UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Strengthening Community Responses to Economic Vulnerability among Trans Women (*Secure*)
Principal Investigators: Kristi Gamarel, PhD, University of Michigan; Larissa Jennings Mayo-Wilson, PhD, University of North Carolina
Co-Investigator(s): Laura Jadwin-Cakmak, MPH, University of Michigan; Lilianna Reyes, MPA, Ruth Ellis Center
Study Sponsor: National Institute 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 for transgender women of color focused on developing financial and business skills.
- If you choose to participate, you will be asked to take three surveys and complete an interview, in addition to joining a 12-week group program and having meetings with a mentor.
- Everyone who decides to participate will be entered into a lottery. Half will be randomly chosen to receive the program right away, and the other half will receive the program about 6 months later. The group that receives the program right away will be enrolled in the study for about 6 months. The group that receives the program later will be enrolled in the study for about 9 months.
- Risks or discomforts from this research include potential discomfort in answering questions and in the group sessions, as well as a loss of confidentiality.
- You may benefit from the opportunity to connect with other trans women of color in group sessions and learning about available community resources. You may also benefit from the information you learn and resources you receive during group sessions.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Your decision to participate or not participate will not have any impact on the services you receive at the Ruth Ellis Center or whether you are eligible for the Trans Sistas of Color Project emergency assistance program. 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 test out a new group program that is focused on helping transgender women of color learn financial and business skills and be supported in increasing their financial stability. Through this study, we want to learn whether transgender women of color in Detroit think the program is useful, if it helps them

achieve their professional goals and feel more financially *Secure*, and whether the women who receive the program see any improvements in their health and well-being, including HIV prevention and/or HIV care services.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? Transgender women of color living in the Detroit Metro Area who are at least 18 years of age, are currently earning less than a living wage, and who report some sexual risk behavior can take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- First, you will take a survey that is about 40 minutes long. The survey will include some sensitive questions, like questions about your economic status, sexual behavior, mental health, and substance use.
- Then, you will be entered into a lottery that will determine whether you will start the *Secure* group program now, or will need to wait about six months to receive the program.
- Whether you start the *Secure* program right away or start later, the program will be the same. You will attend 12 group sessions at the Ruth Ellis Center, once a week for two hours, to learn financial and business management skills, and about taking care of your health. You will also be connected to a mentor, who you will talk to about once a week about your business goals and professional development goals. You will also receive $250 in emergency assistance that you can use on whatever you need, and a $1,200 microgrant that you can use to meet your business goals and/or professional development goals. The $1,200 microgrant will be issued to you after you have worked with your mentor on developing your Secure income generation plan.
- You will take two more 30-minute surveys as part of the study; one will be about 3 months after your first survey, and the final survey will be another 3 months later. If you are in the group that starts the program right away, you will take these surveys after completing the group sessions. If you are in the group that starts the program later, you will take all of the surveys before beginning the group sessions.
- Finally, after you complete the group sessions, you will complete a 30-minute interview to give us your feedback on the program. The interview will be audio-recorded.

4.2 How much of my time will be needed to take part in this study? The first survey that you complete will take about 40 minutes. The second and third survey will each take about 30 minutes. The interview you complete at the end of the program will take about 30 minutes. The Secure program includes 12 weekly 2-hour group sessions (24 hours total) and talking with a mentor about 30 minutes each week during this time (6 hours total). If you are in the group that receives the program right away, you will be enrolled in this study for about six months. If you are in the group that receives the

program later, you will be enrolled in this study for about 9-12 months, depending on when the group sessions start.

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 interview, or during group sessions.

The researchers will try to minimize this risk of discomfort by providing you with local mental health resources if you want them. You do not have to answer any questions you do not want to answer, and you may take a break at any time. During group sessions, you do not need to share any information you do not want to share. All participants in the group will be required to agree to keep other group members' information private.

Because this study collects information about you, one the primary risk 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 may benefit from the opportunity to connect with other transgender women of color in the group sessions and be connected to local medical and social service resources. You may also benefit from the information you learn during group sessions and receiving a microgrant to put toward your own small business or other professional development goals. Others may benefit from the knowledge gained from this study, and you may feel good about participating in a study that may benefit other transgender women of color in the future.

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.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive up to $2,140 for your participation in the study. You will receive up to $690 for completing study activities; this includes $40 for completing the first two surveys; $30 for completing the interview; $20 for each group session attended; $20 for gas reimbursement OR transportation via Uber/Lyft for each group session; and a $50 bonus if you complete all surveys and the interview. You will also receive $250 in emergency assistance, and you

may qualify for $1,200 in microgrant funds. 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. If you are a University of Michigan employee, your research payments are tracked separately and are not included as part of your payroll.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? Only essential study staff with training in maintaining confidentiality will access your information. Your name, contact information, and other identifying information will be stored in a password-protected, encrypted database. The information you provide through surveys and the interview will be linked to you through a unique study identifier and stored in a secure, password-protected file separate from any identifying information. The interview will be audio-recorded and then typed up. Only study staff and the transcriptionist (typist) will have access to the audio-recordings. The audio recording will be deleted once it has been typed up.

Because this study includes taking part in group sessions with other participants, we cannot guarantee privacy 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. 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 from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your de-identified information with other researchers.

- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

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:

- Your de-identified information with other researchers for future studies.
- Dr. Larissa Mayo Wilson-Jennings at the University of North Carolina-Chapel Hill is a Principal Investigator of this study and will have access to identifiable records.
- 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.
- If you receive any payments of $100 or more 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.

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 future research projects and for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. Your identifiers will be destroyed in 3 years., meaning that we will delete any identifying information that is linked to your study data so that the information collected from you is no longer linked to your name or other identifying information.

After the study is over, we will not keep your name or other information that can identify you directly. 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.

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
Email: kgamarel@umich.edu
Phone: 734-647-3178

Study Coordinator: Ini-Abasi Ubong
Email: iubong@umich.edu
Phone: 734-596-3240

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 2144
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 to Participate in the Research Study
By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and I/we will keep a copy with the study records. 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.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

11. OPTIONAL CONSENT

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.

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.