

Attachment 2 Consent Forms

**Barriers and Facilitators to HIV Prevention, Care, and Treatment Among Transgender Women in
Atlanta, GA, Philadelphia, PA, and Washington, DC
Participant Consent Form – Transgender Women**

Introduction

The Centers for Disease Control and Prevention (CDC) is working with Atlas Research and Abt Associates to do a study. We are studying things that can help prevent HIV. We are also studying things that help transgender women receive better care for HIV.

What we are doing

We are doing this study because we want to learn about how transgender women keep themselves from getting HIV. We also want to know how transgender women take care of themselves if they have HIV and other issues they face. We are doing this study in three cities. This study will include 40 transgender women and 10 healthcare providers. Each will be asked to do a 5-10 minute survey and one-hour interview.

Your participation

We are asking you to be a part of this study. Your participation is completely voluntary. You can stop at any time. You can also skip any question you do not want to answer. If you choose to not be in this study, it will not change the services that you receive with [ADD CBO name], or with your current healthcare provider.

The interview will have questions about things like getting or spreading HIV. It will also ask about your health care and hormone use. It will ask about experiences with violence from a partner. We will also ask about things like your age and race and about your current housing or job status. We are also asking you to give us permission to audio-record the interview. If you do not give your permission to audio-record the interview, you will not be able to participate.

Risks

The risks to you are minimal. These risks may include some stress when answering questions about your HIV status, sexual behavior, and experiences with violence. You can always ask to skip a question if you do not want to talk about them.

Another risk is if someone outside of the study sees your survey or interview information. We will make sure to take the names of people and places out of written or typed notes to protect your privacy. All study papers and computers will be kept in locked cabinets. We will only use password protected computers.

Privacy

For the interview, we will ask you to not say any names of people or places. If you do, we will edit that information when we type up the audio-recording. Instead of your name, we will give you a study ID for your survey and interview. We may report information from interviews and surveys in a presentation or science article. When the study ends, all audio-recordings and notes will be destroyed. If you tell us that you are being harmed, or someone you know is being harmed, we may have to tell someone in case you or they need help.

There will be people checking on our study to make sure that we are doing all of these steps the right way to protect you. These people include members of the Abt Institutional Review Board (IRB), Atlas, and the CDC. All of these people are required to keep your identity private. Any information that could identify you will be kept private and will not be in any report.

"All answers that you give will be kept private. This is because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must

report to the proper authorities suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others."

Data from your interview and survey may be used by other researchers if they have permission from the CDC. Any time we share your information, we will make sure that it only has your study participant number on it and nobody will know your name. Anyone who reads your interview will follow the same rules as we do to keep your identity private.

What are the benefits of being in this study?

Taking part in this research study may not benefit you personally. The information we learn will help us to develop better HIV programs for transgender women.

Token of Appreciation.

If you participate in an interview, you will receive a \$40 gift card.

Cost

There are no costs to you for taking part in this study.

Who to contact if you have been harmed or have any concerns

This study has been approved by the Institutional Review Board (IRB) of Abt Associates. You can call Jamie Hart, at 202-717-8716 or email jhart@atlasresearch.us with any questions about the study. You can also call Cynthia Klein, at 404-946-6310 or email Cynthia_Klein@abtassoc.com. If you have questions about your rights, you can call Katie Speanburg with the Abt Associates IRB at 877-520-6835 with any concerns about taking part in this study.

You do not have to keep a copy of this form. If you would like to keep a copy of this form, you can.

Statement of Agreement to Participate in the Research Study

(answer yes/no)

Do you agree to participate in the study now that I have told you what it is about?

Please confirm that you are 18 years of age or older

Interviewer's Name (Printed)

Interviewer's Signature

Date

Time

**Barriers and Facilitators to HIV Prevention, Care, and Treatment Among Transgender Women in
Atlanta, GA, Philadelphia, MD, and Washington, DC
Consent Form – Healthcare Providers**

Introduction and purpose

The Centers for Disease Control and Prevention (CDC) has funded Atlas Research and Abt Associates to conduct a voluntary study about barriers and facilitators to HIV prevention, care, and treatment among transgender women. This study highlights CDC's ongoing efforts to strengthen HIV prevention efforts for transgender women and other highly affected populations.

What we are doing

As part of this study, we are interviewing HIV-positive and HIV-negative transgender women, and healthcare providers who provide HIV care to transgender women. Interview questions will focus on barriers and facilitators to HIV prevention, care, and treatment experienced by transgender women, the role of healthcare providers in engaging transgender women in protective behaviors, and the role of healthcare providers in engaging transgender women in HIV care and treatment.

Your participation

We are inviting you to voluntarily participate in a 45-60 minute interview about your experiences as a healthcare provider for transgender women; and to complete a short demographic questionnaire (e.g. gender, sexual identity, and race/ethnicity). Please note that we are collecting this personal information from all participating healthcare providers.

Your participation is voluntary. Your decision on whether or not to participate will not affect your position or employment status in any way. If you do agree to participate, you may stop the interview at any time without penalty. You can skip any questions. Additionally, if you were referred by one of your patients, your agreement or disagreement to participate will not be communicated to the person who referred you. We are also asking you to give us permission to audio-record the interview. If you do not give your permission to audio-record the interview, you will not be able to participate.

Privacy

We have developed data security procedures to keep the information collected for this study private. All identifying information will be kept in locked cabinets and on restricted password protected computers and only accessed by authorized study personnel and will not be shared with your employer.

As part of these procedures, we will ask that you do not include individual names or locations in your interview responses. All audio-recordings from the interview will be transcribed by project team members and redacted for sensitive information to the best of our ability. The redacted transcripts and demographic questionnaires will be assigned a unique participant study ID. The redacted transcripts and data from the questionnaires will be provided to CDC in electronic de-identified datasets. All reported data will comply with CDC's Privacy Standards and Data Sharing Policy. All collected data will be used to prepare manuscripts or conference presentations. At the end of our contract, all interview recordings and notes will be destroyed.

The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of Abt Associates' Institutional Review Board (IRB), Atlas, and the CDC. All of these individuals will follow the same rules as we do keep your identity private.

If you consent to participating in this study, you are giving permission to the researchers who are associated with this research project at the CDC to use the data you provide for this study. Data may be used by investigators and team members involved with the research described above, as well as other researchers who have obtained permission from the CDC to use the data from this study for additional research projects. Data will be provided to CDC de-identified.

Risks/discomfort

We do not anticipate any immediate risk from your participation in this study. It should be noted though that there is always a small risk of breach of privacy should the data be lost or stolen and that, given the

relatively small number of participants within each organization, it is possible that your data could be re-identifiable; however, the procedures mentioned in the privacy section are in place to reduce these risks. These data will only be used for research purposes. The risks associated with participation in this study are no greater than those encountered in daily life.

Benefits

There are no direct benefits to you for participating in this study. However, your answers may provide us with information that could be used to develop new strategies and interventions to improve HIV prevention, care, and treatment for transgender women in the United States.

Token of Appreciation. For your participation in the study, you will be provided with \$40 as a token of appreciation for your time.

Cost

There are no costs to you for taking part in this study.

Who to contact if you have been harmed or have any concerns

This research has been approved by the Institutional Review Board (IRB) of Abt Associates. If you have any questions about the study please contact the Principal Investigator, Dr. Jamie Hart, at 202-717-8716 or email jhart@atlasresearch.us. You may also contact the co-Principal Investigator, Dr. Cynthia Klein, at 404-946-6310 or email Cynthia_Klein@abtassoc.com. If you have questions about your rights as a research participant or questions, concerns or complaints this study, you can contact Katie Speanburg with the Abt Associates IRB at 1-877-520-6835. You will receive a copy of this consent for your records.

Statement of Agreement to Participate in the Research Study

(answer yes/no)

Do you agree with the conditions described to voluntarily participate in this study? _____

Please confirm that you are 18 years of age or older

Interviewer's Name (Printed)

Interviewer's Signature

Date

Time