Adaptation and Implementation of an Evidence-based Approach to Advance HIV Prevention and Care

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October 2024

A. PROTOCL SUMMARY

A1. Study Aims

Transgender women (due to space limitations hereafter: TW) in Vietnam are at high risk of HIV infection due to stigma, discrimination, and limited access to healthcare. Existing evidence-based interventions (EBI), with careful cultural adaptation, can address HIV risks and improve the general health of TW. *TransAction* was developed by Dr. Cathy Reback (Co-Investigator), in collaboration with TW in Los Angeles County, to enhance self-efficacy and social support, and decrease HIV risks, among TW experiencing multiple health disparities.[1] *TransAction* is an evidence- and theory-based intervention designed to be implemented in resource-limited and/or community settings, with demonstrated evidence to improve health outcomes among TW. TW that participated in *TransAction* reported decreased HIV sexual risks including engagement in exchange sex, substance use, and use of medically unmonitored hormones.[1] Based on these findings and the needs of TW in Vietnam, we chose to adapt *TransAction* to advance HIV prevention and care for TW in Vietnam.

The study team at the University of California, Los Angeles (UCLA), Friends Research Institute (FRI), and the University of Medicine and Pharmacy in Ho Chi Minh City (HCMC) of Vietnam has conducted preliminary research on the adaptation of *TransAction* for TW in Vietnam. Guided by the implementation science ADAPT-ITT framework,[2] we have conducted the first five steps (**A**ssessment, **D**ecision, **A**daptation, **P**roduction, **T**opical expert), which included understanding the specific concerns/misconceptions around PrEP/ART, identifying needs in treating co-occurring conditions, feedback on the original *TransAction*, and theater testing the modified *TransAction* outline to solicit the Community Advisory Boards' (CAB) input.[3] With this preliminary work, we will conduct a 2-phase, 3-year R34 to complete the final steps of the ADAPT-ITT process and pilot test the *TransAction* adaptation (**I**ntegration, **T**raining, **T**esting). The following **Specific Aims** are proposed**:**

Aim 1: Complete the intervention development and peer facilitator training of the *TransAction* adaptation in the context of Vietnam. Phase 1, Community-based organizations (CBOs) serving TW in HCMC and adjacent provinces will play a critical role in the adaptation of *TransAction* including protocols, materials, and health/social service navigation plans. Photovoice methods will be used to collect stories representing TW's HIV prevention/care, active service seeking, effective family communication, and social empowerment, and these photovoice stories will be used to develop posters, brochures, videos, and other multi-media materials to be used in outreach, online/offline individual/group sessions, and social events. A mini-contest will be conducted among TW to design innovative social events. TW peer facilitators will be identified and trained to deliver the *TransAction* intervention activities.

Aim 2: Conduct a pilot testing of the adapted *TransAction* to evaluate the feasibility, acceptability, and preliminary outcomes among TW in Vietnam. Phase 2, The adapted *TransAction* will be piloted with 80 HIV status-neutral TW aged 16 and above in HCMC and its adjacent provinces (~20% living with HIV). The participants will be randomized (1:1) to either the intervention or control condition. Intervention participants will participate in individual risk reduction counseling sessions and skill-building groups and open discussion support groups, with the option to participate either online or offline based on their needs and preferences. Participants in both intervention and control conditions will be invited to social events. Intervention outcomes, including placement along the HIV prevention/care continua, multilevel/multifaceted stigma and coping, self-efficacy, service utilization, HIV risks, social support, general well-being, and quality of life, will be assessed at baseline, 3-, and 6-month follow-ups. Implementation outcomes, including feasibility and acceptability associated with online/offline activities, will be evaluated by examining implementation documentation, investigator evaluation, and survey/focus groups with peer facilitators, CBO members, and TW participants.

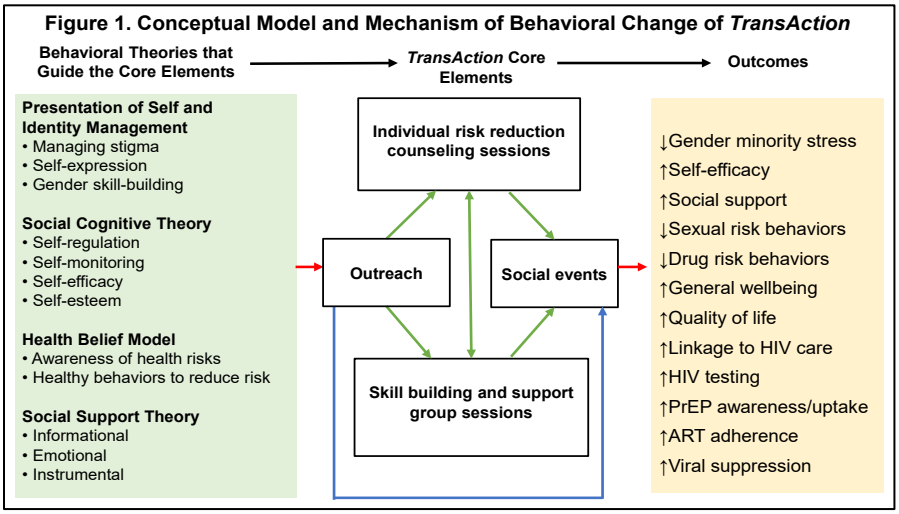
A2. *TransAction*

In 1995, in collaboration with TW in LAC, Dr. Reback developed *TransAction* to reduce HIV risk behaviors and increase self-efficacy and social support among TW with multiple syndemic health disparities.[1] *TransAction* was specifically designed to be operationalized with minimum expenditures, enhancing its suitability in resource-constraint settings. To date, *TransAction* is the longest-running service program for TW in LAC and has been operating, with uninterrupted public funding, for over 28 years (LAC, Division of HIV/STD Programs, PH-001039, PI: C. Reback).

TransAction is a peer-support, manual-driven intervention developed based on combined theoretical principles: 1) Presentation of Self and Identity Management[4,5] focuses on both pragmatic (e.g., how to manage stigma/transphobia/trans-prejudice) and stylistic (e.g., make-up and hair suggestions, tips on how to dress and speak) issues important to participants, and at the same time stresses belief in one's fundamental self-worth (i.e., self-esteem) and the ability to change one's circumstances through action (i.e., self-efficacy); 2) Social Cognitive Theory[6,7] informs *TransAction* through its focus on the role of self-monitoring, self-regulation, self-esteem, and self-efficacy in explaining healthy behavior change, suggesting that increased perception of one's self-worth (i.e., improved self-esteem) coupled with increased belief in one's personal agency (i.e., improved self-efficacy) leads to increased self-monitoring and self-regulation, which promotes the enactment of healthy behavior; 3) Health Belief Model[8] contributes to the content and structure of *TransAction* through the introduction of information on the health risks facing TW (e.g., substance use, medically unmonitored hormone use, engagement in unprotected sex) and information on how to avoid or reduce such risks; and 4) Social Support Theory[9,10] suggests that the perception ofsupport and acceptancefrom others acts as a buffer against stress, self-harm, and the enactment of harmful behaviors. The theory underscores the value of fostering supportive relationships to promote overall health and resilience.

TransAction encompasses a holistic, multi-layered HIV risk reduction intervention comprising four core components: street- and venue-based outreach, peer-led individual risk reduction counseling sessions, skill-building and support group sessions, and social events. These components were designed to reduce HIV risks, promote health care utilization, encourage healthy gender expression options, and improve self-efficacy and social support, with the ultimate goal to advance HIV prevention/care continua outcomes (Figure 1).

Figure 1. Conceptual Model and Mechanism of Behavioral Change of *TransAction*



Findings from *TransAction* showed that increased attendance in intervention sessions was associated with significant reductions in the number of male sexual partners (coef. = -0.20), anonymous male sexual partners (-0.30), exchange male sexual partners (-0.25), engagement in drug/alcohol use (-0.37), injection drug use (-0.20), unmonitored injection hormone use (-0.55), engagement in sex while high (-0.23), and sex work (-0.20; all coefficient estimates $p \leq 0.05$).[1] **Given the dearth of EBIs for TW, particularly interventions designed to be delivered in resource-limited settings, *TransAction* is well positioned to serve as a model HIV health promotion intervention for adaptation in Vietnam**.

A3. Preliminary Work of *TransAction* Adaptation in Vietnam

During 2020-2021, the study team received pilot funding to conduct formative work toward the cultural adaptation of *TransAction* in Vietnam.[3,11] The adaptation was guided by the ADAPT-ITT framework,[2] which consists of eight sequential steps to adapt HIV EBIs to suit new target populations

or settings. The study team went through the first five sequential steps (i.e., **A-D-A-P-T**) to systematically adapt *TransAction*. Each step has specific objectives and study activities summarized in Table 1.

The preliminary adaptation study reported that TW in Vietnam experience similar vulnerabilities as those in the U.S., which include stigma and discrimination, mental stressors, healthcare and social disparities, and high HIV risks. In addition, several unique challenges facing TW in Vietnam were revealed: 1) Unlike Western culture that emphasizes individuality, Vietnamese culture emphasizes family as the essential source of one's identity. **Familial rejection** was an ongoing source of pain and sense of shame for many TW, yet they still held a desire to regain family acceptance. 2) Due to **the delay in recognizing trans rights at the policy level**, TW's healthcare, employment, education, and basic civil rights are deterred by the inconsistency between gender identity and presentation and their legal identification cards. 3) **Limited access to gender-affirmative care**. Gender-neutral examination rooms or confidentiality protection for TW patients are extremely limited; stigma and denial of care are common in healthcare settings. Gender-affirmation care is scarce and international travel to receive care is unaffordable for most. 4) Due to constrained societal, cultural, and legal protection, TW in Vietnam are stationed in extremely subordinate roles within sexual relationships (both with exchange and non-exchange partners), thus TW often experience coercion to engage in **heightened HIV sexual risk behaviors**. Concurrently, the awareness and access to biomedical HIV prevention strategies (PrEP/PEP/treatment as prevention [TasP]) is limited. Many TW reported hesitancy to use PrEP due to the concern of drug-drug interactions between ART and hormone therapies.[3,11]

Table 1. ADAPT-ITT Model: Phases, Objectives, and Study Activities

	Phases	Objectives	Study Activities
COMPLETED	**Assessment**	• Explored the cultural and social contexts of HIV risks • Identified the gaps in and barriers to TW's health (HIV prevention and care, STIs, mental health, substance use) and service-seeking and utilization	• In-depth interviews with TW (n=27) • Focus groups with TW (n=6; n=26)
	Decision	• Selected the components of *TransAction* to be adapted • Decided cultural adaptation of the selected intervention adaptable components	• In-depth interviews with service providers (n=8)
	Administration	• Evaluated the TW's impression, memorability, and persuasion of the adapted *TransAction* intervention	• *TransAction* intervention demonstration • Theater testing with the TW (n=11)
	Production	• Summarized the formative study findings • Developed an outline of the adapted *TransAction* intervention	• Monthly research team meetings • CAB meetings (4 meetings)
	Topical experts	• Gather local experts' feedback on the adapted *TransAction* intervention outline	• Focus groups with TW (n=3; 15 Ps) and in-depth interviews with providers (n=4)
TO BE COMPLETED	**Integration**	• Integrate experts' feedback to develop *TransAction* intervention materials and protocol	• Phase 1: Intervention development
	Training	• Identify and train peer facilitators to implement the adapted *TransAction* activities	• Phase 1: Peer facilitator identification and training
	Testing	• Evaluate the acceptability, feasibility, and preliminary outcomes of the adapted *TransAction* Intervention	• Phase 2: Intervention pilot with TW (N=80)

The core components *TransAction* (i.e., outreach, individual sessions, group sessions, and social events) were perceived to be valuable and essential by TW, service providers, and CAB members. Through sequential discussions, it was decided that *TransAction* content and delivery mode would be adapted accordingly: 1) Develop a **family support skills-building session** with communication techniques for gender/sexual identity disclosure, reducing interpersonal stigma from family members, and engaging/re-engaging family support. 2) Create **culturally appropriate strategies to promote increased self-esteem and skills** specifically designed to cope with stigma, violence, and assault. 3) Identify **locally accessible gender-inclusive and trans-friendly healthcare and social services** including safe gender-affirmation care, HIV/STI testing and treatment, PrEP/PEP, substance use prevention and treatment, education and vocational training opportunities, and legal services. 4) Develop **online intervention strategies** to reach broader TW communities, especially those living in the provinces who do not have convenient access to centralized health resources in HCMC.[3] However, due to the limited funding and time, we did not have the opportunity to integrate the experts'

feedback into the adapted *TransAction*, nor could we create the culturally responsive intervention materials. These developments and subsequent implementation work, representing the final three steps of the ADAPT-ITT model (i.e., **I-T-T**) are to be accomplished in this proposed study (see Table 1).

A4. Collaborating CBOs and CAB

UMP HCMC has long-standing partnerships with CBOs that have exemplary relationships working with local LGBTQ+ populations. These include: 1) **Strong Ladies**, which was founded in 2013 by TW and specifically dedicated to improving the physical and mental health of LGBT populations in HCMC; 2) **Galant Clinic**, which was established in 2017 to provide HIV/STI care and PrEP to LGBTQ+ clients, 3) **G3VN** (3rd Gender Vietnam), founded in 2011, provides health and mental health care, HIV testing, group sessions, public health campaigns, and social events to TW and MSM; 4) **The Gate**, founded in 2013, focuses on HIV/AIDS prevention communication for TW and MSM; 5) **Aloboy** provides harm reduction services, group sessions, social event, HIV testing, HIV/STI care, and PrEP/PEP to young TW and MSM; 6) **G-Net Bien Hoa**, founded in 2015, provides HIV counseling and testing, PrEP/ART, STI testing and treatment for LGBTQ+ in Bien Hoa Province and surrounding areas; 7) **S-Do Can Tho** is a CBO dedicated to health, wellbeing, and equal health and social service of LGBTQ+ communities in Can Tho province since 2012. These seven CBOs collectively serve several thousands of LGBTQ+ individuals annually.

There is one TW/MSM CAB in HCMC, which is comprised of community influencers, CBO stakeholders and service providers, community partners, health educators, and participants. The CAB was formed in 2018 by Life Centre, an umbrella entity that oversees TW/MSM community sites, to improve HIV prevention and care, and provide policy advocacy. We successfully collaborated with the CAB during the pilot study. In this project, CAB members will participate in all stages of the study, including TransAction component development, recruitment/retention of participants, implementation of the intervention pilot, data collection for outcome/implementation evaluation, interpretation of study findings, and address study-related challenges as needed.

B. STUDY OVERVIEW AND TIMELINE

The 3-year study will proceed in two phases. The first three months will be reserved for start-up activities (preparing for IRB materials, contacting participating CBOs, organizing the project kick-off meeting, and organizing community-advisory boards). In the meantime, contents in the TransAction Intervention manuals that were deemed to be retained in the Vietnamese context from the previous study will be translated into English and then back-translated to Vietnamese for accuracy checking. Activities to develop TransAction intervention materials and delivery plans, including photovoice to develop visual narrative materials for individual/group sessions, social event planning, local resource directory update, and outcome measure pilot testing, will happen in the last three quarters of Year 1. The study investigators will identify peer facilitators and provide training for them to deliver Phase 2 intervention in the first quarter of Year 2.

Phase 2 (Intervention Pilot) will begin in the second quarter of Year 2. Six months will be allocated to the recruitment and randomization of 80 TW in Ho Chi Minh City and neighboring areas. The adapted TransAction activities will be delivered in the last two quarters of Year 2. Specifically, individual sessions and group sessions will be provided on a rolling basis, and social events will be delivered twice, approximately three months apart. There will be a baseline survey before intervention activities, and the 6-month follow-up assessment will be completed toward the end of the first quarter of Year 3. Upon completion of the 6-month intervention period, final focus groups will be conducted in the second quarter of Year 3. The last two quarters of Year 3 will be reserved for data analysis (both quantitative and qualitative), finding dissemination, and development of an R01. Please see the table below for the detailed timeline.

Table 1. Timeline of the Study												
	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Startup activities (e.g., IRB application and site contact)												
U.S. investigators site visits												
Ph1: Material translation and back translation												
Ph1: Photovoice for visual/narrative development												
Ph1: Social event design and planning												
Ph1: Local resorce directory development												
Ph1: Pilot testing outcome measures												
Ph1: Peer facilitator identification and training												
Ph2: Participant recruitment and randomization												
Ph2: Implementation of intervention pilot												
Ph2: Baseline to 6-month follow-up												
Ph2: Final focus groups												
Ph2: Data analysis and finding report												

C. PHASE 1: DEVELOPMENT OF VIETNAMESE ADAPTED TRANSACTION INTERVENTION AND TRAINING

TW representatives from the participating CBOs (described in C4) will play a key role in the development of the culturally adapted *TransAction* intervention manual and visual/narrative materials. The representatives will also be involved in strategizing and preparing for the pilot in Phase 2. Approximately 20 representatives from the seven CBOs will participate in Phase 1; these representatives will be excluded in Phase 2.

C1. Manualize *TransAction* for Vietnamese Culture and Content

TransAction contents determined to be retained and adapted in the preliminary study (first two columns of Table 2)[3] will be translated into Vietnamese by bilingual UMP team members. A translate-back-translate procedure will be used to ensure the translation is accurate. Based on the findings of our preliminary study, the investigator team will work with CAB members to thoroughly review the *TransAction* manual and modify the content to better suit the local context. This may involve adjusting activities, languages, and skills to be more culturally relevant and appropriate. For instance, topics related to violence against TW will be modified to include Vietnamese-specific strategies for safer sex encounters, both online and offline via text messages, social media, and dating apps as well as local resources for reporting violence. The intervention material will also be updated to include information on local HIV health and social resources and legal/policy developments related to TW's rights in Vietnam. In recognition of the family-oriented culture in Vietnam, a new family support session will be added to the intervention, where the study team will work with CAB members to identify typical challenging scenarios that TW face when interacting with their natal family (e.g., disclosing their gender identity) and identify effective and culturally appropriate communication strategies to engage family members. We will also prepare contents and potential scenarios of an individual session, which serve as an opportunity for TW to invite a family member to have open conversations to address misconceptions and foster mutual understanding, guided by a trained peer facilitator. The updated intervention will also address

Table 2. *TransAction* Contents to be Retained, Adapted, Added, and Removed

To be retained	To be adapted	To be added	To be removed
• HIV testing/education • ART adherence • Substance use • Mental health • Sexual health (including STI) • Social/emotional support • Safe sex work	• Culturally appropriate skills to build self-esteem and prevent violence • Local HIV prevention (PrEP/PEP) and treatment • Local gender affirmation care • Local employment/job training • Legal issues (including name/gender change)	• Family skill building/family disclosure • Myth of PrEP/ART and hormone drug-drug interaction	• Cultural diversity issues • Cosmetics and grooming • Hygiene/personal care • Emergency shelter/food/shower

specific concerns of Vietnamese TW, such as misconceptions about the interaction between PrEP and hormone therapy, which have been previously identified.[3]

C2. Develop Visual and Narrative Materials for Individual/Group Sessions

Photovoice will be used to involve TW representatives in the process of developing visual/graphical materials to be used in individual/group sessions.[12,13] The representatives will be encouraged to use their cellphones to capture images/videos that reflect their experiences related to the proposed outcomes including promoting self-esteem, reducing HIV risks (including PrEP/PEP/ART utilization and adherence), engaging in healthcare/social services, coping with stigma, fostering family communication/disclosure, and enhancing peer/social support. These photos/videos can reflect challenges and, most importantly, moments that represent resilience, strengths, self-esteem, peer support, and active coping strategies for problem-solving.

The study team will provide basic training to the representatives on photography techniques, storytelling, and ethical considerations of photovoice (e.g., obtaining consent from individuals they photograph, avoiding capturing images that may infringe on others' privacy, and being aware of specific regulations in the environment). The representatives will be given 30 days to take photos/videos and record accompanying narratives (either in paper format or audio format). The study team will conduct an initial screening of the submitted photos/videos and accompanying narratives. Shortlisted photos/videos and narratives will be presented in a group discussion with all the representatives, where the meaning of the photos/videos to TW's HIV prevention and general well-being will be discussed. The group will anonymously vote for photos/videos/narratives in terms of their cultural relevance, clarity of message, visual quality, and potential to inspire behavioral change. Approximately three photos/videos will be selected to be used for each individual/group session for a total of 30 photos/videos. The representatives of the winning photos/videos will receive a monetary incentive for their contribution to the project. Selected photos/videos will be further edited to be used in printed materials (for offline activities) and on social media platforms (for online activities). The MPI, Dr. Lin, has substantial experience in graphic design/editing used for photovoice materials.

C3. Design Social Events

In the preliminary study, participants provided intriguing concepts for the quarterly social events, including beauty pageants and gala parties. We will organize a mini-contest among TW CBOs to design the social events. Each CBO will work as a team to submit one concept sheet outlining their vision of the social event. Templates will be provided to ensure that the concept sheet covers all necessary components including theme, agenda, venue, strategies to attract participants, social media utilization, and budget. The study team and CBO will rate the concept sheets based on the following criteria: 1) if the theme and activities are relevant to *TransAction* (e.g., foster support, promote awareness of HIV prevention and treatment), 2) if the theme and agenda are creative and attractive to participants of various backgrounds (e.g., younger/older groups, various stages of gender affirmation), 3) if the activities and advertisement strategies can effectively and inclusively reach the broader LGBTQ+ communities, 4) other logistics (i.e., is the proposed venue accessible, safe and welcoming and within budget). The top two concept sheets will be selected for implementation during the Phase 2 intervention pilot period (PY02 Q3 and Q4), and the winning CBOs will receive a prize and start-up funding to prepare for the social events. The study team and CAB will work closely with the winning CBOs to fine-tune the social event plans and facilitate the preparation process.

C4. Identify and Train Peer Facilitators

During Phase 1 activities, two peer facilitators will be identified through 1) recommendation by local TW CBO members and stakeholders, 2) self-nomination, and 3) investigators' observation to deliver *TransAction* in Phase 2. Peer facilitator eligibilities are: 1) self-identified as a TW, 2) experienced in providing services to TW and/or MSM individuals, 3) familiar with gender-inclusive health/social service agencies in HCMC or adjacent areas, 4) preferably have had past lived

experience with sexual and/or drug use risk behaviors.

Drs. Lin, Larkins, and Reback will travel to HCMC to train the study team on the intervention. Training topics will include research ethics and participants' rights, an overview of the objectives and structure of *TransAction*, thorough reviews of goals, contents, format, and key takeaways for each activity, and basic behavioral intervention theories and skills. Each identified peer facilitator will role-play individual counseling sessions and mock group sessions, following the guidelines developed by PEPFAR for working with key populations.[14] Other specific topics will also include boundaries and responsibilities, communication skills, building trust, self-care, documentation, and emergency protocols. Ongoing technical support and assistance will be provided for the peer facilitators throughout the intervention pilot. These training strategies have been proven to be necessary and effective in our previous interventional studies in Vietnam.

C5. Develop a Local Resource Directory and Service Navigation Plan

During the preliminary study, we have identified a list of relevant local health resources, including HIV prevention (PrEP, PEP) and treatment services, STI testing and treatment, gender-inclusive mental health counseling, substance use treatment, and linkage to gender-affirmative care. Additionally, the CBOs we worked with have pinpointed essential resources to address the substantial social vulnerabilities faced by TW, including educational programs, employment opportunities, legal services, financial aid, and LGBTQ+ support groups. The study team and CAB will review the list to ensure they are current. A resource directory will be developed containing the agency name, service type, contact details, operating hours, and application/referral requirements and procedures. The resource directory will be used during each participant's first individual risk-reduction counseling session for the peer facilitator to work with the participant to develop an individualized service navigation plan. The peer facilitator will then assist the participant with scheduling appointments and arranging transportation. The individualized service navigation planning will be incorporated into the peer facilitators' training as described above.

C6. Pilot Testing Outcome Measures

We have selected outcome measures that have been validated among TW populations with similar cultural backgrounds. All of the outcome measures, if not already available in Vietnamese, will undergo translation-back-translation procedures to ensure the questions' meanings are accurately retained in the Vietnamese questionnaire. We will pilot-test the instruments with representatives to ensure that each question is culturally relevant, appropriate, and easy to understand for TW in Vietnam.

D. PHASE 2: INTERVENTION PILOT OF THE ADAPTED TRANSACTION

D1. Overview of the Pilot Design

In Phase 2, the adapted *TransAction* will be pilot-tested among 80 TW, who will be randomly allocated at 1:1 ratio to intervention and control with outcomes assessed at baseline, 3-, and 6-months.

D2. Participant Recruitment and Retention

Eligibility criteria for Phase 2 participation are: 1) 16 years of age or older (as mandated by regulations in Vietnam, participants under 18 will participate with the consent of their parent/guardian; however, we will consult the CAB about possibilities of obtaining waivers for this requirement), 2) self-identification as a TW or along the trans-feminine spectrum, regardless of stage of gender transition; 3) currently living in HCMC or adjacent provinces and have no plans to move out of the area in the next 6 months. Phase 1 representatives, as well as those who are unable to provide informed consent/assent, will be excluded (see ***Protection of Human Subjects section*** for details).

During the preliminary study, online/offline combined strategies were identified as **recruitment**

strategies including: 1) banners posted on Facebook fan page, Zalo groups, and other social media platforms frequented by TW in Vietnam (e.g., Tinder, OkCupid, Grindr, Jack'd); 2) long-chain referral whereby enrolled participants are asked to recruit a maximum of three potential new participants; 3) in-reach through direct communication by community influencers, providers, and the collaborating CBOs and social services/health centers; and 4) mounted posters and postcards distributed at the collaborating CBOs. Based on the UMP investigators' estimation, we anticipate recruiting half of the participants from HCMC and half from provinces neighboring HCMC. Approximately 20% of the participants will be living with HIV.[15]

Despite potential changes in physical residence due to unstable job conditions, TW remain closely connected with our collaborating CBOs and, thus, we expect **participant retention** to be high, achieving a minimum of 80% follow-up rate at 6-month. This close connection is maintained through social media and the trusting relationships established and safe environments provided by these CBOs. The UMP team also has successful experience in retaining TW in longitudinal studies. The following strategies will be used to retain participants: 1) at enrollment, explicitly provide information on the follow-up activities including when and how they will be contacted; 2) collect detailed tracking information at baseline and 3-month assessment. The contact information will be securely stored with limited access granted to key research investigators; 3) two reminders will be sent: the first one week before the follow-up assessment, and the second one day prior to the follow-up assessment; 4) a study-specific Zalo (the most popular instant messaging app in Vietnam)[16] group will be formed to announce study activities (such as group sessions and social events), and individual Zalo chat will also be used to remind participants of their upcoming sessions assessments, a strategy used successfully in Dr. Lin's (MPI) current study in Vietnam.[17] 5) An escalating incentive scheme will be used to encourage continued participation and reduce attrition. For those who are deemed "lost to follow-up," we will make efforts to arrange a brief exit interview regarding reasons for termination and experiences with the study.

D3. Intervention Allocation

Upon enrollment and completion of the baseline survey by a TW, the study's outreach team will collaborate with investigators for random allocation into either an intervention or control group, using SAS PROC PLAN.[18] To mitigate potential contamination risks associated with members of natural social groups being assigned to different intervention conditions, each TW and their recruited peers (up to three) will be assigned to the same intervention condition. We will explicitly inform TW participants at enrollment about the importance of not sharing content from the intervention sessions with other TW during the study period. Additionally, peer facilitators will receive training to consistently remind participants of the importance of preventing cross-contamination in each individual/group session.

D4. Intervention Delivery

Immediately following the baseline, participants in the **intervention condition** will be invited to participate in the individual and group sessions, all to be completed within three months with both online and offline options provided. The three individual risk reduction counseling sessions will be at least one week apart. Peer facilitators will fully assess participants' health and social needs and make appropriate referrals when necessary. Standard topics to be discussed in the individual sessions will include HIV risk behaviors, regular HIV/CD4/viral load testing, ART/PrEP uptake and adherence, substance use, sexual health, mental health, and family relationships and disclosure. Other topics will be discussed based on each participant's needs. For example, participants may choose to include a family member in their counseling session to garner family support, with the conversation being moderated by a trained peer facilitator. Targeted service navigation and linkages will also be provided, including educational programs, financial aid, microcredit loans, occupational training opportunities, and legal services. The group sessions are comprised of skills-building groups and open discussion support groups to cover a variety of topics, including whole person health, name/gender change, entering the workforce, continuing education, gender transition options, safe sex and safe dating, self-esteem, violence against TW, family/social interaction, financial literacy, and civic engagement.

These sessions will be delivered on a rotation, and the participants can attend the groups in any order. The open discussion support groups will be participant-driven, and community influencers will be invited speakers. Participants can attend an unlimited number of group sessions; however, based on the original *TransAction* findings, a minimum of three group sessions is recommended. Given the sometimes erratic nature of many participants' lives, *TransAction* was designed to be a person-centered, low-intensity approach without the requirement of structured attendance. Individual and group sessions can be attended in any order.[1]

All TW participants, including those in **both intervention and control conditions**, will be invited to two social events. The social event will be organized quarterly (PY02 Q3 and Q4) to coincide with major holidays, such as Dragon Boat Festival in June, and Mid-Autumn Festival in September/October. Themed social events will be organized to disseminate health information, HIV prevention messages, and foster social support in a festive, party-style atmosphere. Food/light refreshments will be served at each social event, HIV and multiple morbidities counseling and testing will be provided, and participants will engage in HIV/STI-related games. Although the social events will be streamed online, we expect most participants to attend in person.

D5. Outcome Evaluation

D5.1. Assessment

At baseline, 3-, and 6-month, participants will self-administer a computerized survey pre-programmed using REDCap (Research Electronic Data Capture).[19] The survey will take about 30-40 minutes to complete. To enhance the flexibility of data collection, participants can opt to receive the survey link to complete the survey on their own devices at their convenience. If a participant needs assistance, they can contact an interviewer via a phone/video call who will assist them. For participants who express difficulty with computer-based surveys or fail to complete the survey within a week, an interviewer will schedule an in-person survey in a private CBO office using a study-provided tablet, with an interviewer available to provide in-person assistance. In addition, we will conduct rapid HIV saliva testing to verify self-reported HIV status (participants who self-report living with HIV, and show documentation of HIV-positive serostatus (e.g., lab results, ART prescription) will not be given an HIV-antibody test). The interviewer will coordinate a meeting for rapid HIV testing at a CBO office or mail a rapid saliva testing kit to the participant. In the latter case, a video call will be arranged to verify their HIV status. For those who test positive, the study team will facilitate HIV confirmatory testing and subsequent ART services. To encourage completion of the follow-up assessments, the incentives will be 200K VND (~ USD 8.5) for baseline, 250K VND (~ USD 10.6) for 3-month, and 300K VND (~ USD 12.7) for 6-month assessment.

D5.2. Outcome Measures

The primary outcome will be the participants' **placement on HIV prevention/care continua**, measured using methods described by Kalichman et al. (2017)[20] and used in our previous studies.[21,22] For TW living with HIV, we will ask about their ART status (never received, formerly received but terminated, or currently receiving), and the time/healthcare setting they received the latest viral load testing. HIV viral suppression status (defined as HIV RNA being less than 100 copies/mL)[22,23] will be confirmed by reviewing participants' medical records with the participants' consent. For TW at risk of HIV, we will query their frequency and most recent date of HIV testing, as well as their PrEP awareness, readiness, and current status.[24] Following the status-neutral principle,[25] the primary outcome, placement along the HIV continuum, will be characterized as an ordinal outcome gauging participants' current stage in the HIV prevention and treatment continua, from 1) HIV+; not taking ART; 2) HIV+; taking ART but not virally suppressed (including no viral load test in the last 6 months); 3) HIV+; taking ART and virtually suppressed; 4) HIV-, not having regular HIV testing; 5) HIV-, having regular HIV testing but not taking PrEP; and 6) HIV-; currently on PrEP. A higher value indicates better placement in HIV prevention/care continua.

Secondary outcomes include:

1) **Multilevel and multifaceted stigma** will be measured using gender minority stress and

resilience (GMSR) scale[26], which captures structural stigma (e.g., challenges in seeking healthcare, housing, employment, public bathrooms, achieving identity documents, and realizing other civil rights); interpersonal stigma (e.g., difficulties in finding relationships, feeling unwelcome/being rejected by friends, coworkers, and families), gender-related victimization (e.g., being harassed, threatened, physically harmed, experiencing unwanted sexual contact), internalized transphobia (feeling of being abnormal, resentment, depression, and embarrassment), and coping with stigma (e.g., disclosure, pride, and future expectations). This scale has been previously used among TW and gender non-conforming individuals in Asia.[27]

2) TW's **self-efficacy** in seeking healthcare and social services (e.g., coping with attitudes that the staff may have, overcoming embarrassment)[28] and self-efficacy in negotiating condom use[29] will be measured. Participants' perceived **social support** from family members, peers, service providers, and online resources will be measured using the Multidimensional Scale of Perceived Social Support (MSPSS) developed by Zimet and colleagues and modified by Wilder to be used among TW population.[30,31] Using the collective self-esteem scale (CSES),[32] we will evaluate participants' perceived **social identity** with TW communities.

3) **Service utilization** will be accessed by inquiring if participants are currently using or facing challenges in accessing gender-affirming care, mental health support, sexual health services, and treatment for other health conditions. ART/PrEP adherence will be measured by self-reported days missing any dose of medication during the previous seven and 30 days, as well as the adherence barriers questions (ABQ-HIV).[33,34] Laboratory confirmation of adherence measures will not be conducted due to the pilot nature of the study.

4) **HIV risks** will be characterized by TW's sexual practices (including the number and type [primary, casual, commercial] of sexual partners, condom use during sex), history of STI, and substance use behaviors (measured using WHO Alcohol, Smoking and Substance Involvement Screening Test [ASSIST][35]; with substance types verified by content experts in Vietnam).

5) Participants' **general well-being and quality of life** will be measured using the short-form 12 (SF-12).[36] Possible presence of **anxiety and depression** will be assessed using the Hospital Anxiety and Depression Scale (HADS).[37] These scales have been previously used among TW populations.[38,39]

Demographic Characteristics and Social Determinants of Health (SDoH) will be collected at baseline using an assessment developed by Dr. Reback, which has been administered to TW experiencing health disparities.[70] The assessment, which collects demographic information, gender-affirmation procedures, birthplace, educational attainment, financial status, insurance coverage, housing status, neighborhood vulnerabilities, food security, family and social background, and legal status, will be adapted in the context of Vietnam. Participants' sexual assault (including partner violence) trauma experiences will also be collected.[40]

D5.3. Data Analysis for Outcome Evaluation

We will conduct descriptive analysis by calculating summary statistics (e.g., mean, median, mode, standard deviation) for each variable at baseline, 3-month, and 6-month assessments and creating visual representations of the data (e.g., bar graphs, pie charts, boxplots) to better understand the distribution of variables and identify trends or patterns. We will account for missing data using multiple imputation.[41,42] Baseline demographic characteristics and SDoH will be compared between the intervention and control conditions to evaluate baseline comparability. Our hypothesis of primary outcome evaluation is that TW in the control group versus those in the intervention group will experience more downgrades in placement on HIV prevention/care continua. A mixed-effects ordinal logistic regression model[43] will be structured to compare declines in the placement in HIV continua between the intervention and control conditions. This outcome evaluation will be performed on an intent-to-treat basis. Fixed effects in the model include time (baseline, 3-, and 6-month), condition (intervention vs. control), and a condition-by-time interaction term. The model will account for within-subject correlations of the repeated measures using a participant-level random effect. Furthermore, potential confounding variables, including demographic characteristics, gender-affirmation

procedures, and SDoH, will be controlled in the adjusted model. This status-neutral approach will enable us to identify common factors associated with movement in HIV prevention/care continua for TW with or without HIV. We will also conduct subgroup analyses to compare the number of participants living with HIV who initiate ART/achieve viral load suppression, as well as the number of participants who received HIV testing/initiated PrEP during the follow-up period, across intervention and control groups. A similar method is employed in the outcome evaluation of another gender-neutral intervention led by Dr. Reback.[44]

For secondary outcomes, we will employ mixed-effects regression models[45] to estimate the intervention effects. SAS PROC MIXED procedure will be used as it is appropriate for the identified continuous secondary outcome variables, and SAS PROC GLIMMIX will be used for categorical outcome variables. The model configuration for secondary outcome analyses will mirror that of the primary outcome analysis, including a participant-level random effect to adjust for the within-subject correlation of repeated measures. We will conduct subgroup analyses to explore outcome differences among participants based on HIV status at baseline, location (HCMC versus provinces), age groups, and stages of trans-affirmation (See the ***Statistical Design and Power*** document for details).

Sample size considerations: With a two-group design, three times repeated outcome measures (baseline, 3-, and 6-month), an evaluable sample size of 64 (considering 20% attrition at 6-month) can detect an effect size of 0.29 for at least 80% power, 5% two-sided alpha, and 0.5 correlation among repeated measures.[46] We acknowledge that this proposed sample size is not powered to generate inferential statistical tests on intervention outcomes. However, the available data should provide a basis for effect-size estimates for the future full-scale intervention trial following the proposed R34. The study will also provide the opportunity to pilot-test key outcome measures and identify appropriate and validated measures relevant to the study objectives and the target population to be selected for the full-scale trial.

D6. Implementation Evaluation

D6.1. Data Sources for Implementation Evaluation

Implementation data will be collected from multiple resources: 1) implementation records (participant recruitment data and channel, date, time, format, facilitators, location, and attendance of each intervention activity, study team/CAB meeting notes, investigators' observation notes and evaluation checklists of intervention activities), 2) peer facilitator log (service provision date, time, targeted participant, and open-ended notes to document challenges and solutions), 3) upon completion of the 6-month assessment, final focus groups with peer facilitators and CBO members (~10 members recruited from participating CBOs), and intervention group participants (~20 members with varying level of participation in *TransAction* activities, that is, approximately 30% will be those who attended all suggested group/individual sessions, 40% of who attended some, and 30% of who missed most sessions). Each focus group will be approximately 60 minutes and facilitated by the Country-PI (Dr. Dung) or the Project Coordinator (Ms. Tran) in one of the participating CBO's conference rooms. Please refer to the ***Protection of Human Subjects*** Section for recruitment and format of the final focus groups. Guided by the Consolidated Framework of Implementation Research[47,48] to solicit feedback on the *TransAction*, its planning, and barriers/facilitators to implementing *TransAction* in individual, inner setting, and outer setting domains), and 4) follow-up surveys to collect numeric ratings of acceptability and appropriateness of intervention activities.

D6.2. Implementation Measures

Feasibility of the intervention will be determined based on: 1) the rate of recruitment and reasons for refusals, via various online/offline recruitment strategies; 2) the time/frequency of intervention component activities and peer facilitators' provision of service (e.g., navigation and referral to local healthcare/social services) logged by peer facilitators, and 3) each participant's attendance in online/offline activities. Reasons for non-attendance, such as logistic difficulties, lack of interest, and concerns of stigma, will be documented.

The study investigators including Dr. Reback, the developer of the original *TransAction*, will observe the intervention activities to evaluate **fidelity**. The evaluation can be conducted either

synchronously, with investigators observing and rating sessions in real-time with translation, or asynchronously, via recorded sessions with translated subtitles—both with participant consent. Using a standard fidelity checklist,[49] the investigators will assess the time spent delivering designed content, adherence to the intervention manual, designated techniques, clarity, and participants' responsiveness. Open-ended field notes regarding actions to better preserve intervention fidelity will be taken to provide timely feedback for the intervention team members.

After each intervention component activity, participants will complete a short survey to rate their **acceptability** of the activity, using implementation outcome measures developed by Weiner and colleagues.[50] The instrument queries if the intervention activity is acceptable (e.g., "the intervention meets my need", "the intervention is appealing to me") and appropriate (e.g., "the intervention seems proper"). Acceptability will also be evaluated in the final focus groups with TW peer facilitators and participants. The topics will include the relative advantage of *TransAction* (if the intervention is better than non-TW-specific alternatives), facilitators/barriers to attending online/offline activities (e.g., TW's barriers to participating in online/offline activities, peer leaders' self-efficacy and training needs), and if the acceptability is influenced by inner/outer setting (if the *TransAction* activities align with local culture and policy).[47,51]

Final focus groups with the peer facilitators and CBO members who have been involved in the pilot phase will gauge the **sustainability** of *TransAction*. Using the Program Sustainability Assessment Tool,[52] peer facilitators and CBO members will rate funding stability, political and environmental support, partnership, organization capacity, communication, plans to deliver *TransAction* in the future, and strategic planning to integrate *TransAction* component activities into CBO's current service provision. TW peer facilitators and CBO members will also engage in open-ended discussions during the final focus groups on these topics.

D6.3. Data Analysis

Quantitative implementation data (e.g., intervention component activity attendance, investigators' evaluations, and participants' acceptability ratings) will be analyzed descriptively. Each implementation indicator will be summarized by activity type, format, content, intervention peer facilitator, and delivery time to decide if any of the intervention topics/formats are associated with lower levels of fidelity or acceptability. We will explore if higher acceptance of certain topics or formats is associated with certain participant characteristics such as age, education, geographic location (HCMC vs. provinces), gender-affirmation care stage, and HIV status. We will also perform mediation analysis to gain insights into the associations between participants' characteristics with intervention attendance, and relationships between intervention attendance and changes in outcome measures. This information can help refine the intervention and identify strategies to improve participant engagement and attendance, ultimately leading to more effective outcomes.

Qualitative implementation data (e.g., open-ended field notes and final focus group data) will be analyzed using thematic analysis.[53] The data segments will be organized into coding categories using ATLAS.ti. A set of codes will be developed based on the focus group guides before examining the data. The codes will be applied to the transcripts and modified based on themes that emerged from the transcripts throughout the coding procedure.[54] Qualitative data analyses will be performed by Drs. Lin, Larkins, and Ms. Nguyen. To ensure reliability, we will read the transcripts, discuss analysis and coding, and establish inter-rater reliability by using rates of agreement. Themes relevant to feasibility, acceptability, and sustainability of *TransAction* will be extracted from the data. These implementation data analyses will be conducted simultaneously with the pilot implementation so that the findings will be used to inform the modification of the intervention components and delivery plan promptly.

E. PROTECTION OF HUMAN SUBJECT

E1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

Transgender women (TW) in Vietnam live under harsh, cultural and societal pressure resulting in stigma/discrimination, social isolation, and physical violence, which contribute to substance use, HIV sexual risk behaviors, and poor healthcare utilization including suboptimal advancement along the HIV prevention and care continua. Despite these health disparities and adversities experienced by TW in Vietnam, there are no TW-specific interventions designed to address their needs. *TransAction* is an evidence- and theory-based intervention, developed by Dr. Cathy Reback (Co-Investigator) and TW in Los Angeles County, comprised of four core elements: outreach, individual risk-reduction counseling sessions, skill-building and support groups, and social events. *TransAction* is designed to be delivered in resource-limited settings so it is well-positioned to serve as an evidence-based HIV health promotion intervention model for adaptation in Vietnam. Building upon our strong existing US-Vietnam collaborative relationships as well as the preliminary steps of adaptation following the ADAPT-ITT framework, we will complete the final steps of adapting and testing *TransAction* for TW in Vietnam. This R34 proposal b. In Phase 1, the study team will take a community participatory approach to work with TW community-based organizations (CBOs) to develop *TransAction* protocols, materials, and health/social service navigation plans in the context of Vietnam. TW peer facilitators will be identified and trained to deliver the intervention activities. In Phase 2, the adapted *TransAction* will be pilot-tested with 80 HIV status-neutral TW from HCMC and adjacent provinces with a two-arm, randomized design. TW in the intervention condition will participate in individual risk-reduction counseling sessions and skill-building and support groups using an online/offline hybrid modality. Both intervention and control groups will be invited to social events. Intervention outcomes, including placement on HIV prevention/care continua, HIV risks, gender minority stress and resilience, self-efficacy, and general health will be assessed at baseline, 3-, and 6-month. Implementation outcomes, including feasibility, fidelity, and acceptability, will be evaluated based on data collected from multiple sources.

The research activities will be conducted jointly by the University of California, Los Angeles (UCLA), Friends Research Institute (FRI), and the University of Medicine and Pharmacy in Ho Chi Minh City (HCMC). At UCLA, Dr. Chunqing Lin, the Multiple Principal Investigator (MPI-contact) of the study, will be responsible for monitoring all project field activities in the U.S. and Vietnam and ensuring adherence to the project goals and timelines. Dr. Sherry Larkins (MPI) will co-lead the project implementation, focusing on community-based organizations liaisons and staff training and supervision. Both Drs. Lin and Larkins will work closely with Dr. Cathy Reback (Co-Investigator at FRI), the developer of *TransAction*, on the development of Vietnamese *TransAction* materials and peer facilitator identification and training. At UMP, Dr. Do Van Dung will be the Country PI/Co-Investigator directing the project implementation in Vietnam, and Ms. Nguyen Nhu Trang Nguyen (Founder and Director of Life Centre) will serve as Co-Investigator ensuring cultural appropriateness and relevance of *TransAction* adaptation and implementation. Under the supervision of Dr. Dung and Ms. Nguyen, the study teams in HCMC will be responsible for the implementation of the study in Vietnam, including liaison with CBOs on the preparation of study materials in Vietnamese, identifying local resources, participant recruitment, data collection, and intervention delivery. The study protocol and all materials will be reviewed and approved by the Institutional Review Boards (IRB) at UCLA and UMP before any contact with human subjects. We are committed to conducting the proposed study according to the highest standard of ethical conduct.

b. Study Procedures, Materials, and Potential Risks

The study will proceed in two phases. The **study procedures and materials** are described by the study phases below:

Phase 1: The study activities in Phase 1 will include 1) manualizing *TransAction* for Vietnamese culture and content, 2) developing visual and narrative materials for individual/group sessions, 3) designing and planning for social events, 4) identifying and training peer facilitators; 5) developing a local resource directory and service navigation plan; 6) pilot testing outcome measures. These

activities will be conducted in close collaboration with TW representatives from CBOs in HCMC and neighboring provinces. These representatives will be deemed as members of the study team and they will be excluded from the Phase 2 pilot. Thus, no research participants will be involved in Phase 1.

Phase 2: In Phase 2, a two-arm intervention pilot will be conducted with 80 TW in HCMC and neighboring provinces.
The TW will be recruited using the following strategies: 1) banners posted on Facebook fan page, Zalo groups, and other social media platforms frequented by TW in Vietnam (e.g., Tinder, OkCupid, Grindr, Jack'd); 2) long-chain referral whereby enrolled participants will be asked to recruit a maximum of three potential new participants; 3) in-reach through direct communication by community influencers, providers, and the collaborating CBOs and social services/health centers; and 4) mounted posters and postcards distributed at the collaborating CBOs. If there are TW who are interested in learning more about the study, they can talk to or call the research staff using the contact information printed on the flyers. Recruitment staff will meet with potential participants to screen eligibility criteria, which include: 1) 16 years of age or older, 2) self-identifying as a TW or along the trans-feminine spectrum, regardless of the stage of gender transition; 3) currently living in HCMC or adjacent provinces and having no plans to move out of the areas in the next 6 months, and 4) have the cognitive capacity to participate in study activities as judged by the study recruiter. TW who participated in Phase 1 as a representative will be excluded. During the recruitment process, recruiting staff will disclose the study procedure, review the confidentiality and voluntary nature of the study, and discuss the risks and benefits of participation. Written informed consent will be obtained from the TW participants.

Pilot intervention activities: after baseline, the 80 TW will be invited to the following intervention activities: 1) three individual risk reduction counseling sessions, at least one week apart. Topics to be discussed in the individual sessions will include accessing individual health needs and subsequent referrals to appropriate services, HIV risk behaviors, ART/PrEP uptake and adherence, family relationships and disclosure, substance use, and sexual health. 2) skills-building groups and open discussion support groups, which cover a variety of topics, including name/gender change, entering the workforce/continuing education, gender transition options, HIV/STI, safe sex and safe dating, self-esteem, violence against TW, family interaction, as well as participant-driven open discussions. A minimum of three group sessions is recommended. 3) quarterly social events, which are inclusive, festive, party-style events to foster social support and disseminate health information. The social events will coincide with major Vietnamese holidays with food/light refreshments provided. All intervention activities are to be completed within three months.

The primary data sources for Phase 2 will include 1) surveys at baseline, 3-, and 6-month with TW and 2) final focus groups with TW participants.

1) Surveys with TW: At baseline, 3-, and 6-month, TW participants will self-administer a questionnaire survey using REDCap, a secure web application for online surveys. If they face technical issues or need clarification on specific questions, they can contact an interviewer who will walk them through the process via a phone/video call. For individuals who express difficulty with computer-based surveys at recruitment, or those who failed to complete the self-administered survey within a week, our interviewers will schedule in-person surveys in a private office in one of the participating CBOs where the participant can complete the survey on a study-provided tablet, with an interviewer available to provide in-person assistance. For those who self-report as HIV negative in the surveys, the interviewer will coordinate a meeting for rapid HIV testing at the project office or mail a rapid saliva testing kit to the participant. In the latter case, a video call will be arranged to verify their HIV status. To encourage completion of the follow-up assessments, the incentives will be 200,000 VND (~$8.5 USD) for baseline, 250,000 VND (~$10.6 USD) for 3-month, and 300,000 VND (~$12.7 USD) for 6-month assessment.

2) Final focus groups with peer facilitators, CBO members, and TW participants: Upon completion of the 6-month survey, we will approach all peer facilitators and CBO members who are involved in the study (approximately 10 members) to a focus group to seek their feedback on the intervention implementation. Separate focus groups will be arranged for TW in the intervention condition. Peer facilitators/CBO members and TW participants will join the focus groups separately. We aim to include 20 TW participants, purposefully selected based on their engagement in the intervention activities: approximately 30% of those who attended all recommended intervention activities, 40% of those who attended some, and 30% of those who missed most activities. Should more than 20 express interest in participating in the focus groups, we will organize additional focus groups to accommodate them. Focus group participation will be voluntary and anonymous. Each focus group will be approximately 60 minutes and facilitated by the Country-PI (Dr. Dung) or the Project Coordinator (Ms. Tran) in one of the participating CBO's conference rooms behind closed doors. During the final focus groups, we will solicit participants' feedback for each intervention component and suggestions for improvement (detailed focus group questions provided in C8.6.2 of the Research Strategy). The focus group discussions will be audiotaped. The incentives for the focus group will be 300,000 VND (approximately 12.7 USD).

All data collected for the study will be confidential, and no personal identifying information will be labeled on the survey data. All data will only be identified by an assigned participant identification number (PID) to protect privacy. All computerized data (audiotapes and transcripts of the focus groups, electronic consent forms, and computerized survey data) will be stored in a database that is double-password protected. There will be no hard copy collected in the study. Only key personnel of the research team will have access to the data and PID information, and the data are collected for research purposes only.

Potential risks that may occur during the study include: 1) participants' privacy and confidentiality might be compromised, including loss of privacy associated with participation in the assessments or intervention sessions; 2) participants might feel coerced to enter or remain in the study; and 3) Focus group and survey questions might cause awkwardness or discomfort for study participants. Steps to minimize these risks are described in session 2-b.

c. Vulnerable Subjects, if relevant to your study

This study will involve TW because this study is to investigate strategies to promote their self-efficacy, build social support, reduce HIV risks, and engage them in HIV prevention and care continua.

Recruitment of pregnant women, fetuses, neonates, or children: TW aged 16-18 are eligible to participate in Phase 2 of the study with the consent of their parents or legal guardians. Parent/guardian consent is mandated by regulations in Vietnam for minors to participate in research studies; however, we will consult the CAB about the possibility of obtaining waivers for this requirement to enhance flexibility for TW aged 16-18 to participate in the study.

E2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

We will follow the procedures outlined in the 1991 Code of Federal Regulations (45 CFR 46.102) that defines research as a systematic investigation designed to develop or continue to generalize knowledge. In addition, we will follow 45 CFR 46, Subpart D, to provide additional Protections for TW aged 16-18 involved as participants in the pilot. The principles that will guide our research are respect for persons, beneficence, and justice. The informed consent/assent procedures will conform to these policies and the UCLA/UMP IRB consent standards. The consent/assent process and materials will be reviewed and approved by the UCLA IRB and UMP IRB. All of our staff will comply with the NIH-required training in human subject protection and good clinical practice

(GCP) procedures and will be extensively trained in proper procedures for obtaining informed consent.

The informed consent procedure will take place in private settings. When meeting with potential participants, trained research staff will follow a standardized script to ensure that all ethical issues and study procedures are thoroughly reviewed. The informed consent sheet will have detailed descriptions of study purposes, procedures, potential risks and discomforts, potential benefits, payments for participation, confidentiality, participation and withdrawal, identification of investigators, and rights of study participants. The staff members will review the contents with the potential participants and answer their questions. The recruitment staff will emphasize the voluntary nature of the study, that their decision to participate or not will not affect their treatment or other services, and that they have the right to withdraw from the study at any time without penalty. In particular, TW will be assured that their decision to participate will not affect their healthcare or social services in any way. All prospective participants will be screened to assess if they can understand the study's purpose and give voluntary informed consent. Informed consent will be obtained before any data collection. Participants will provide electronic written informed consent on REDCap.

For TW under 18 at the time of the recruitment, per mandated by regulations in Vietnam, TW will be asked to identify a legal guardian (we will consult the CAB about the possibility of obtaining waivers for this requirement to enhance flexibility for TW aged 16-18 to participate in the study while compliant with ethical standards). Our research staff will arrange an information session with both the potential participant and the identified legal guardian. This session provides an in-depth overview of the study, including its purpose, procedures, potential benefits/risks, voluntary participation, and confidentiality, in language that is understandable to adolescents. The legal guardian will receive an informed consent form with thorough study-related information in writing. Alongside the guardian consent forms, assent forms specifically designed for adolescents will be provided for the potential TW participants. The accent forms are also written in an age-appropriate manner, ensuring that adolescent participants understand the procedures and their rights within the study. Ample opportunities will be given for both the guardians and the potential adolescent TW participants to ask questions or seek clarification regarding any aspect of the study. Once the guardians and participants have reviewed the information and had their questions addressed, they will provide signatures on the consent and assent forms, indicating their dual agreement to participate.

b. Protections Against Risk

The following steps will be taken to minimize potential risks to study participants:

Protection of participants' identities and confidentiality. The following confidentiality protection steps will be taken: 1) all project staff, including recruiters, interviewers, and facilitators, will participate in initial research ethics training. We will make it explicitly clear that the research team staff should not disclose TW's responses in the study to anyone including their service providers. The staff members will be continuously monitored and supervised to ensure that they understand and comply with the ethics involved in this research; 2) all focus groups, surveys, and group intervention sessions will either take place in private settings behind closed doors or via Zoom. UCLA Health provides HIPAA-compliant Zoom, which offers a higher level of security to collect data; 3) the final focus group participants will be using a nickname when participating in study activities so that the audiotapes of focus group discussions will not include any personal identifying information of the participants; 4) focus group participants and intervention participants will be instructed to keep the content of the discussion confidential; 5) information that could disclose participants' identity will not be written down on any assessment forms, and any personal identifiers linked to data will be removed and replaced by PID on all records; 6) the study will not collect hard copy data. The baseline and follow-up surveys in Phase 2 will be conducted via REDCap, which is a secure, web-based application recommended by UCLA Clinical and Translational Science Institute. All computerized data files (including electronic consent forms, audiotapes and transcriptions of focus group discussions, and computerized survey data) will be double-password protected and saved in secure project computers; 7) the data will only be used for research purposes, and access will be limited only to the key personnel in the research

team; and 8) all forms of data will be destroyed when the study is finished. We have successfully implemented these steps to protect study participants' identities and confidentiality in our previous studies.

As part of the intervention activities, Phase 2 TW will have the option to participate in online individual and group sessions. In addition to the aforementioned measures, special efforts will be made to **protect the confidentiality of the online intervention activities**: 1) While using Zoom for any type of intervention, we will strictly follow the UCLA IT team's guidance to maintain optimal security. The security recommendations include generating a random meeting ID, enabling waiting room, setting password, and updating the latest version of Zoom application; 2) the online discussion will take place in a "secret" group, i.e., the members can only join the group upon invitation and approval by a group administrator (a researcher of the study), and the contents of the group discussion is only viewable by current group members; 3) the study participants will be using nicknames when participating in online discussions or use an "avatar" to disguise their appearance; 4) the study participants will be instructed not to reveal any personal identifying information during the online discussion, and they will provide written agreement to safeguard the confidentiality of online discussions; 5) TW who choose to participate in online activities will undergo cyber-security training to enhance their digital literacy. The strategies to prevent potential breaches of data, such as using a password to protect their phones, avoiding using public open-WiFi networks, adjusting their privacy status in various digital platforms, deleting sensitive information from their phones, etc., will be taught in the training. The UCLA Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) is a multidisciplinary research team with expertise in online research.

Steps to be taken to ensure that potential participants do not feel coerced to enter or remain in the study. Research staff members recruiting all participants will follow an IRB-approved standardized script to ensure that all ethical issues are disclosed and reviewed, and that the study procedures are followed. For TW participants (as well as legal guardians of TW participants under 18), it will be made explicit in the consent document both verbally and in writing—that their study participation is voluntary, that it is unrelated to their employment, entitlement to health and/or social services, and that they can withdraw from the study at any time without jeopardizing their employment or entitlement to agency services. TW participants have the right to decline to participate in certain intervention components or assessments while remaining in the study. Recruiters and interviewers will be trained to probe for comprehension in reviewing the consent forms.

Assessment questions might create awkwardness or discomfort. Interviewers will be trained at the inception of the study to handle awkwardness, embarrassment, or psychological discomfort of participants, and will be under ongoing monitoring and supervision. In particular, interviewers and peer facilitators will be trained to use age-appropriate language when facing TW participants under 18. Both the assessment and recruitment teams will be trained to identify signs of any possible acute distress and to respond to the occasions when study participants exhibit stronger and more serious signs of emotional distress, and individuals who express suicidal intent, have psychiatric emergencies, or exhibit other indicators of acute distress. All participants will be provided with a 24-hour phone number (+84 28 3855 8411) through which the In-country Principal Investigator, Dr. Do Van Dung, may be contacted to answer questions or to provide directions in case of emergency. UMP has an aggressive set of safety procedures to ensure that participants receive a high and consistent level of monitoring that also meets reporting requirements to their IRB. Safety issues are reviewed weekly in staff meetings, during which staff will discuss potential emergent issues for all participants. The second level of safety procedures involves verbal reports of suicidal or homicidal intent with suspicious reports evaluated by the Project Coordinator or In-country Principal Investigator. All staff will receive training identifying suicide/homicide risk and/or dangerous intoxication, and how to appropriately respond to these signs. Experienced clinical supervisors will be available for immediate consultation in the event of unexpected acute psychological problems, and all field staff will be made

familiar with local referral resources and procedures for psycho-social services or other emergency needs. If any reported or suspected criminal violence is found during the study, research staff will report it to the proper local authorities following the study protocol.

E3. Potential Benefits of the Proposed Research to Research Participants and Others

Participants participating in the study may garner valuable information regarding their HIV sexual behaviors, HIV Prevention and Care Continua, skills to increase self-efficacy, social support, and healthcare utilization. The potential benefits to society include decreased HIV transmission with a resultant decrease in HIV morbidity and mortality, as well as a reduction in the overall social costs and public health burden for the potential for avoiding concomitant HIV risk behaviors and possible HIV infection and other STIs.

E4. Importance of the Knowledge to be Gained

Societal benefits from the proposed study are potentially enormous. Transgender women are facing tremendous adversities, including stigma/discrimination, isolation, violence, and sexual abuse, that negatively impact their health and their efforts to seek HIV treatment and care. This study intends to adapt an evidence-based intervention to reduce HIV risks and enhance engagement in HIV prevention and care continua for TW in Vietnam. The study will lead to implementable and scalable approaches to combat HIV and ultimately enhance TW's health outcomes.

F. RECRUITMENT AND RETENTION PLAN

F1. Recruitment plan

As recommended by TW representatives in our preliminary study, online/offline combined strategies will be utilized to recruit the participants: 1) recruitment banners posted on Facebook fan page, Zalo groups, and other social media platforms frequented by TW in Vietnam (e.g., Tinder, OkCupid, Grindr, Jack'd); 2) Study flyers will be posted the collaborating CBOs, 3) Gatekeepers and providers in the collaborating CBO will distribute study postcards to their TW clients and verbally introduce the study; 4) Enrolled participants will be asked to recruit a maximum of three potential new participants. Based on our collaborating agency's previous experience, study recruitment and enrollment for the intervention pilot will take place over approximately a 6-month time span.

When a potential TW contacts research staff, trained research staff will follow a standardized script to screen for eligibility and begin the informed consent process. The research staff will ensure that all ethical issues and study procedures will be thoroughly reviewed when recruiting potential participants. All study procedures, potential risks/benefits, and confidentiality of the study will be fully disclosed. The recruitment staff will emphasize the voluntary nature of the study, that their decision to participate or not will not affect their treatment or other services, and that they have the right to withdraw from the study at anytime without penalty. All prospective participants will be screened to assess if they can understand the study's purpose and give voluntary informed consent. Informed consent will be obtained prior to any data collection.

TW aged 16 will be eligible for the intervention pilot. If a TW under 18 expresses interest, the research staff will inform them that, according to local requirements, consent from a legal guardian is necessary for participation (we will consult our community advisory board regarding the possibility of waiving this requirement). The participant will be encouraged to choose a guardian with whom they have a close relationship. Following this, the study staff will organize an information session for both the potential participant and their chosen legal guardian. This session will cover detailed information about the study, including its objectives, procedures, potential risks and benefits, and confidentiality protocols. The informed consent/assent form will be written in clear language, tailored to be easily understandable by adolescents. The guardian will have the opportunity to ask any questions about the study before giving informed consent. In addition to the guardian's consent, adolescent

participants will provide their assent, indicating their personal agreement to take part in the study. This dual-consent process ensures that both the guardian and the adolescent are fully informed and agree to the terms of participation.

Recruitment of participants for final focus groups: After the 6-month assessment, we will invite TW participants, as well as peer facilitators and CBO stakeholders who have been involved in the intervention pilot, to participate in final focus groups to provide their feedback for the intervention. All peer facilitators and CBO members who are involved in the study (approximately 10 members) will be invited with clear information that participation in this focus group is not part of their job duty and they have the right to decline participation with no impact on their current employment. Separate focus groups will be arranged for TW in the intervention condition. We aim to include 20 TW participants in the intervention condition, purposefully selected based on their engagement in the intervention activities: approximately 30% of those who attended all recommended intervention activities, 40% of those who attended some, and 30% of those who missed most activities. Within each engagement stratum, the selection of TW participants for the final focus group will be conveniently based. Should more than 20 express interest in participating in the focus groups, we will organize additional focus groups to accommodate them. TW participants will also be informed of the voluntary nature of participating in this final focus group. Oral informed consent will be obtained for this study activity.

F2. Retention plan

The TW participating in Phase 2 will be contacted during an approximately 6-month period. The following strategies will be used to retain participants:

F2.1. Priming Participants to Prioritize Follow-up.
The trained staff that will be conducting the enrollment process will emphasize several times that it is critical that we be able to reach participants for follow-up. Participants will be told that it is important that we reach them to observe their change overtime and collect their feedback on the adapted TransAction, whether or not they are doing well or poorly; that their participation in the study could increase scientific knowledge about the adaptation of TransAction, and help others TW in similar situations even if they do not benefit directly from participation; that their research information will be confidential; and that we are grateful for their contribution to the study. We will also request that participants (including guardians of minor participants) inform staff if any of their contact information changes. Participants will be given the study team's business card, which is filled in with their approximate follow-up appointment date and the incentive amount. We will also ask participants to repeat verbally in their own words when the follow-up is due and confirm that they will respond to our contact attempts. The follow-up plan will be reiterated after the baseline visit.

F2.2. Detailed Locator Information.
Consistent with our usual practice, we will collect detailed locator information at baseline including cell phone numbers; contact information for family members (legal guardians of minor participants), friends, and associates; street names and aliases; location of usual hang-outs; and social media contacts. All tracking contacts will be made with strict adherence to confidentiality procedures, with staff identifying themselves only as calling from a "health study" to any individuals other than the participant. The tracking database will be stored on a separate computer with different access codes and passwords from the assessment data files. The participants will be asked to review and update their locator information at 3-month follow-up.

F2.3. Tracking Procedures:
An Excel spreadsheet that includes information on each participant's progress through the study will be established. Upon enrollment, each participant is entered into the spreadsheet and their follow-up due dates auto-populate using a prewritten formula. The spreadsheet will flag participants based on

their follow-up due date, triggering alerts and countdown clocks to permit a rapid appraisal of which participants are coming due for which follow-up assessment, and how much time is remaining in their follow-up window. In addition to the time-based flags, additional alerts map to specific tracking procedures that should be employed. These procedures include direct contact attempts to the numbers supplied via phone and text; direct messaging via social media platforms; letters sent to the participant if an address is provided, community-based tracking via street- and venue-based outreach to locations frequented by the participant, and similar procedures to track the participant through family members (legal guardians of minor participants), friends, and associates. Participants will be labeled by their study participant ID only to maintain confidentiality.

Proactive Approach. One week and the day before each follow-up assessment, a reminder will be sent to the participant using the preferred method. A study-specific Zalo (the most-used instant messaging app in Vietnam) group will be formed among TW participants to announce study activities (such as group sessions and social events), and individual Zalo chat will also be used to remind participants of their upcoming individual sessions and study assessments. This approach has been used successfully in Dr. Lin (MPI)'s current study in Vietnam. In addition, an escalating incentive scheme (i.e., incrementally larger incentives are offered as participants complete successive follow-up visits) will be used to encourage continued participation and reduce attrition. The study recruiter will keep detailed logs of their follow-up contact attempts for each participant, using the aforementioned tracking Excel spreadsheet to mark off and detail the type, timing, and outcome of each contact attempt. This approach helps the Project Coordinator and Investigators to efficiently identify which strategies have been attempted and which may have been underutilized. Follow-up status and challenges will be routinely reviewed at weekly staff meetings. If follow-up rates fall we will use a proactive management approach to identify the root source of the challenges and troubleshoot potential solutions. This may include discussions with the collaborating sites and the Community Advisory Board.

We believe that the systematic application of these strategies will promote retention in the study, and yield a high follow-up rate. However, there may be times when retention will become impossible. For those who are deemed "lost to follow-up," we will make efforts to arrange a brief exit interview regarding reasons for termination and experiences associated with the study.

G. DATA AND SAFETY MONITORING PLAN

Efforts will be made to monitor and maintain high quality data collection and management consistently. Drs. Chunqing Lin and Sherry Larkins, the Multiple Principal investigators, are responsible for ensuring the integrity of the research procedures and the safety of the participants.

G1. Responsibility for Safety Oversight

All project protocols involving research participants are subject to review and approval by the UCLA IRB as well as University of Medicine and Pharmacy (UMP) IRB. All project staff members, including focus group facilitators, interviewers, recruiters, and peer facilitators who are responsible for delivering the adapted TransAction Intervention are required to have IRB training certificates to ensure that they understand all the ethical issues involved in this research as well as adherence to the guidelines and regulations. The recruiters will follow a standardized script approved by the UCLA IRB and UMP IRB to ensure that all ethical issues are reviewed and that the study procedures are clearly reviewed with the participants. The MPIs and the In-country Principal Investigator will be responsible for conducting periodic literature searches on HIV risks and health disparities among transgender women to identify any emerging findings that might influence study risks and benefits.

G2. Report of Safety-Relevant Information to NIMH

The Principal Investigator will be responsible for informing NIMH of any actions taken by the UCLA

IRB or the UMP IRB as a result of their regular annual or bi-annual review and any special reviews of this study. In addition, the MPIs will inform NIMH of any major changes in the protocol or its status including: protocol amendments; suspension or termination of subject accrual or of the protocol itself; changes in the informed consent or IRB approval status; and other problems or issues that could have a significant impact on participants.

G3. Serious Adverse Event Reporting
Adverse event reporting will follow UCLA and UMP policies. Serious adverse events (SAEs) include any of the following outcomes for the participant: 1) death; 2) acute life-threatening incidents; 3) hospitalization or the prolongation of a hospitalization; or 4) persistent or significant disability. SAEs may be communicated to the In-country Principal Investigator by participants or staff. SAEs will be reported regardless of whether they are considered study related.

G4. Reporting of Unanticipated Risks or New Findings
The MPIs will report any information related to unanticipated risks or new information that may change the risk-benefit ratio to the UCLA and UMP IRBs, the UCLA DSMB and the NIMH Program Officer. This information may come from the current study or findings from other studies. Any changes in the protocol or consent as a result of this information will be promptly reported to the NIMH Program Officer. The MPIs will also report any irregularities in the conduct of the study such as participant enrollment; obtaining informed consent; and, data collection and processing.

G5. Quality Control of Data
The following strategies will be used to ensure the integrity of the data: 1) all computers containing project data will have double-encryption, and secured FTP sites will be used for data transfer to safeguard confidentiality. 2) Only data analysis personnel connected with the study will have access to data files. 3) We will have clear written instructions and guidance for data collection, transcription, data entry, storage, and management. 4) The Project Coordinator and other team members will be thoroughly trained regarding quality control of assessments and completion of forms and their work will be reviewed on an ongoing basis. 5) The Project Coordinator will review data collection on a weekly basis to ensure accuracy, completion, and progress with respect to data collection milestones. The Project Coordinator will bring to the attention of the In-country Principal Investigator any assessments that are problematic. 6) Prior to conducting the quantitative analyses the raw data will undergo extensive examination by the Data Manager.

G6. Data and Safety Monitoring Board (DSMB)
The UCLA Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) based in the Department of Family Medicine has a DSMB to provide comprehensive and regular input into whether there are appreciable changes to participants' risks to participation while the study is ongoing. Assignments for review are made to avoid any scientific or programmatic conflicts of interest while also ensuring the committee has relevant expertise for the review. One member of the panel will be the Medical Safety Officer for the study and will review and evaluate all reported adverse events that are identified by the MPI and In-country Principal Investigator and report to the rest of the panel. In addition, the Medical Safety Officer will assist the MPI and the In-country Principal Investigator to evaluate whether an active subject should be discontinued from further participation in the study for safety reasons.

G7. Stopping Rules
The study may be stopped for any one or more of the following reasons as determined by the DSMB: 1) safety/adverse events; 2) unfavorable benefit-risk ratio; and 3) inability to answer questions. The DSMB's decision to stop the study with regard to safety/adverse event considerations will be based on the number and severity of adverse and serious adverse events that are considered related to study participation. The study may also be terminated if the DSMB concludes that there has been an

emergence of unexpected serious adverse events. If there are serious flaws in the data or the implementation of the study, the DSMB may recommend termination because the questions concerning efficacy are unable to be adequately addressed. These problems include serious problems in the recruitment/enrollment of participants; threats to internal or external validity, and/or statistical conclusion validity. As with the other types of reasons for study termination, noted above, the DSMB will make this decision in consideration with other relevant information regarding the study.

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Appendix A: Confidentiality Statement for Staff

TransAction Project
Statement of Confidentiality

University of California, Los Angeles (UCLA) Department of Psychiatry and Biobehavioral Sciences assures each respondent that the confidentiality of responses to the information requests in the Vietnam TransAction Project will be maintained by UCLA, Friends Research Institute (FRI), and University of Medicine and Pharmacy (UMP) in Ho Chi Minh City. No information obtained in the course of this activity will be disclosed in a manner in which the particular individual supplying the information or described in it is identifiable, unless such individual has consented to such disclosure, to anyone other than authorized project staff of UCLA, FRI, and UMP.

Agreement

I, _____, agree to provide field data collection services for the benefit of UCLA, FRI, and UMP in connection with the Vietnam TransAction Project. Further, I

a) am aware that the research being conducted by UMP and is being performed under contractual arrangement with the UCLA.

b) hereby accept all duties and responsibilities of performing specified data collection tasks and will do so personally in accordance with the training and guidelines provided to me. At no time will I engage the services of another person for the purpose of performing any data collection tasks for me without the prior written approval of UCLA;

c) agree to treat as confidential all information secured during interviews or obtained in any project-related way during the period of providing services to UCLA;

d) agree to treat as confidential and proprietary to UCLA any and all research instruments, materials, and documentation provided or accessed during the course of my service on this project;

e) am aware that the completed data collection research instruments form the basis from which all the analysis will be drawn, and therefore, agree that all work for which I submit invoices/receipts will be of high quality and performed in compliance with all project specifications;

f) fully agree to conduct myself at all times in a manner that will obtain the respect and confidence of all individuals from whom data will be collected and I will not betray this confidence by divulging information obtained to anyone other than authorized representatives of UCLA; and

g) understand that my obligations under this agreement will survive the termination of any assignment with UCLA and/or my employment by UCLA.

_____Employee's Signature

_____Date

Appendix B: Adverse Events Form

University Of California, Los Angeles
Office for Protection of Research Subjects
HUMAN SUBJECTS PROTECTION COMMITTEE

REPORTING ADVERSE EVENTS OCCURRING AT NON-UCLA LOCATIONS

For multi-site studies, adverse events occurring at non-UCLA locations are to be reported promptly to the HSPC by the investigator when the investigator is made aware of adverse events reported to other IRBs, the FDA or the sponsor.

Date of Report:

I. **PROTOCOL INFORMATION**

Principal Investigator: HSPC # :
Drs. Chunqing Lin and Sherry Larkins
Title of Project: *TransAction: Adaptation and Implementation of an Evidence-based Approach to Advance HIV Prevention and Care for Transgender Women in Vietnam*

II. **RELATIONSHIP TO PROTOCOL**

A. In your judgment is the adverse event related, possibly related, unknown, or not related to the protocol?

☐ Related ☐Possibly Related ☐Unknown ☐Not Related *****

B. Provide a brief rationale for your judgment which helps the HSPC to better understand your assessment of the significance of the adverse event in terms of human subject protection. If data are available, address whether or not the same adverse event has occurred previously and provide incidence data.

* If the adverse event is judged by you as NOT related to the protocol, please complete item II.B, sign off on next page and return this form as well as a copy of the report of adverse event from the funding agency to the OPRS.

III. **CHANGE IN PROTOCOL:** In your judgment is a change in your protocol necessary to reduce or eliminate risk?

☐ Yes (If checked, attach two copies of a revised protocol with changes highlighted on one copy.)

☐ No (If checked, provide a brief rationale below.)

IV. **CHANGE IN INFORMED CONSENT/ASSENT DOCUMENT(S)**: Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of subjects?

☐ Yes (If checked, attach two copies of a revised consent form with changes highlighted on one copy.)

☐ No (If checked, provide a brief rationale below.)

V. **RE-CONSENT/ASSENT**: Is it necessary to inform subjects/legal representatives who have already consented to participation in the study of the adverse event?

☐ Yes (If checked, attach two copies of a revised protocol or a revised consent form with changes highlighted on one copy.)

☐ No (If checked, provide a brief rationale below.)

_____ _____

Signature of Principal Investigator Date Phone Number of PI

Appendix C: Tracking Form

1. PID _____

2. Date of Assessment _____ 3. Interviewer ID _____

4. Local CBO Name _____

5. Name _____ 6. Age _____

7. Home Address _____

8. Home phone # _____

9. Cell phone # _____

10. Other phone # _____

11. Social medial accounts:
    Zalo: _____
    Facebook:_____
    Other:_____

12. Are you going to live in the same address in the coming 3 months?
    Yes _____ No _____

13. Where will you be living three months from now?
    a. Same address
    b. Different address in the same city
       Address _____ Phone number_____
    c. In different city/area
       Address _____ Phone number_____

14. Can we contact you through the following ways?
    a. Call me ___ b. Home visit ___ c. Contact my family member ___
    d. Contact my friend _____ e. Write me a letter ___
    f. Social media (please specify which platform)_____
    g. Other means (please specify which means) _____

15. The relatives who most likely know your whereabouts in the future:
    a. Name _____ b. Relationship _____
    c. Address _____
    d. Phone number _____e. Social Media_____
    f. Is it O.K. to contact him/her if we can't find you? _____

    a. Name _____ b. Relationship _____
    c. Address _____
    d. Phone number _____e. Social Media_____
    f. Is it O.K. to contact him/her if we can't find you? _____

16. The friends who most likely know your whereabouts in the future:

a. Name _____ b. Relationship _____
c. Address _____
d. Phone number _____e. Social Media_____
f. Is it O.K. to contact him/her if we can't find you? _____

a. Name _____ b. Relationship _____
c. Address _____
d. Phone number _____e. Social Media_____
f. Is it O.K. to contact him/her if we can't find you? _____

17. Are there any other ways which we can find you if you will have moved? Please specify:
_____