well as a 45-minute, follow-up interview for select participants

   - Pre-intervention survey: Approximately 20m

- Intervention: 50-min intervention session weekly for six weeks plus a 3h interactive, income-generating skills-building session
- Post-intervention survey: Approximately 20m
- Post-intervention interview: Approximately 45m (select participants)

Social support person participants: 6 weeks, as well as a follow-up interview for select participants
Pre-intervention survey: Approximately 15m

- Pre-intervention survey: Approximately 15m
- Intervention: 50m intervention session weekly for five weeks plus a 3h interactive, income-generating skills-building session
- Post-intervention survey: Approximately 20m
- Post-intervention interview: Approximately 45m (select participants)

The overall duration of the study (Stages 1 and 2) will be two years.

4. *Provide a brief data analysis plan and a description of variables to be derived.*

Stage 1: We will analyze interview, focus group, and stakeholder meeting transcripts using framework analysis. Transcript data will be coded in NVivo and broadly categorized into participant feedback on the different intervention components with more detailed subcategories of codes and topics (such as content, feasibility and acceptability, and delivery) developed within these broader categories based on the data. Each interview will be placed into a framework developed from the broad and more detailed categories of responses, using a template developed in Microsoft Excel. Two independent coders will enter each interview/focus group into the framework and any discrepancies will be discussed and resolved. The final framework will be shared with data collectors and other study team members for discussion and to inform decisions on adaptations to the B-SBNT intervention. The study team will adapt the existing intervention manual and materials based on findings from Phases 1-4. Topical experts and other key stakeholders will provide feedback on drafts of the adapted manual and materials, which the study team will integrate in Phase 6. We will then pilot the resulting adapted intervention in Stage 2.

Stage 2: We will use descriptive statistical methods and qualitative data analysis to examine intervention acceptability and fidelity of the intervention. Enrollment data will be used to describe the characteristics of the MAT clients and their social support persons. We will calculate the proportion of sessions attended. We will explore the reasons for missed sessions. These data will provide important information on the characteristics of study participants, the dose of the intervention, retention, reasons for missed sessions, and the acceptability of session content and approach. We will examine key outcomes such as changes in knowledge and attitudes, and changes in network and social engagement.

5. *Answer the following **if they are relevant to your study design**:*

A. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

N/A

B. *If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected*

for use in future research (beyond this study), complete the "Biospecimen Repository" section below.

N/A

C. *If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.*

N/A

D. *If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.*

N/A

E. *If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants*.

N/A

F. *If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:*

a. *Will the study staff be blind to participant intervention status*?

N/A

b. *Will participants receive standard care or have current therapy stopped*?

N/A

c. *Will you use a placebo or non-treatment group, and is that justifiable*?

N/A

d. *Explain when you may remove a participant from the study*.

N/A

e. *What happens to participants on a study in which there is a medical intervention when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*
N/A

f. *Describe the process for referring participants to care outside the study, if needed*.

N/A

VI. Data Custody, Management, Security, and Confidentiality Protections:

Data security and management plans must meet institutional standards. If you need assistance, contact jhsph_cybersecurity@jhu.edu.

Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.

1. **Data Sources**: Identify the source(s) of data.

☒ Participant/Parent-Guardian/Legally Authorized Representative

☐ JHM medical records (from Epic)

*Note: Please complete the **Data Trust Risk Tiers Calculator** available on the Applications and Forms page on the JHSPH IRB website: https://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/, and upload a copy of the those documents to the "Miscellaneous" section of your PHIRST application. In addition, review the Data Protection Attestation for Research and/or Healthcare Operations at the link below and certify your attestation of compliance to those requirements: (*https://intranet.insidehopkinsmedicine.org/privacy_office/_docs/additional_information/Data%20Protection%20Attestation.pdf.

☐ **I certify my attestation of compliance to JHM Data Protection Requirements**

☐ non-JHM medical records

☐ Outside data provider (CMS, National Death Index, Insurance Co., etc.)

☐ Other existing records

2. **Data Content**: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☒ Yes Continue with Question 3

☐ No Skip to Question 9

3. Data Identification: Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the boxes below for "Recruitment" and "Study Data" needs:

Recruitment	Study Data	PII/PHI to be accessed/collected
☒	☐	Name, signature, initials or other identifiable code
☐	☐	Geographic identifier (address, GPS location, etc.)
☐	☐	Dates (birth, death, clinical service, discharge, etc.)
☒	☐	Contact information (phone number, email address, etc.)
☐	☐	Identification Numbers (SSN, driver's license, passport, etc.)
☐	☐	Health Records Identifiers (medical record #, insurance plan, etc.)
☐	☐	Text of clinical record notes
☐	☐	Device identifiers (implants, etc.)
☐	☐	Internet identifiers (IP address, social media accounts, etc.)
☐	☐	Biometric identifiers (fingerprints, retinal scan, voice print, etc.)
☐	☒	Audio Recordings
☐	☐	Video or full-face photographic images
☐	☐	Genomic / Genetic data
☐	☐	Other identifiers: (list here)

4. Identifiers: If you have checked any of the boxes above, how will you protect personal identifiers?

☒ Will delete all identifiers (explain **when** you will delete identifiers):

We will delete all identifiers (collected for recruitment and retention purposes) when the follow-up assessment for the pilot intervention trial is completed.

☒ Will separate identifiers from analytic data and will store the link/code. *Please explain where you will store link/code:* We will maintain a separate database with contact information for pilot intervention trial participants for the purpose of follow-up/retention during the trial and for the post-intervention follow-up assessment. We will not link this contact information to any analytic data collected from participants.

☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:*

5. Will you obtain consent (or Authorization if governed by HIPAA) from participants for this study?

☒ Yes

☐ No

6. Data Transit Plans and Protections: Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

☐ Will delete all identifiers prior to transfer

☒ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:* Identifiers will only be collected for the purpose of recruitment and retention during the pilot trial. We will not link identified to any analytic data collected from participants.

☐ Other:

7. Device(s) used for <u>data collection</u>: Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

☐ Provided or managed by JHSPH IT

☒ Study-provided, and not managed by JHSPH IT. These must include the following protective controls:

- Data encrypted while "at rest" (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - Each person accessing the device is uniquely identified (username)
  - Passwords are sufficiently strong to prevent compromise
  - All access is logged and recorded
  - Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness
- ☐ Other. Specify:

8. Data Collection: Describe the format of data received/collected. Check all that apply.

☒ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)

☒ Audio recording

☐ Video recording

☐ Received directly by research team member and entered into file/database

☐ Mobile or Web App (custom developed). *Review guidance and provide attestation of compliance*

☒ Mobile or Web App (purchased). *Specify product and version*: Network Canvas version 6.1.2

☐ Online survey. *Specify mechanism/platform*:

☐ 3rd party collector. *Specify*:

☐ Existing data shared with JHSPH by data provider via electronic access/transfer

☐ Duplicate and backup copies will be secured with same rigor as original data

☐ Other. *Specify*:

9. Devices/Platforms used for Analysis, Storage, Processing: Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply.

☒ Pre-approved storage and analysis platforms managed by JH/JHSPH for which security and risk mitigation measures are known.

Identify preapproved storage platform(s) being used:

JHM Preferred:	**Other Approved**:	
☐ JH SAFE Desktop	☒ JH OneDrive/JHSPH OneDrive	☐ JHSPH HPCC
☐ JH PMAP	☐ JHSPH Shares	☐ JHM/JHSPH Qualtrics
	☐ JHSPH Sharepoint	☐ MARCC Secure Environment
	☐ JHU RedCap	☐ JH IT-managed Network Storage

_____

☐ Platform(s) not managed by JH/JHSPH, not pre-approved, and require a risk assessment review from JHSPH Data Security. Describe:

Describe risk mitigation measures in place:

Note: The following are examples of platforms/storage solutions that are **not pre-approved to store identifiable information** and require a risk assessment from JHSPH Data Security.

- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)
- JHU Independent Departmental Servers
- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device

10. Access to Data and Access Controls: How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive *guidance* illustrates how to share files with "people you specify". *JHSPH-Shares* addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact *jhsph_cybersecurity@jhu.edu.*

☒ Will provide access to data in accordance with OneDrive/JHSPH-Shares guidance posted on JHU IT websites

☐ Will use secure access controls to limit access to individual-level data

☐ Will use secure access controls to provide other researchers controlled access only to aggregated study data

11. Data Sharing: Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

Consider the following:

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*

- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

☐ Will not share data with outside investigators

☒ Will share aggregated data only

☐ Will share individual-level data without identifiers

☐ Will deposit data into an existing data repository for future research (e*xplain*):

☐ Other sharing information:

12. Duration and Destruction: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

Data will be deidentified and retained for future analyses.

A. Certificate of Confidentiality:

All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://grants.nih.gov/policy/humansubjects/coc.htm)

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

VII. Risks of the Study:

A. *Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan*.

Stage 1: There is a risk that some questions asked during interviews or focus groups may make participants feel uncomfortable or experience negative emotions. The main risk for participants in the study is breach of confidentiality.

Stage 2: There is a risk that some topics discussed during intervention group sessions may make participants feel uncomfortable or experience negative emotions. The main risk for participants in the pilot trial is breach of confidentiality. There is a risk that if confidentiality is breached then others

outside of the study may learn of any reported illicit drug use reported by participants during intervention sessions. Participants may also experience emotional distress when discussing drug and alcohol use or other topics covered in intervention sessions.

B. *Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.*

The following steps will be taken to minimize the risks describe above:

Staff training. All study investigators have completed human subjects research ethical training through the Collaborative Institutional Training Initiative (CITI Program) or comparable training courses. Local data collectors will be trained in: ethical conduct of research, including informed consent and confidentiality; sensitivity training in working with high-risk men and women, particularly people who use drugs; and data collection procedures. Intervention facilitators will also be trained in the intervention manual.

Recruitment. The study team will ensure confidentiality during recruitment. All recruitment discussions will take place in private.

Informed consent. Oral informed consent will be obtained from Stage 1 participants and written consent from Stage 2 (pilot trial) participants prior to their participation. All consent forms will be translated into the local language (Swahili) and certified by a translator to ensure correct use of the language. Oral instead of written consent will be used for Stage 1 since this study presents no more than minimal risk to participants. The participant will be offered a copy of the consent form, which will include information on how to contact the study staff and IRBs to ask for further information or report adverse events associated with his or her participation in the research.

Data collection procedures. For Stage 1, key informant interviews and focus groups will take place in a private, quiet location, either at the study office, CBO office, or private office in the MAT clinic. Interviews and focus groups will be audio-recorded with participant permission. Audio recordings will be deleted from the digital recorder once the audio files have been successfully transferred to a password-protected study computer and backed up. All participants will be informed that they can skip any questions during the interview/focus group or withdraw from the study at any time without penalty. For Stage 2 (pilot trial), intervention sessions will take place in a private, quiet location, either at the study office or CBO office. All participants will be informed that they do not have to answer any questions or share any information that they are uncomfortable with sharing (such as substance use, particularly in group session), and that they can withdraw from the trial at any time without penalty.

Data management and storage. Hard copies of interview, focus group, and observations notes and intervention assessment forms will be stored in locked file cabinets in the study office. Any handwritten notes will be shredded at the end of the study period once all quality control and quality assurance procedures have been completed and verified, and converted to electronic versions. All de-identified, transcripts, notes, and intervention data will be stored and backed up on a secure, password-protected cloud server, JH OneDrive. Electronic survey data (pre- and post-intervention survey data) will also be stored and backed up on JH OneDrive.

Referrals to care. Participants who experience emotional distress during an interview, focus group, or intervention session will be referred to mental health care or social services offered through the Muhimbili National Hospital. Participants who report behaviors that may place themselves or others at risk of HIV, will be referred to the MAT clinic, local HIV clinics, or a community-based organization that could link them to HIV or other services. The Muhimbili MAT clinic has social workers and substance use disorder specialists, as well as community-based organizations that provide support and outreach services for people who use drugs in Dar es Salaam, and can refer participants to these services, as needed. Participants requesting support to deal with a violent situation will be referred to a mental health specialist or social worker at the Muhimbili MAT clinic.

C. *Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?*

Stage 1: The potential risks described above may occur during recruitment or data collection (key informant interview or focus group) and will likely be minimal to the participant.

Stage 2: The potential risks described above may occurring during recruitment, pre-/post-intervention survey data collection, or during the intervention pilot sessions and will likely be minimum to the participant.

D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc*.

Participants may have to travel to the designated interview, focus group or intervention locations, which may require out-of-pocket transportation costs. Study participation will also cost participants their time. For Stage 1, the burden is expected to be limited to one data collection encounter (key informant interview, focus group, or key stakeholder workshop) and will not exceed 4 hours. We will attempt to mitigate the burden on participants enrolled in MAT by coordinating activities with existing clinic visits. For Stage 2, the burden is expected to be greater with the multiple components of the trial (baseline and follow-up assessments and participation in the intervention sessions).

E. *Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.*

All in-depth interviews and focus groups will be conducted in a private, quiet, and safe location to protect participant privacy. Study documents, including transcripts and notes, and consent forms will not include participants' names or any other identifying information.

VIII. Direct Personal and Social Benefits:

A. *Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).*

There is no direct benefit from the study for participants. Participants may welcome the opportunity to share their experience with being on MAT or knowing someone enrolled in MAT if approached in a non-judgmental manner. They may view the interview or focus group, especially, as an opportunity to reshape processes of MAT and ART delivery and support.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

Findings from the study will be used to develop a social network intervention to help build the social support network of patients to remain on MAT and adhere to ART. Retention in MAT is important in facilitating and improving access of people who inject drugs to HIV prevention and treatment services, and facilitating ART adherence.

IX. Payment or Token of Appreciation:

A. Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the JHSPH IRB strongly encourages providing such tokens. If yes, please describe below.

Stage 1: Tea and snacks will be provided for Phase 3 focus group participants during the focus group. Tea and snacks will be provided for the key stakeholder workshop of Phase 5.

Stage 2: Tea and snacks will be provided during each of the group intervention sessions.

B. *If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain*.

Stage 1: Phase 1: Key informants will be provided a one-time, monetary payment of 20,000 Tanzanian shillings ($8.68 USD equivalent) for their participation. Phase 3: Focus group participants will be provided a monetary payment of 10,000 Tanzanian shillings ($4.34 USD equivalent) at the end of the focus group to reimburse for costs of study participation, including transportation. Phase 5: Topical experts and other key stakeholders participating in the key stakeholder workshop will receive a sitting fee of 120,000 Tanzanian shillings ($52.06 USD equivalent) per standard practice.

Stage 2: Trial participants will receive 10,000 Tanzanian shillings per intervention session (7 intervention sessions for MAT clients and 5 sessions for social support persons), 10,000 Tanzanian shillings for completing each of the pre-intervention and post-intervention survey, and 10,000 Tanzanian shillings for completing a follow-up, qualitative interview.

C. Include the possible total remuneration and any consequences for not completing all phases of the research.

Stage 1: The total possible renumeration for Stage 1 key informant will be 20,000 Tanzanian shillings, 10,000 Tanzanian shillings for focus group participants, and 120,000 Tanzanian shillings for participants in the key stakeholder workshop.
Stage 2: The total possible renumeration for Stage 2 participants will be 100,000 Tanzanian shillings (approx. 43 USD equivalent) for MAT client participants and 80,000 Tanzanian shillings (approx. 34 USD equivalent) for social support person participants.

X. Study Management:

A. Oversight Plan:

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be "engaged" in the human subjects research project and their roles .*

   The PI will provide scientific oversight over all aspects of the study. The Tanzania-based Co-Investigator, will manage day-to-day study operations at the field site, including supervising the

local study team and managing study recruitment and data collection. The PI will have at least weekly calls with the Tanzania-based Co-Investigator in addition to weekly debriefing meetings with the entire study team. The PI will manage all data analysis along with study Co-Investigators.

2. *What are the qualifications of study personnel implementing the project*?

   The PI, Dr. Haneefa Saleem, is an Assistant Professor in the Department of International Health at JHSPH. She has conducted research focused on the intersections of substance use and HIV, including mitigating the risks and harms associated with injection drug use. She served as Co-investigator and oversaw data collection and analysis on research grants sponsored by the National Institute on Drug Abuse (NIDA) and the CDC in Tanzania. These research studies aimed to develop and evaluate a pilot take-away methadone treatment delivery model (CDC) and an integrated HIV and MMT service delivery model at the first publicly-funded MAT program in sub-Saharan Africa, located at the Muhimbili National Hospital in Dar es Salaam, Tanzania.

   The main Tanzanian collaborators/Co-Investigators for this project are Dr. Iddi Haruna Nkya and Dr. Jessie Mbwambo. Dr. Haruna Nkya is a Psychiatrist and Lecturer in the Department of Psychiatry and Mental Health at Muhimbili University of Health and Allied Sciences (MUHAS) and clinician at the Muhimbili MAT clinic. He has previously worked with Dr. Saleem on mixed methods research examining the integration of HIV care and treatment at the Muhimbili MAT clinic. Dr. Jessie Mbwambo is a Consultant Psychiatrist at the Muhimbili National Hospital and Senior Researcher also in the Department of Psychiatry and Mental Health at MUHAS. She has over 25 years of experience conducting HIV prevention and treatment research and leads the Tanzania AIDS Prevention Program, which overseas several community-based organizations that provide outreach to people who use/inject drugs in Dar es Salaam. She was instrumental in starting the first methadone maintenance treatment program in Tanzania. The PI has worked extensively with Dr. Mbwambo on HIV research projects in Tanzania. Dr. Haruna Nkya and Dr. Mbwambo will oversee field data collection and will assist in analysis, interpretation, and dissemination of findings.

   All study investigators have completed training in the responsible conduct of research, human subjects research protections, and additional training in research ethics.

3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website. If* the study is a clinical trial, consider using the JHSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).

   The PI and Co-Investigators will train study personnel involved with the data collection and preliminary analysis in human subjects research protections using the JHSPH Ethics Field Training Guide and supplemented by additional ethics training that the PIs have conducted in Tanzania for studies involving vulnerable populations, specifically people who use drugs and people in recovery for addiction. The ethics training will be included as a one-day module as part of the initial one-week training for the data collection team. Though all study members will be fluent in English and the training will be conducted in English, they will be provided copies of both the English and Swahili versions of the JHSPH Ethics Field Training Guide.

4. *If the JHSPH PI is responsible for data collection and will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team*.

   The PI, Dr. Saleem, will visit the study site for the one-week training with the study team on research ethics, data collection, and reporting procedures, and to supervise initial recruitment, consent and data collection for Stage 1 (depending on travel advisories and the global COVID-19 situation). The PI will visit the site during planning for the pilot trial and possibly during the

administration of the pilot intervention (again depending on travel advisories due to COVID-19 pandemic). The study team will participate in weekly meetings to debrief on issues related to recruitment, consent, data collection, and emergent findings. The PI will call into these weekly meetings, when not at the site, and co-lead these meetings with the Tanzanian Co-Investigators. In addition to the weekly debriefing meeting, the PI will have bi-weekly calls with the study investigators to discuss any study issues, including issues concerning members of the study team. Outside of scheduled study team and investigators' meetings, the PI will communicate to study investigators, as needed, through email or phone/Zoom call.

B. **Protocol Compliance and Recordkeeping:**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. (For assistance, contact: housecalls@jhu.edu *Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?*

The PI and Tanzanian Co-Investigators will oversee and monitor that the study team is following the protocol and properly recording and storing study data collection forms. When the PI is not on-site, the Tanzanian Co-Investigators will provide weekly updates on the recording and storage of data collection forms. If any deviations from the protocol are found, the study team will be provided a refresher training session by Study Investigators on recording and storing data collection forms. The PI will provide oversight on IRB regulatory correspondence and other off-site study documentation.

C. **Safety Monitoring:**

1. *Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role and what is that person's specific charge?*

   Given the nature of the study, there will not be a medical monitor on site. Investigators will ensure that informed consent is obtained prior to performing any data collection procedures, that all participants meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan. The Tanzanian-based Co-PI, Dr. Iddi Haruna Nkya, is a clinical psychiatrist at the MNH MAT clinic. He will train and supervise all intervention counselors, conducting weekly supervision meetings with intervention counselors.

   The the full investigator team will review study conduct (recruitment, protocol deviations) on a bi-weekly basis. Investigators will review adverse events, including serious adverse events, individually in real-time and in aggregate on a monthly basis. The PI, Dr. Saleem, will ensure all protocol deviations and adverse events are reported to the JHSPH and MUHAS IRBs according to the applicable regulatory requirements.

2. *If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following*:

   a. *The DSMB membership, affiliation and expertise*.

   b. *The charge or charter to the DSMB*.

c. *Plans for providing DSMB reports to the IRB*.

3. *Describe plans for interim analysis and stopping rules, if any*.

The anticipated risk for participants is low. However, if excess harm (e.g. severe physical or emotional distress during interviews or focus groups) is observed, the study will be suspended until the PI is able to consult with the JHSPH and MUHAS IRB to make the final determination for stopping the study. If the study is stopped early for any reason, participants will be informed of the results.

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

*NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.*
***Anticipated** AEs may be reported with the Continuing Review/Progress Report.*

Describe your plan for reporting to the JHSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity.

Given the nature of the study, we do not anticipate any adverse events or serious adverse events. However, the PI will evaluate the event and promptly submit written reports of all events that meet the definition of "unanticipated problems involving risks to participants and other," in accordance with the Johns Hopkins Bloomberg School of Public Health (JHSPH) IRB Policy No. 103.06 – "Reports of unanticipated problems involving risks to participants or to others (Problem/event reporting)" to the JHSPH IRB and the MUHAS IRB, using designated reporting forms, as soon as possible after she learns of the event, but in all cases within 10 working days. If the unanticipated adverse event is deemed alarming by the Project PI, she will immediately report the event to the respective IRB offices.

E. **Other IRBs/Ethics Review Boards:**

*If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances). **For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The JHSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact jhsph.irboffice@jhu.edu with questions.***

Non-JHSPH IRB/REC	FWA Number
Research Ethics Committee Directorate of Research and Publications, Muhimbili University of Health and Allied Sciences (MUHAS)	FWA00004301

F. **"Engaged" in Human Subjects Research:**

For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.

Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:

	JHSPH	MUHAS	
For federally funded studies, collaborators' FWA	00000287	00004301	
Primary Grant/Contract Recipient	X		
Grant/Contract Subrecipient		X	
Hiring Data Collectors		X	
Training Data Collectors	X	X	
Obtaining Informed Consent and/or Identifiable Data		X	
Accessing/Analyzing Identifiable Data	X	X	
Overseeing storage, access and use of biospecimens	N/A	N/A	

COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:

XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. *Describe your study design and methods. The study design must relate to your stated aims/objectives.*

We will use a limited, longitudinal study design to detect changes in preliminary outcomes of MAT clients participating in the Stage 2 pilot trial. We will extract data from the MAT clinic records of the 20 participating MAT clients:

- Time enrolled in MAT
- Time since HIV diagnosis (if relevant)
- Methadone dose
- Drug use (heroin, cocaine, cannabis or benzodiazepines)

- Alcohol use
- Methadone adherence
- Antiretroviral therapy (ART) adherence (pharmacy refills)

We will assess changes in substance use (via drug test results), alcohol use (via breathalyzer tests), methadone adherence, and HIV treatment adherence (for clients living with HIV). Data will be extracted for the six-month period prior to the intervention and the six-month period following the end of the intervention.

2. *Provide an estimated sample size and an explanation for that number*.

   We will include 20 current MAT clients at the Muhimbili MAT Clinic in our sample. This includes all MAT clients who will participate in the pilot trial.

3. *Provide a brief data analysis plan and a description of variables to be derived.*

   We will use descriptive statistics to characterize MAT clients participating in the pilot trial. We compare trends in methadone and ART adherence for the 6-month period prior to the intervention and 6-month period after the intervention.

B. **Participants:**

1. *Describe the subjects who provided the original data and the population from which they were drawn.*

   Participants will be current MAT clients at the Muhimbili MAT Clinic who participate in the pilot trial.

Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.

2. *If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.*

   N/A

3. *Explain whether (and how) you plan to return results to the participants either individually or as a group*.

   We will not return the results of these analyses to participants as the data collected will come from clinical records and all participants will be clients who receive standard of care and undergo standard procedures for detection of drug and alcohol use or low adherence to methadone or ART.

XII. Oversight Plan for Student-Initiated Studies:

A. *For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements,*

and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.

B. *What is the data custody plan for student-initiated research? (Note: Students may not take identifiable information with them when they leave the institution.)*

XIII. <u>Creation of a Biospecimen Repository</u>:

Explain the source of the biospecimens, if not described above, and what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.

A. Describe where the biospecimens will be stored and who will be responsible for them.

B. Describe how long the biospecimens will be stored, and what will happen at the end of that period.

C. *Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens*.

D. Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.

E. If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.

F. *Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form*.

G. Explain whether the repository will have Certificate of Confidentiality protections.

H. Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.

I. *Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.*

XIV. Data Coordinating Center:

Complete if JHSPH serves as the Data Coordinating Center.

A. *How will the study procedures be developed?*

B. *How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?*

C. *Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.*

D. *How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?*

E. *What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?*

F. *What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.*

G. *Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?*

H. Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?

XV. Drug Products, Vitamins, Food and Dietary Supplements:

Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.

A. List the name(s) of the study product(s), and the manufacturer/source of each product.

Name of Study Product	Manufacturer/Source

B. List each study product by name and indicate its approved/not approved status.

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name)	Cleared for Use at Local Study Site

C. *If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.*

a. Who will hold the IND?

D. If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.

E. If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.

F. *Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.*

G. *What drug monitoring and/or regulatory oversight will be provided as part of the study? Please describe.*

XVI. Medical Devices:

*Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).*

A. *List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.*

Name of Study Product	Manufacturer/Source	Powered?

B. *List each study product by name and indicate its status as approved by a government authority or not approved.*

Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved

C. *If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a **diagnostic device**, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".*

D. *If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.*

E. *If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.*