Official Title: HIV-Related Stigma Intervention for Malaysian Clinicians
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HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: *Implementing Stigma Reduction Tools via a Popular Teletraining Platform to Reduce Clinician Stigma in HIV Testing, Prevention, and Linkage to Care in Malaysia*

Principal Investigator
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Name:
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Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. **Is this project externally funded?** **X** YES NO

If so, please list the funding source: *This project is funded by a grant from the National Institute on Mental Health (R34MH124390).*

2. Research Site(s)

X University of Delaware

X Other (please list external study sites) : *Data will be collected in Malaysia, including in Kuala Lumpur and at the University of Malaya (UM). Additional contributions will be made by Dr. Marwan Haddad from Community Health Center, Inc. (CHC).*

Is UD the study lead? **X** YES ☐ NO (If no, list the institution that is serving as the study lead)

3. **Project Staff**
Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
Valerie Earnshaw (UD faculty)	Principal Investigator	Yes
Zachary Collier (UD faculty)	Co-Investigator	Yes
Jonathan Cox (UD faculty)	Co-Investigator	Yes
Adeeba Kamarulzaman (UM faculty)	Co-Investigator	Yes
Rumana Saifi (UM faculty)	Co-Investigator	Yes
Raja Iskandar Shah Azwa (UM faculty)	Co-Investigator	Yes
Sharifah Faridah Binti Syed Omar (UM faculty)	Co-Investigator	Yes
Marwan Haddad (CHC faculty)	Co-Investigator	Yes
Elizabeth "Carly" Hill (UD staff)	Project Manager	Yes
James Wallace	Research Assistant	Yes

4. **Special Populations**
Does this project involve any of the following:

Research on Children? *No*

Research with Prisoners? *No*

If yes, complete the Prisoners in Research Form and upload to IRBNet as supporting documentation

Research with Pregnant Women? *No*

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe

> *The first phase of this study involves research with people at risk of HIV (i.e., key populations) and people living with HIV, many of whom are vulnerable populations in the context of Malaysia. For example, men who have sex with men and transgender women are at risk of HIV. In Malaysia, civil and religious laws criminalize same-sex sexual behavior and illicit drug use.*

5. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

> *Clinicians who stigmatize people at risk of or living with HIV provide worse HIV testing, treatment, and linkage to care services to these populations. To date, the vast majority of stigma-reduction interventions for clinicians have occurred in single healthcare facilities. We propose to deliver evidence-based stigma reduction tools through a popular teletraining platform for clinicians, Project ECHO®. Project ECHO® (Extension for Community Healthcare Outcomes) has trained, supported, and empowered 70,000+ clinicians to provide a wide range of specialty care services in 37+ countries globally, including HIV testing, prevention, and linkage to care. It uses a "hub and spoke" model wherein non-specialists in community setting "spokes" learn from and collaborate with specialists at academic "hubs" via*

videoconferencing technology (i.e., Zoom software). By delivering stigma-reduction tools through Project ECHO®, we could substantially extend the reach of stigma-reduction interventions for clinicians.

There are four phases of our project:

- ***Phase 1:*** *We will explore experiences of stigma among people at risk of and living with HIV using Photovoice, a qualitative data collection technique involving photography and story-telling (n=35).*
- ***Phase 2:*** *We will explore clinicians' perspectives on an intervention to address stigma through online focus groups (n=40).*
- ***Phase 3:*** *We will conduct a brief pre-test of our intervention protocol with a small sample of clinicians (n=5).*
- ***Phase 4:*** *We will pilot test our intervention protocol among clinicians, comparing it to two control conditions (n=78). Our intervention materials will include Photovoice presentations created by participants in Phase I of the study. Importantly, these presentations will screened to ensure that they do not contain identifying information (e.g., faces).*

6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

Phase 1: *People belonging to groups at risk of HIV (including men who have sex with men, transgender women, female sex workers, and people who inject drugs) and people living with HIV will be recruited to engage in a Photovoice study. An online version of the Photovoice study will be offered during the COVID-19 pandemic, while social distancing is recommended. An in-person version will be offered once social distancing is no longer necessary.*

Online procedures: Participants will be involved in the study for one week. On the first day, participants will talk with a study research assistant via WhatsApp. The research assistant will introduce the study, obtain informed consent, share the study website with participants, and guide participants through the introductory videos. Over the following week, participants will take photographs in response to prompts. They will submit their photographs, along with a short story to accompany the photograph, via the study website. Prompts include:

- *What makes you happy?*
- *What makes you sad?*
- *What is important to you?*
- *What challenges do you face?*
- *What do you want doctors to know about you?*
- *How do you think doctors see you?*

In-person procedures: Participants will be involved in the study for one week, including two day-long workshops with several days of taking photographs in between the workshops. At the first workshop, they will learn about photography from a professional photographer. Over the next several days, they will take photographs of their surroundings using either their cell phone or a camera provided by the study team. Participants will respond to the prompts listed above. At the second workshop, they will learn more about photography and story-telling and write a story to accompany their photographs. Workshops will only be open to research participants.

The photographs and stories will be turned into Photovoice presentations (i.e., 2-3 minute

narrated photograph montage), narrated by a member of the study team. These presentations will be incorporated into our intervention (see Phases 3 and 4). Consistent with traditions of photovoice studies (which are a form of Participatory Action Research) and as requested by our community partners, participants will have an opportunity for their final PhotoVoice presentation to be shared with an audience of community stakeholders for advocacy purposes (Wang & Redwood-Jones, 2001). Agreeing to share PhotoVoice presentations is not a prerequisite of participation: Participants can participate in the study without agreeing to share their photovoice presentations with a community audience. Our permission form for sharing photographs is included with our measures and was deemed appropriate for the local context by the University of Malaya IRB.

Phase 2: *Clinicians will be recruited to engage in an online focus group lasting for 3 days. Recruitment flyers will be posted, with permission, to social media sites of local professional organizations. The recruitment flyers will direct interested individuals to a Qualtrics survey containing the study consent form and a brief questionnaire including items measuring socio-demographics, focus groups preferences (i.e., weekends versus weekdays), and contact details (i.e., email address). A research assistant will contact interested individuals to sign them up for focus groups. Four separate groups will be conducted (n=10 participants per group). Each focus group will focus on a different group of participants at risk of HIV (i.e., men who have sex with men, female sex workers, transgender women, or people who inject drugs). An asynchronous online focus group format will be used in which 2-3 questions will be posted daily over the course of 3 days to a secure website (i.e., FocusGroupIt) by a trained interviewer, and participants will respond to questions at their convenience (similar to Facebook).*

Phase 3: *We will pre-test our intervention protocol with five clinicians on a condensed schedule over the course of two weeks. Participants will sign into Zoom for 5 sessions (each lasting 90 minutes) to engage in the intervention. They will then be invited to participate in an in-depth interview regarding their perceived acceptability and feasibility of the intervention.*

Phase 4: *We will pilot test our intervention protocol with clinicians and compare it to two other intervention arms. Clinicians will be randomly assigned to one of three training conditions:*

1. *Participants randomized to the first control condition (n=26) will complete HIV Connect, which is an online course developed by the Malaysian Society of HIV Medicine designed to educate primary care physicians in Malaysia about HIV. It consists of a series of 9 modules and accompanying assessments featuring HIV infectious disease experts who instruct on topics including epidemiology and natural history of HIV, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), sexual history taking and STI testing, and others. Participants will complete 1 module and assessment per month so that the intervention is delivered along the same timeline as the other two conditions (i.e., 9 months). The course is available free of charge to all registered medical practitioners in Malaysia. Clinicians earn Continuing Medical Education credits after completing each module and assessment, and a certificate of completion upon finishing all modules and assessments.*
2. *Participants randomized to the second control condition (n=26) will complete the standard version of Project ECHO for HIV Prevention, without added evidence-based stigma reduction tools. Participants will meet with the Project ECHO® Hub specialists and their learning community on a bi-weekly basis for 90 minutes over the course of 9 months. Their Hub specialists will include the infectious disease, mental/behavioral health, and family medicine specialists, but exclude the stigma expert and community representative. They will be joined periodically by guest*

speakers with expertise in infectious disease, pharmacology, case management, and other clinical topic areas. Each session will feature a didactic training incorporating standardized procedures for HIV testing, prevention, and/or linkage to care, and patient case presentation and discussion.

3. *Participants randomized to our intervention (n=26) will complete Project ECHO® for HIV Prevention intervention with added evidence-based stigma reduction tools. Participants will meet with the Project ECHO® Hub specialists and their learning community on a bi-weekly basis for 90 minutes over the course of 9 months. Their Hub specialists will include the infectious disease, mental/behavioral health, and family medicine specialists, as well as the stigma expert and community representative. The stigma expert and community representative will monitor discussion and address stigmatizing content (e.g., via discussion and didactic training), thereby shaping social norms. The Hub specialists will be joined periodically by guest speakers with expertise in infectious disease, pharmacology, case management, and other clinical topic areas as well as stigma and key population communities. Each session will feature a didactic training, key population Photovoice presentation, and patient case presentation. In addition to addressing HIV testing, prevention, and linkage to care through the presentation of standardized procedures to facilitate education and behavioral design, didactic trainings will include content to increase education surrounding key populations. Weekly Photovoice presentations will facilitate extended contact with key populations and PLWH. Patient-case presentation and discussion will highlight at least one patient from a key population per week, facilitating clinical skills for and changing social norms surrounding working with key populations.*

   All phase 4 participants will be invited to complete surveys. A subset of participants (up to 10 per condition) will be invited to participate in focus groups at the end of the intervention.

Citation: Wang, C. C. & Redwood-Jones, Y. A. (2001). Photovoice ethics: Perspectives from Flint photovoice. *Health Education & Behavior, 28*(5), 560-572.

7. **STUDY POPULATION AND RECRUITMENT**

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

Phase 1: *Individuals will be eligible to participate if they are: 18 or older and identify as a man who has sex with men, person who injects drugs, transgender woman, female sex worker, or person living with HIV (n=35). Participants completing the in-person version of the study will have to be able to attend two Photovoice trainings held in Kuala Lumpur. Participants completing the online version of the study will have to have access to a cell phone with a camera and internet access.*

Phases 2-4: *Individuals will be eligible to participate if they are: 18 or older, a practicing general practitioner or family medicine specialist, and have internet access (n=123).*

Attach all recruitment fliers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.

Recruitment materials have yet to be developed. We will submit an amendment with

recruitment materials when we have developed them.

Phase 1: *We will recruit participants at risk of or living with HIV by posting an advertisement for the study on listservs and social media platforms maintained by the Malaysian AIDS Council, Kuala Lumpur AIDS Support Services Society, and PT Foundation, which are organizations that our collaborators at the University of Malaya have long-standing relationships with and serve people at risk of or living with HIV in Kuala Lumpur. Thus, all participants will be affiliated with local HIV-related organizations that serve people at risk of and living with HIV. Participants freely subscribe to these listservs. Interested individuals will email the study coordinator to express interest. The research assistant will then coordinate a phone call via WhatsApp to describe the study and determine eligibility (i.e., verbal confirmation that individual is a member of a risk group for HIV or living with HIV, but not which risk group they belong to). Participants completing the online study will then be introduced to the study website by the research assistant. Participants completing the in-person study will be given information about the location and time for the photography workshop.*

Phases 2-3: *We plan to recruit clinicians by emailing information about the study to members of the Malaysian Medical Association and via established informal networks on social media such as DOBBS (Doctors Only Bulletin Board System) and the Malaysian Primary Care Network. To date, we have had success recruiting Malaysian clinicians via email (participation ranging from 33.4-39.6% of clinicians contacted via email).*

Phase 4: *We will recruit clinicians from the memberships of the Malaysian Medical Association, Family Medicine Association of Malaysia (FMSA), and Malaysian Primary Care Network The organizations will share an advertisement to their social media site, which will direct participants to Qualtrics. Participants will be given more information about the study and consent to completing a brief survey and being assigned to a study condition (i.e., step 1 consent). They will then be randomly assigned to a study condition. Clinicians' previous experience with HIV testing will be taken into consent in the randomization process to ensure equal distribution of previous experience among study conditions. Once they have been assigned, we will contact them again, provide additional information about their condition, and consent them to the full study (i.e., step 2 consent).*

Describe what exclusionary criteria, if any will be applied.

Clinicians who participate in the Phase 3 pre-test will not be eligible to participate in the Phase 4 pilot test.

Describe what (if any) conditions will result in PI termination of subject participation.

N/A

8. **RISKS AND BENEFITS**

List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).

Phase 1: *The most significant potential risk to people at risk of or living with HIV is a <u>breach of confidentiality</u>: Participants may face consequences if others were to learn that they are a member of a population that is at risk for HIV or living with HIV due to their participation in this study. This risk is similar to what participants face in their day-to-day lives through their participation in the organizations from which we will recruit them (i.e., Malaysian AIDS Council, Kuala Lumpur AIDS Support Services Society, and PT Foundation).*

Phases 2-4: *Risks include the possibility of slight discomfort when considering stigma experienced by key populations and PLWH in clinical settings. Additionally, breaches in confidentiality may result in employment-related repercussions if participants express an unpopular viewpoint. These risks are not expected to be greater than those that participants face in day-to-day lives.*

In your opinion, are risks listed above minimal* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

Phase 1: *Given that individuals will only be invited to participate if they are already affiliated with organizations serving men who have sex with men, transgender women, female sex workers, people who inject drugs, and people living with HIV, the risks of participating in this study will be similar to those encountered in these participants' daily lives. We will not recruit participants who are not already affiliated with HIV organizations. Additionally, members of our study team have recruited individuals from these populations for many studies over the last several decades. In this time, there have been no known breaches of confidentiality experienced by research participants. We therefore believe that risks associated with this study are minimal.*

Phases 2-4: *Experiences of slight discomfort and breaches are confidentiality are risks similar to those faced by clinicians in their everyday lives. We therefore believe that risks associated with these studies are minimal.*

*(*Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)*

What steps will be taken to minimize risks?

Phase 1: *We will take several measures to protect members of key populations and PLWH participating in our Photovoice procedures from a breach of confidentiality:*

a. *We will not record participants' names at any point during the study. Given that a breach of confidentiality represents that largest risk to participants, we will apply for Institutional Review Board approval to use a consent form that does not require participant signatures. Participant names will not be recorded in affiliation with their Photovoice data. Because we will be working with very small samples of participants (i.e., 6-7 members per key population group), we will not collect socio-demographic data that could be used to identify participants (e.g., age, gender, ethnicity, religion).*
b. *The study website is HIPAA-compliant. We consulted with IT experts at the University of Delaware regarding the security of PhotoVoice submissions. Even though we are not collecting HIPAA data, we ultimately decided to build a HIPAA-compliant website because it offers a very high level of security features (similar to those for medical provider websites). All data submitted by study participants will be both encrypted in transit and at rest. Although participants will be required to log into the website to access study materials and submit Photovoice responses, they will not be asked to use their personal email address or any other personally identifiable information to do so. The study team will create and distribute unique login identifiers and passwords to all study participants.*
c. *All communication with study participants engaged in the online version of the study will occur via WhatsApp, which offers end-to-end encryption of calls and texts. Thus, communication with study participants will be secure.*

d. *We will ensure that photographs do not include identifying information. At the online and in-person Photovoice trainings, Mr. Cox will introduce techniques to protect participant identities (e.g., capturing people's shadows rather than faces). Participants will be instructed to not include identifying information in their photographs, and they will be given examples of responses that do not include identifying information (please see submitted examples). Any photographs including identifying information will be destroyed and will not be included in final Photovoice presentations. We have developed a photograph de-identification protocol based on HIPAA guidance and recommendations for de-identifying photographs in medical settings (Nettrour, Burch, & Bal, 2019). Two members of our team will independently review each photograph for four different categories of identifiers (i.e., facial photography, identifiers intrinsic to the participant, identifiers on the participant, and identifiers around the participant). They will report any identifiers on our "photograph de-identification form." Photographs will then be categorized as (1) not including identifiers and thus eligible for inclusion in Photovoice presentations, (2) including identifiers that cannot be edited out and thus must be permanently deleted, or (3) including identifiers that can be edited out and thus will be edited and re-reviewed.*
e. *We will not use participants' voices to narrate Photovoice presentations. Participants will develop story scripts to accompany their photograph presentations. Members of the research team will read the story scripts for the final Photovoice presentations, and clinicians will be told that Photovoice narratives are read by actors. Participant voices will not be recorded at any point during the study.*
f. *All final Photovoice presentations will be screened to ensure that they include no identifying information. Mr. Cox, Dr. Earnshaw, and Dr. Saifi will choose the Photovoice presentations to be included in the intervention. They will then share these presentations with members of the study team, including Drs. Kamarulzaman, Azwa, and Omar, who will screen the Photovoice presentations for identifying information. If any identifying information is found, the Photovoice presentations will be edited to ensure anonymity.*
g. *All electronic data to be analyzed will be stored on a password-protected server with access restricted to members of the study team.*

Phases 2-4: *To protect clinicians from discomfort, we will emphasize during the informed consent process that they may choose to not engage in conversations that make them uncomfortable, skip survey and/or interview questions, and end the study at any time. To protect clinicians from a breach of confidentiality, we will store all electronic data on a password-protected server with access restricted to members of the study team. Clinicians will be given an alphanumeric participant ID code. All participant data (e.g., survey results) will be stored along with this participant ID, rather than participants' names. The log linking participant IDs with participant names will be stored on a password-protected server with access restricted to members of the study team during the duration of the study. After the study, the log will be destroyed so that there is no record linking participants with their data. Additionally, we will use a HIPAA compliant version of zoom when conducting interviews and focus groups with clinicians. Additionally, participants of the online focus groups (Phase 2) will be able to use a pseudonym instead of the real name while responding to questions.*

Nettrour J. F., Burch, M. B., & Bal, B. S. (2019). Patients, pictures, and privacy: Managing clinical photographs in the smartphone era. *Anthroplasty Today,* 57-60.

Describe any potential direct benefits to participants.

Phase 1: *Participants may enjoy the opportunity to learn about photography or find the opportunity to document and share their experiences via Photovoice to be fulfilling.*

Community groups in which participants are involved may use the Photovoice presentations for advocacy purposes, which could lead to policy changes that benefit the populations that participants represent. Yet, participants are unlikely to personally benefit from participation in this phase.

Phase 2: *Participants may find the opportunity to provide feedback on the intervention to be fulfilling. Yet, participants are unlikely to personally benefit from participation in this phase.*

Phase 3: *Participants may benefit by receiving some limited specialty training in HIV testing, prevention, and linkage to care.*

Phase 4: *Clinicians participating in the intervention pilot will benefit by receiving specialty training in HIV testing, prevention, and linkage to care. We believe that this will be desirable for some because some clinicians volunteer to receive this training via HIV Connect. Additionally, clinicians earn Continuing Medical Education credits after completing each module and assessment of HIV Connect, and a certificate of completion upon finishing all modules and assessments. We will seek approval for the Project ECHO arms to also be eligible for Continuing Medical Education credits, and will amend this protocol to reflect this benefit if our application is approved. Clinicians receive Continuing Medical Education credits for completing Project ECHO in the U.S. and elsewhere.*

Describe any potential future benefits to this class of participants, others, or society.

Clinician stigma remains a potent and persistent driver of disparities in HIV testing, prevention, and linkage to care globally. It is unlikely that we will eliminate these disparities and achieve equity in HIV testing, prevention, and linkage to care until we effectively address clinician stigma. The proposed project will result in important knowledge regarding the acceptability, feasibility, and preliminary impact of a significant and innovative strategy for reducing clinician stigma at large scale: the implementation of evidence-based stigma reduction tools via a popular teletraining platform. In light of the protections that we have in place within our study procedures, we believe that the risks to participants of this project are minimal. We therefore believe that the risks to participants are reasonable in relation to the importance of the knowledge that may be gained from this study.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

N/A

9. **COMPENSATION**

Will participants be compensated for participation?

Yes

If so, please include details.

Compensation has been set to be commensurate with previous studies with these populations in Kuala Lumpur, Malaysia.

Phase 1: *Participants who complete the study in person will be compensated 50RM/hour, which is approximately $11.60. Participants will be compensated for their time during the two workshops. As noted in the consent form, participants who do not complete the study will receive pro-rated compensation. Participants who complete the study online will be*

compensated 50RM/submission (responding to each submission is expected to take approximately one hour). Participants will also be compensated for their time completing the consent process and watching the introductory videos, as well as completing a survey regarding their experiences completing the study online (25 RM/activity because each activity is expected to take approximately one-half hour).

Phases 2-4: *Doctors will be compensated 75RM/hour of study participation, which is approximately $17.40. Participants of Phase 2 will be compensated 1 hour per day for responding to online focus group questions, for up to 3 days of participation (maximum = 225RM). Participants of Phase 3 will be compensated for their time spent completing pre-test trainings and engaging in the qualitative interview, for up to 9 hours of compensation (maximum = 675RM). Participants of Phase 4 will be compensated for their time completing surveys, for up to three hours of compensation (maximum = 225RM). Participants invited to complete focus groups will also be compensated for their time (75RM). As noted in the consent forms, participants who do not complete the studies will receive pro-rated compensation. Participants of Phase 4 will also be given lunch vouchers on days when they participate (30RM or about $7).*

The compensation schedule is set differently for Phases 3 versus 4 participants because Phase 3 participants are expected to receive less benefit from their engagement in the study. Participants in Phase 3 will receive very limited training in HIV testing, prevention, and linkage to care that is unlikely to address many of their training needs. Participants in Phase 4 will receive a much more comprehensive training program covering these areas that is likely to address most of their training needs, and also may be eligible to receive Continuing Medical Education credits.

10. **DATA**

Will subjects be anonymous to the researcher?

No.

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)

Phase 1: *No identifying information will be collected from participants.*

Phases 2-4: *Clinicians will be given an alphanumeric participant ID code. All participant data (e.g., survey results) will be stored along with this participant ID, rather than participants' names. The log linking participant IDs with participant names will be stored on a password-protected server with access restricted to members of the study team during the duration of the study. After the study, the log will be destroyed so that there is no record linking participants with their data.*

Results from all studies will be reported in aggregate.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see http://www.udel.edu/research/preparing/datastorage.html)

Paper files will not be collected.

All digital files, including audio files and transcripts, will be stored on password protected files on UD maintained servers with regular and secured back-up. Data will be collected using UD applications (e.g., Qualtrics and HIPAA-compliant Zoom).

Additionally to keep photo data secure, a HIPPA-compliant website has been created for the study. Photos taken on cell phones will be uploaded through the website. Photos and captions written by participants will be encrypted both at rest and in transit.

How long will data be stored?

Coded data will be stored indefinitely.

Will data be destroyed? **X** YES ☐ NO (if yes, please specify how the data will be destroyed)

After the study, the log linking participant IDs with participant names will be permanently deleted so that there is no record linking participants with their data.

Will the data be shared with anyone outside of the research team? ☐ YES **X** NO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

How will data be analyzed and reported?

Phase 1: *Following standard qualitative data analysis methods, we will review all of the final presentations, explore repetitions across presentations to identify themes, and then develop a codebook listing themes with a detailed description, inclusion/exclusion criteria, and examples. We will upload the final presentations, story scripts, and photographs into Dedoose (a qualitative coding software system that facilitates collaboration between coders, and can be used to analyze text, photograph, and video data). Two coders will review videos, and then mark areas of text and photographs pertaining to themes. They will practice with a random sample of 20% of data, coding independently and reviewing together. We will clarify ambiguity in the codebook by adding examples. Training will continue until coders consistently identify and mark each theme. Coders will then work on each interview independently, after which we will measure coder consistency, evidenced by Kappas of ≥.70. We will use Dedoose to examine the distribution of themes. Results are expected to provide evidence regarding stigma perceived by participants from clinicians.*

Phase 2: *We will apply the same analytic steps and use the same software to analyze the focus group data as those that we will apply to the Photovoice data (Phase 1), except that our analysis will concentrate on focus group transcripts. Results are expected to provide evidence regarding clinician perspectives on stigma in healthcare settings, and insight into the context for intervention delivery.*

Phase 3: *We will apply the same analytic steps and use the same software to analyze the interview data as those that we will apply to the Photovoice and focus group data (Phases 1-2), except that our analysis will concentrate on interview transcripts. All qualitative interviews will be transcribed by our trained research assistants. Results are expected to provide insight into aspects of the intervention that we may need to change before implementing it in Phase 4.*

Phase 4: *Quantitative analyses will be conducted in R version 3.6.2 and include an examination of descriptive statistics and generalized linear models. We will examine changes in mean self-reported stigma (i.e., prejudice, stereotypes, and discrimination) across the 3 time-points of data collection. We will use a two-way repeated measures ANOVA to determine whether any change in stigma is associated with the interaction between the type of condition (factor one) and time (factor two). Qualitative analyses will follow the same*

analytic steps and use the same software as those that we will apply Phases 1-3, except that our analysis will focus on interview transcripts. All qualitative focus groups will be transcribed by our trained research assistants. Results are expected to provide insight into the acceptability and feasibility of the intervention, including barriers to and facilitators of implementation and reasons for withdrawal, as well as participants' perceptions of impact on stigma and care delivery.

11. **CONFIDENTIALITY**

Will participants be audiotaped, photographed or videotaped during this study?

Phase 1: *Participants will take photographs, however they will be instructed not to take photographs that include identifiable images (e.g., faces). Participants will not be audiotaped, photographed, or videotaped by the study team.*

Phase 2: *No audiotapes, photographs, or videotapes will be taken.*

Phases 3-4: *Participants will be audiotaped during their qualitative interviews and focus groups.*

How will subject identity be protected?

Phase 1: *We will ensure that photographs do not include identifying information. At the first Photovoice training, Mr. Cox will introduce techniques to protect participant identities (e.g., capturing people's shadows rather than faces). Participants will be instructed to not include identifying information in their photographs. Any photographs including identifying information will be destroyed and will not be included in final Photovoice presentations. All final Photovoice presentations will be screened to ensure that they include no identifying information. Mr. Cox, Dr. Earnshaw, and Dr. Saifi will choose the Photovoice presentations to be included in the intervention. They will then share these presentations with members of the study team, including Drs. Kamarulzaman, Azwa, and Omar, who will screen the Photovoice presentations for identifying information. If any identifying information is found, the Photovoice presentations will be edited to ensure anonymity.*

Phases 3-4*: Audiotapes will be transcribed by a research assistant. During transcription, any references to participant identities will be removed. After transcription is complete, audiotapes will be deleted.*

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).

As an NIH-funded study, it will automatically receive a Certificate of Confidentiality.

12. **CONFLICT OF INTEREST**

(For information on disclosure reporting see: http://www.udel.edu/research/preparing/conflict.html)

Do you have a current conflict of interest disclosure form on file through UD Web forms?

Yes

Does this project involve a potential conflict of interest*?

No

* As defined in the University of Delaware's Policies and Procedures ,a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

If yes, please describe the nature of the interest:

N/A

13. **CONSENT and ASSENT**

__X_ Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

Please note that we have submitted consent forms following the University of Malaya's consent templates.

Phases 2-4: *These studies will be conducted online and so we will not be able to collect signatures on study forms. We will include a signature box for participants to type in their name to document that they have read the information sheet and agree to continue with the study.*

____ Additionally, child assent forms will be used and are attached.

__ X __ Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

Please note that we have submitted consent forms following the University of Malaya's consent templates.

Phase 1: *The primary risk to participants is a breach of confidentiality. We therefore request a waiver of consent so that we do not have to keep records that include participants' names.*

__ __ Waiver of Consent (Justify request for waiver)

14. **Other IRB Approval**

Has this protocol been submitted to any other IRBs?

This protocol has been approved by the University of Malaya Medical Research Ethics Committee.

If so, please list along with protocol title, number, and expiration date.

Title: Implementing Stigma Reduction Tools via a Popular Teletraining Platform to Reduce

Clinician Stigma in HIV Testing, Prevention, and Linkage to Care in Malaysia

Number: 202047-8467

Expiration date: 20-5-2021

15. **Supporting Documentation**

Please list all additional documents uploaded to IRBNet in support of this application.

1. Progress report form
2. Protocol with and without tracked changes
3. Amendment form
4. Updated measures
   - 4.1.1 Focus group measures
5. Informed consent forms with and without tracked changes
   - 5.1.1 Including 2 consents for the 2 step consent process for Phase 4
6. Examples of de-identified PhotoVoice responses
7. Recruitment flyers for PhotoVoice study
8. Recruitment flyers for Project ECHO study