RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Microeconomic Intervention to Reduce HIV Transmission in Economically Disadvantaged Transgender Women

VCU INVESTIGATOR: Eric Benotsch, Ph.D.

SPONSOR: National Institutes of Health

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

The purpose of this research study is to learn more about the economic situations, discrimination experiences, and risk behaviors of transgender women. The ultimate purpose of the study is to test an intervention to improve financial conditions and reduce HIV risk behaviors in transgender women.

You are being asked to participate in this study because you are a transgender woman.

What will happen if I participate?

In this study you will be asked to participate in a test of a microeconomic intervention.

Some trans women who participate will receive the intervention right away. Others will receive it in six months. Who gets it right away versus later is randomly determined. This is so we can test the effects of the intervention.

If you are randomly assigned to receive the intervention right away, you will come to six sessions on six different days. Each session will last for around 2 ½ hours (around 15 hours total).

If you are randomly assigned to receive the intervention in 6 months, you will come to three sessions on three different days. Each session will last for around 4 hours (12 hours total).

Sessions will be held at VCU or at one of our community partners. We will take breaks and provide food. During the sessions the facilitators will provide education on a variety of topics, including economic services that are available to people living in Richmond, job skills (such as creating a resume and dealing with discrimination at work), personal finance education, gender transition ideas, and HIV prevention. These sessions will occur in a group of about 4-10 transgender women.

Some of the topics to be discussed are personal – for example, discussions about finances and HIV risk behavior. The sessions will be digitally recorded so we are sure to get your ideas and understand how participants are reacting to the sessions, but no names will be recorded on the tape. At the end of each session, we will ask you to complete some questionnaires telling us what you thought of the session – for example, what you liked, what you didn't like, and how we could improve the session. Some questions will be open-ended so you can share your ideas.

Some participants will also receive some financial assistance for finding a job and for gender transition costs. Who receives that financial assistance will be also randomly determined.

If you participate, you will also be asked to complete a questionnaire four times. The questionnaire is a longer version of the questionnaire you completed on a tablet computer.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies. Sometimes discussing these subjects causes people to become upset. Some questions will ask about private things like your sexual behavior. You do not have to answer any questions you do not want to answer and you may leave the study at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

You may not get any direct benefit from this study, but, the information we learn from people in this study may help us design better programs for transgender women. It is possible that you will find some of the information to be useful.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $15.00 per hour (in cash) for your participation in the intervention sessions. For example, if you participate in 15 hours, you will receive a total of $225 or if you participate in 12 hours, you will receive $180.

You will also receive payment for each time you complete the questionnaire. The first time you complete it, we will pay you $20. That amount will go up by $5 for each additional time you complete the questionnaire -- $25 for the second time (3 months later), $30 for the third time (3 months after that), and $35 the fourth time (3 months after that). If you complete all four questionnaires, we will give you an additional $50 bonus.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU
- Officials of the Department of Health and Human Services

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

Audio recordings from this study will be destroyed at the completion of the study.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

In general, we will not give you any individual results from the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. This certificate will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited.

The researchers may share information about you or your participation in the research project without your consent if you indicate an intention to harm yourself or others, as described above.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Eric Benotsch, 804-828-0133 or ebenotsch@vcu.edu

and/or

Laurie Cathers, 804-683-9060 or s2lasaff@vcu.edu

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human_research/volunteers.htm

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date