UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Addressing violence and HIV cascade of care outcomes among transgender women
Principal Investigator: Kristi Gamarel, Ph.D., University of Michigan
Co-Investigator(s): Lilianna Reyes, M.S.W., Trans Sistas of Color Project; Laura Jadwin-Cakmak, M.P.H. & Gary W. Harper, Ph.D., M.P.H., University of Michigan
Study Sponsor: National Institutes of Mental Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the study is to test out a new group program, *Kickin' it with the Gurlz*, designed to help transgender women of color heal from trauma and improve their health.
- If you choose to participate, you will be asked to have a 1-on-1 meeting with a facilitator to learn about the program and receive resources (30-60 minutes), and then to attend weekly group sessions (2 hours long) for 8 weeks. You will also be asked to complete 3 surveys (before starting the program, after the final group session, and one month after the group ends) that each take 30-40 minutes. Finally, at the end of the group, you will be asked to complete an exit interview that takes about 30 minutes.
- Risks or discomforts from this research are minimal and include potential discomfort during data collection or program sessions, as well as potential breach of confidentiality.
- The direct benefits of your participation are that you will receive a referral list for services and resources available in the Detroit Metro Area, you may improve your engagement in care, and you may benefit from the opportunity to spend time talking about feelings and experiences.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to evaluate *Kickin' it with the Gurlz*, a new group-based program developed by the Love Her Collective to help transgender women of color heal from trauma and take care of their whole self. This study has 3 goals:

- To learn whether transgender women of color like the program, find it helpful, and would recommend it to others.

- To learn if transgender women of color experience any health benefits after participating in *Kickin' it with the Gurlz*, including mental health symptoms, access to gender affirmation, and engagement in HIV care.
- To get input on how we should design future research studies with transgender women of color.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? This study is for transgender women of color who are at least 18 years old, live in the Detroit Metro Area, have a history of trauma, and are living with HIV. Participants must also live in the Detroit Metro Area and speak English. Participants who are HIV-negative or do not know their HIV status are not eligible for this study, but do have the opportunity to take part in the *Kickin' it with the Gurlz* group sessions and enroll in another study with surveys focused on HIV prevention.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? All in-person research activities will occur at the Ruth Ellis Center; research activities will also be conducted by phone and Zoom. If you consent to take part in this research study, we will ask you to share your contact information, and we will contact you to schedule and to remind you of study activities.

You will complete an online survey that asks about your overall health, mental health symptoms, engagement in HIV care, access to gender affirmation, and whether you are currently experiencing violence. This survey will take about 40 minutes to complete.

If you are currently receiving HIV care, we will ask you to share the contact information of your medical provider and to sign a medical release so that we can get information about your HIV care and viral load from your provider. This is optional, and you still participate in the study if you choose not to sign a medical release.

After completing the survey, you will be connected to one of the program facilitators for a 1-on-1 session, where the facilitator will share what to expect about the program, identify what referrals and/or community resources you would like, and answer questions. The initial 1-on-1 session will take 30-60 minutes. Group sessions will start after the initial 1-on-1 session. Group sessions with other transgender women of color will occur once a week for 8 weeks, and are about 2 hours long. The group will include participants of any HIV status. Your HIV status will be kept private and not be shared with other participants. Group session topics will focus on learning how to heal from trauma and take care of your overall health and well-being. At the end of each session, you will complete a brief feedback form. If you want, you can continue to have 1-on-1 sessions to connect you with referrals and resources until the end of group sessions.

After the final group session, you will take another survey that takes about 30 minutes. You will also complete an exit interview at the end of the 8-week program; the interview will take about 30 minutes and will be audio-recorded. About one month after group

sessions end, we will contact you in order to take the survey one final time; it will take about 30 minutes.

4.2 How much of my time will be needed to take part in this study? Participants will be asked to take a survey (about 40 minutes) and have a 1-on-1 session with a facilitator (30-60 minutes) before starting group sessions. Participants will be asked to attend 8 group sessions (2 hours each), held once a week. During this time, participants may schedule additional 1-on-1 sessions with their facilitator if they want, but this is not required. After the final group session, participants will take another survey (30 minutes) and complete an exit interview (30 minutes). Finally, we will contact participants approximately one month after the group program ends to take a final survey (30 minutes).

4.2.1 When will my participation in the study be over? Your participation will be over about 3 months after the start of group sessions.

4.3 If I decide not to take part in this study, what other options do I have? If you do not want to be in this research study, there are other ways of treating symptoms of post-traumatic stress syndrome (PTSD), and there are other programs that can help you engage in HIV care. You can check with your health care provider to discuss other options. You can also ask staff on this research study for information about local mental health services, HIV care providers, and HIV case management even if you choose not to participate in the study.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
You may experience some discomfort in responding to questions during surveys or the exit interview, or during 1-on-1 and group sessions. You do not have to answer any questions you do not want to answer, and you may take a break at any time.

The researchers will try to minimize the risk of discomfort by providing participants with counseling resources and agreeing to ground rules with other group participants before beginning group sessions.

Because this study collects information about you, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?
You might benefit from being in the study because you will receive a list of local services and resources, you may improve your engagement in care, and you may benefit psychologically from the opportunity to spend time talking about your thoughts and feelings.

5.3 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

6.2 Is there any reason I might be discontinued from the study?
If you, the investigators, or the study sponsor feel that it is not in your best interest to continue the study for some reason (for example, you experience severe distress from participating in group sessions), you may be discontinued from the study early. If this happens, the investigators will speak with you about it and will help refer you to needed services.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?
You will receive up to $465 for your participation in this study - $305 for completing study activities, and an additional $160 in gas gift cards ($20/group session). Payments will be provided after completion of each study activity: $40 for completing the initial survey, $20 for each of the 8 group sessions you attend, $35 for the survey after the final group session, $20 for completing the exit interview, and $50 for the final survey one month later. You will have a choice of receiving the payment as a Visa gift card (delivered via mail) or an Amazon or Walmart digital gift card (delivered via email). For any sessions that are held in-person, you will also be provided a meal and transportation to/from the Ruth Ellis Center (via Uber/Lyft or $20 gas gift card). If you withdraw from the research before the end of the study, you will only receive compensation for the research activities you have completed.

Because this study pays more than $100, the University of Michigan will collect and safely store your name, address, social security number, and payment amount for tax reporting purposes. If you receive more than $600 in payments in a calendar year, this information will be sent to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?
Only essential study staff will access your information. The data you provide will be linked to you through a unique study identifier. Your name and any identifying

information will be stored separately from other study data. Audio recordings of exit interviews will be deleted after they are analyzed. All data will be de-identified after the study is completed; all identifiers will be destroyed within 6 months of completion of data collection.

Because this study includes taking part in group sessions with other participants, we cannot guarantee confidentiality of anything shared during group sessions. However, we will set “ground rules” with all group attendees as the beginning of each session that includes an agreement to keep information shared during group sessions confidential. If group sessions are occurring in-person, they will be held in a private room at Ruth Ellis Center. If group sessions are occurring virtually on Zoom, all participants will be asked to join the group from a private location where they cannot be overheard by others. You do not have to share anything that you do not want to.

8.1.1 Special Protections This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes sharing your de-identified data with other researchers.

If required by local or state law, we will report to the appropriate authorities in specific cases, such as if we learn of abuse, neglect or endangerment of any vulnerable person.

We will disclose your information if the National Institute of Mental Health, the agency funding this research, requests information to audit or evaluate our procedures.

Please note that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage**:** https://humansubjects.nih.gov/coc/index

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

- Because you will receive more than $100 for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for study recordkeeping and for future research projects. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you.

We will assign you a coded study identifier that will be linked to your research information so that we can connect the different surveys you take; this connection to you will be destroyed within 6 months of study completion. Audio-recordings of the exit interviews will also be deleted within 6 months of study completion.

The researchers plan to contact you again as part of this project. We will contact you to schedule and to remind you of study activities (group sessions, exit interview, surveys).

The results of this study could be published in an article or presentation, but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We will put the information we collect from you into a repository. The repository contains information about many people. Your information will be de-identified.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures

- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Kristi Gamarel, Ph.D.
Email: kgamarel@umich.edu
Phone: 734-647-3178

Co-Investigator & Project Director: Laura Jadwin-Cakmak, M.P.H.
Email: ljadwin@umich.edu
Phone: 734-763-2884

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

We will obtain your consent by asking you to verbally state whether or not you agree to take part in this research study. Make sure you understand what the study is about before you agree.

We will email you a copy of this document for your records if you agree to receive it. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

Do you consent to participate in this research study?

☐Yes
☐No
Date: _____

11. OPTIONAL CONSENT TO CONTACT

Consent to be Contacted for Participation in Future Research

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

Agreeing to be contacted for future research is entirely voluntary and will not affect your ability to participate in this study or the services that you will receive.

Do you agree to be contacted about future research opportunities?

☐Yes

☐No

Date: _____