

**Barriers and Facilitators to HIV Prevention, Care, and Treatment among Transgender Women in  
Atlanta, GA, Philadelphia, PA, and Washington, DC (T-Qual)**

**Generic Information Collection Request under OMB #0920-1091**

**Section A: Supporting Statement**

**December 7, 2016**

**CONTACT**

Damian J. Denson, PhD, MPH  
Technical Monitor  
Centers for Disease Control and Prevention  
Division of HIV/AIDS Prevention  
1600 Clifton Road, NE, Mailstop E-37  
Atlanta, GA 30333  
Phone: 404-639-6125  
Fax: 404-639-1950  
E-mail: [dvd5@cdc.gov](mailto:dvd5@cdc.gov)

## TABLE OF CONTENTS

---

1. Circumstances Making the Collection of Information Necessary.....	3
2. Purpose and Use of the Information Collection.....	4
3. Use of Improved Information Technology and Burden Reduction.....	5
4. Efforts to Identify Duplication and Use of Similar Information.....	6
5. Impact on Small Businesses or Other Small Entities.....	6
6. Consequences of Collecting the Information Less Frequently.....	6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	6
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.	6
9. Explanation of Any Payment or Gift to Respondents.....	7
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....	8
11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....	9
12. Estimates of Annualized Burden Hours and Costs.....	9
12A. Estimated Annualized Burden Hours.....	9
12B. Estimated Annualized Burden Costs.....	10
13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....	10
14. Annualized Cost to the Federal Government.....	10
15. Explanation for Program Changes or Adjustments.....	10
16. Plans for Tabulation and Publication and Project Time Schedule.....	11
17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	11
18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	11
References:.....	12

## EXHIBITS

---

Exhibit 2.1: Overview of Key Variables.....	5
Exhibit 12.1: Estimated Annualized Burden Hours.....	9
Exhibit 12.2: Estimated Annualized Burden Costs.....	10
Exhibit 14.1: Annualized Cost to the Government.....	10
Exhibit 16.1: Project Time Schedule.....	11

## LIST OF ATTACHMENTS

---

### **Attachment 1** Recruitment Materials

### **Attachment 2** Consent Form

### **Attachment 3** Data Collection Instruments

- 3a. Eligibility Screener: Transgender Women
- 3b. Demographic Questionnaire: Transgender Women
- 3c. Demographic Questionnaire: Healthcare Providers
- 3d. Interview Guide: HIV-Negative Transgender Women
- 3e. Interview Guide: HIV-Positive Transgender Women
- 3f. Interview Guide: Healthcare Providers

### **Attachment 4** Abt IRB Letter of Approval

### **Attachment 5** Certificate of Confidentiality

- **Goals of the study:** The purpose of this qualitative research study is to identify barriers and facilitators to HIV prevention, care, and treatment among transgender women.
- **Intended use:** Data collected through this study will be used to improve HIV services and programs for transgender women; the results of this study are not intended to be generalized to the larger population.
- **Methods to be used to collect data:** Data will be collected from 50 individuals through semi-structured, in-depth qualitative interviews.
- **The subpopulation to be studied:** Data will be collected from 20 HIV-positive transgender women, 20 HIV-negative transgender women, and 10 healthcare providers who provide care to transgender women. Participants will be recruited from Atlanta, GA, Philadelphia, PA, and Washington, DC.
- **How data will be analyzed:** Qualitative coding and thematic analysis of 50 in-depth interview transcripts using computer-assisted qualitative data analysis software.

## Supporting Statement

### A. Justification

#### 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention’s (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for a qualitative extramural research study entitled, “Barriers and Facilitators to HIV Prevention, Care, and Treatment among Transgender Women in Atlanta, GA, Philadelphia, PA, and Washington, DC (T-Qual)” under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 12/31/2018). CDC will sponsor this data collection activity. Data collection will be carried out by CDC’s contractor, Atlas Research, in conjunction with its subcontracting partner, Abt Associates.

Little research has been conducted to understand the unique complexities surrounding transgender women’s experiences related to HIV prevention, care, and treatment even though HIV incidence is higher among transgender women as compared to other populations. To effectively address the HIV epidemic in this population, more must be known and understood about the nature of transgender women’s risks for HIV infection, and what evidence-based HIV prevention, care and treatment strategies are available and can be adapted to better meet the needs of transgender women. Qualitative research provides a unique opportunity to address these gaps.

According to a 2008 systematic review of 29 studies measuring HIV prevalence among U.S. transgender populations, pooled data from four studies reporting HIV test results indicated a 28% HIV prevalence among transgender women, and data from 18 studies reporting participants’ self-reported HIV status indicated 12% HIV prevalence (Herbst et al., 2008). Furthermore, a higher proportion of African American transgender women have tested positive for HIV infection (56.3%), compared to Latina and White transgender women (Herbst, et al., 2008).

Many transgender women engage in behaviors that increase their risk for HIV infection, including having multiple sex partners, condomless receptive anal sex, alcohol and drug use, and needle exchange for recreational drugs, hormone therapy (HT) or injecting silicone (Bockting, Robinson, & Rosser, 1998; Brennan, et al., 2012; Crosby & Pitts, 2007; Nemoto, Operario, Keatley, & Villegas, 2004). Transgender women are stigmatized and ostracized by society (transphobia), which can make them extremely vulnerable to engaging in sex work and experiencing homelessness. Several studies have shown that perceptions of low risk, low educational attainment and experiencing discrimination from potential employers and society at large, may drive transgender women to engage in sex work to survive (Herbst, et al., 2008; Kosenko, 2011; Nemoto et al., 2004; Sevelius, Patouhas, Keatley, & Johnson, 2014). Along with this, studies have indicated that the need to have gender identity affirmed may lead transgender women to engage in unprotected anal sex with main partners or clients (Crosby & Pitts, 2007; Nemoto, et al., 2004; Sevelius, 2013).

Furthermore, transgender women experience multiple health care needs that are unattended such as behavioral health issues (Nuttbrock, et al., 2013), drug use and abuse (Nemoto et al., 2004; Sevelius et al., 2014), access to safe hormone therapy (Herbst et al., 2008) and antiretrovirals (ARVs) for HIV/AIDS care and treatment (Sevelius et al., 2014). These risk behaviors and unmet healthcare needs unfold in the context of stigma, social isolation, economic necessity, and violence (Herbst, et al., 2008; Kosenko, 2011; Lombardi, Wilchins, Priesing, & Malouf, 2001; Nemoto et al., 2004; Sevelius, 2013).

A study conducted by Sevelius and colleagues (2014) found that transgender women experience several barriers when attempting to engage in HIV prevention, care, and treatment including avoiding HIV testing sites that are not considered trans-friendly, avoiding medical care because of previously experienced transphobia from service providers, prioritization of hormonal treatment over ARVs, concerns about confidentiality (e.g. seeing people they know at the health clinic), drug and alcohol use, and lack of social support and mental health services. Sevelius and colleagues concluded that the single most important facilitator to engage transgender women in care was availability of gender-affirming healthcare, in which healthcare providers were educated in transgender health, and able to provide both HIV care and hormone therapy. Thus, the lack of gender-affirming healthcare was seen as a significant barrier to HIV care. To address this gap in programming, it is important that service providers address the multi-level risks and needs of transgender individuals (e.g. safe space, healthcare, mental health) (Gelaude, Sovine, Swayzer, & Herbst, 2013). Currently there is a dearth of effective HIV prevention and treatment interventions for transgender individuals (Operario & Nemoto, 2010). CDC's Compendium of Evidence-based Interventions and Best Practices for HIV Prevention has not identified any HIV prevention interventions or best practices for transgender participants that satisfy CDC's evidence-based criteria for efficacy (CDC, 2014). Several risk reduction interventions have been developed for transgender women (Bockting et al., 1998; Bockting, Robinson, Forberg, & Scheltema, 2005; Garofalo, Deleon, Osmer, Doll, & Harpe, 2006; Garofalo, Johnson, Kuhns, Cotten, Joseph, & Margolis, 2012; Nemoto et al., 2004; Taylor, Bimbi, Joseph, Margolis, & Parsons, 2011). However, four of the above mentioned interventions have not been rigorously evaluated and two are currently undergoing RCTs (Garofalo et al., 2012; Taylor et al., 2011).

One of the most promising prevention innovations to reduce HIV transmission rates is pre-exposure prophylaxis (PrEP) as a part of a comprehensive HIV prevention approach. The publication of Clinical Practice Guidelines for PrEP by CDC (May 2014) has highlighted an urgency to investigate circumstances that facilitate or hinder access to PrEP. Yet despite years of PrEP research, we know very little about transgender women and PrEP. Unfortunately, studies seldom include transgender women in their sample or they only include small subsamples of transgender women. For instance, a study conducted with both men who have sex with men (MSM) and transgender women on barriers and facilitators to PrEP, included 177 MSM in their sample and only seven transgender women (Golub, Gamarel, Rendina, Surace, & Lelutiu-Weinberger, 2013). Furthermore, a recent analysis of the iPrEx trial found that PrEP could be effective in preventing HIV infection among transgender women. However, transgender women (especially those who are at higher risk for HIV) experience barriers to adherence (Deutsch, et al., 2015). Additional research is needed to increase our understanding of barriers and facilitators to HIV prevention, care and treatment experienced by transgender women at an individual, interpersonal and structural level; as well as the role that their healthcare providers can play in engaging transgender women in protective behaviors.

## **2. Purpose and Use of the Information Collection**

The purpose of this information collection is to conduct in-depth interviews among transgender women and their healthcare providers to identify barriers and facilitators to HIV prevention, care, and treatment. The information collected through this study will also be used to improve local and national HIV prevention and/or treatment services and programs for transgender women.

The planned study design will sample 20 HIV infected and 20 HIV uninfected transgender women identified and recruited through local transgender-serving CBOs, and a small convenience sample of 10 healthcare providers referred by the transgender women participants or identified by study staff. Study instruments will include an in-depth qualitative interview with both closed and open-ended questions. Participants will be selected from three Metropolitan Statistical Areas (MSAs) with high HIV prevalence: Atlanta, GA; Philadelphia, PA; and Washington, DC. Due to potential challenges in identifying and recruiting transgender women, we anticipate that multiple sampling and recruitment strategies will be utilized to ensure an adequate number of participants.

We will use qualitative, in-depth interviews to collect data for this study (**Attachments 3d-f**). Interviews will include a short, structured response instrument to collect participants' demographic information (**Attachments 3b-c**). The in-depth interviews will primarily include open-ended questions with some closed-ended questions designed to elicit information on HIV prevention, care and treatment among transgender women in the jurisdictions (**Attachments 3d-f**). Key variables to be explored through the interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the Abt Associates IRB (**Attachment 4**).

CDC, in partnership with the contractor staff, will identify and develop appropriate dissemination opportunities for these findings. The results of this study are not intended to be generalized to the larger population. CDC and/or its partners may also analyze these data and publish results in peer-

reviewed journals. Stakeholders from the participating CBOs will also be briefed by contractor staff on the study findings (e.g., memo summarizing findings).

**Exhibit 2.1: Overview of Key Variables**

<b>HIV-positive and HIV-negative Transgender Women (Attachments 3d-e)</b>	<b>Healthcare Providers (Attachment 3f)</b>
<ul style="list-style-type: none"> <li>• Demographics</li> <li>• HIV testing</li> <li>• HIV prevention</li> <li>• HIV care and treatment</li> <li>• Transition-related care and treatment</li> <li>• Experiences with ancillary services</li> <li>• HIV risk behaviors</li> <li>• Insurance and assistance programs</li> </ul>	<ul style="list-style-type: none"> <li>• Demographics</li> <li>• Practice type</li> <li>• Services provided</li> <li>• Professional training</li> <li>• Experience providing HIV prevention, care, and treatment</li> <li>• Experience providing care to transgender patients</li> <li>• Experience providing transition related care</li> </ul>

**3. Use of Improved Information Technology and Burden Reduction**

The contractor will conduct individual interviews at a time and location that is convenient to the selected key participants. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and respondent for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer’s ability to read both. Thus, the contractor will conduct the individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, the contractor will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

**4. Efforts to Identify Duplication and Use of Similar Information**

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of the contract, and determined that this study is collecting unique information from the populations. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

**5. Impact on Small Businesses or Other Small Entities**

This study will partner with transgender-serving community based organizations to aid in recruiting potential respondents by identifying eligible potential participants through their routine and regularly occurring activities and referring them to the study. We do not anticipate substantial burden.

**6. Consequences of Collecting the Information Less Frequently**

The present study will provide the primary qualitative data needed to understand barriers and facilitators to HIV prevention, care, and treatment among transgender women at the greatest risk for HIV infection and transmission in the U.S. If this evaluation were not conducted, it would not be possible to identify barriers and facilitators and to use this information to strengthen HIV prevention, care, and treatment with these vulnerable populations. The length of data collection is 2-3 months and data will only be collected once.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This data collection effort does not involve any special circumstances.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

A 60 day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 02/24/2015, Volume 80, Number 36, Page Number 9727-9728. No public comments were received.

In addition, the following contractor staffs at Atlas Research and Abt Associates were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

<p>Jamie Hart, PhD, MPH Senior Project Investigator Vice President Atlas Research 805 15th St NW #910 Washington, DC 20005 202-717-8716 <a href="mailto:jhart@atlasresearch.us">jhart@atlasresearch.us</a></p>	<p>Julia Rollison, PhD Director of Research and Evaluation Atlas Research 805 15th St NW #910 Washington, DC 20005 240-717-8710 <a href="mailto:jrollison@atlasresearch.us">jrollison@atlasresearch.us</a></p>
<p>Clarke Erickson, MPA Project Manager, Data Collection Lead Atlas Research 805 15th St NW #910 Washington, DC 20005 202-717-8080 <a href="mailto:cerickson@atlasresearch.us">cerickson@atlasresearch.us</a></p>	<p>Joanne Keatley, MSW Consultant University of California – San Francisco Center of Excellence for Transgender Health 415-476-6146 <a href="mailto:joanne.keatley@ucsf.edu">joanne.keatley@ucsf.edu</a></p>
<p>Alex Mijares, MPH Data Analysis Lead</p>	<p>Cynthia Klein, PhD Senior Qualitative Research Advisor</p>

Abt Associates 2200 Century Parkway, Suite 950 Atlanta, GA 30345 404-946-6378 <a href="mailto:Alex_Mijares@abtassoc.com">Alex_Mijares@abtassoc.com</a>	Abt Associates 2200 Century Parkway, Suite 950 Atlanta, GA 30345 404-946-6310 <a href="mailto:Cynthia_Klein@abtassoc.com">Cynthia_Klein@abtassoc.com</a>
Marian Creasy Data Collection Analysis Abt Associates 4550 Montgomery Ave Suite 800N Bethesda, MD 20814 301-347-5732 <a href="mailto:Marian_Creasy@abtassoc.com">Marian_Creasy@abtassoc.com</a>	

**9. Explanation of Any Payment or Gift to Respondents**

Interview participants will each receive a \$40 token of appreciation in the form of gift cards or money orders. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses.<sup>1,2</sup>

Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups into research. In a recent study of recruitment and retention of Black men who have sex with men (BMSM) by a Community Based Organization (CBO), recruiters found it difficult to obtain information from the BMSM because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program.<sup>3</sup> Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later. In this study, offering a token of appreciation improved participation among BMSM.<sup>3</sup> A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons’ enrollment and retention in research studies found that remuneration enhanced retention among this group.<sup>4</sup>

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included similar populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

**10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The NCHHSTP PRA Coordinator has reviewed this project and determined the Privacy Act does not apply since personally identifiable information (PII) will not be transmitted to the CDC.

We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the



CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals’ data will be kept private and protected to the extent permitted by law.

In addition, the study plans to utilize a Certificate of Confidentiality to protect the privacy of respondents enrolled in the study. The certificate protects respondents by withholding from all persons not connected with the conduct of such research, the names or other identifying characteristics of respondents without their consent (**attachment 5**).

**11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

IRB Approval

This study has been reviewed and approved by the Abt Associates’ IRB (**Attachment 4**).

Sensitive Questions

This study is an initiative aimed to understand barriers and facilitators to HIV prevention, care, and treatment among transgender women at greatest risk for HIV infection and transmission. As such, our information collection entails measurement of sensitive HIV-related information. All contracting staff will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations as needed. No sensitive information will be collected during the semi-structured interviews with healthcare providers about the people they work with or any specific patients. We will inform all participants that they may skip any question or stop participation at any time for any reason.

**12. Estimates of Annualized Burden Hours and Costs**

Exhibits A12.1 and A12.2 provide details about how the estimates of burden hours and costs were calculated. We calculated the overall burden per respondent by multiplying the frequency of response by the time to complete each data collection item. We anticipate that screener forms will take 5 minutes to complete. We anticipate 50 percent of transgender women screened will be eligible for the study. Healthcare providers will be referred to the study directly from the transgender women study participants, so they will not be screened. The in-depth interviews for transgender women and healthcare providers are expected to take a total of 60 minutes (1 hour) each. We will complete interviews for 40 transgender women and 10 healthcare providers in Atlanta, GA, Philadelphia, PA, and Washington, DC. We anticipate screening 80 potential transgender women respondents. The total number of burden hours is 61.

**12A. Estimated Annualized Burden Hours**

**Exhibit 12.2: Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Eligibility Screener: Transgender Women (Att. 3a)	80	1	5/60	7

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Demographic Questionnaire: Transgender Women (Att. 3b)	40	1	5/60	3
General Public-Adults	Demographic Questionnaire: Healthcare Providers (Att. 3c)	10	1	5/60	1
General Public-Adults	Interview Guide: HIV-Negative Transgender Women (Att. 3d)	20	1	1	20
General Public-Adults	Interview Guide: HIV-Positive Transgender Women (Att. 3e)	20	1	1	20
General Public-Adults	Interview Guide: Healthcare Providers (Att. 3f)	10	1	1	10
<b>Total</b>					<b>61</b>

## 12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.3. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2015 ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately \$1,417.03. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate (\$23.23).

### Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Eligibility Screener: Transgender Women (Att. 3a)	7	\$23.23	\$162.61
General Public-Adults	Demographic Questionnaire: Transgender Women (Att. 3b)	3	\$23.23	\$69.69
General Public-Adults	Demographic Questionnaire: Healthcare Providers (Att. 3c)	1	\$23.23	\$23.23
General Public-Adults	Interview Guide: HIV-Negative Transgender Women (Att. 3d)	20	\$23.23	\$464.60

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Interview Guide: HIV-Positive Transgender Women (Att. 3e)	20	\$23.23	\$464.60
General Public-Adults	Interview Guide: Healthcare Providers (Att. 3f)	10	\$23.23	\$232.30
<b>Total</b>				<b>\$1,417.03</b>

### 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

### 14. Annualized Cost to the Federal Government

The estimated annualized cost to carry out the data collection activities is \$476,304. This estimate includes the cost of recruitment, screening, conducting the interviews, analysis and reporting, as well as the total cost of the tokens of appreciation (\$40 per completed interview, for a total of \$2,000).

#### Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC COR (GS-14 0.20 FTE)	\$23,362
	CDC Technical Monitor (GS-13, 0.20 FTE)	\$19,770
	CDC Scientist (GS-14, 0.10 FTE)	\$9,885
	CDC Project Coordinator (GS-12, 0.30 FTE)	\$23,471
	<b>Subtotal, Direct Costs</b>	<b>\$76,488</b>
Contract Costs	<b>Annual Contract Costs (Atlas, #200-2013-57341)</b>	<b>\$399,816</b>
	<b>TOTAL COST TO THE GOVERNMENT</b>	<b>\$476,304</b>

### 15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

### 16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of respondents collected in the first part of the interview (e.g., city, age, race/ethnicity, job category). Data collection will occur between January to April 2017, analyses will be carried out in May – July 2017, and the final data set and report will be submitted in August 2017. The project timeline is detailed in exhibit 16.1.

#### Exhibit 16.5: Project Time Schedule

--	--

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol, IRB and PD approvals	October - July 2016
OMB Submission	October 2016
Recruitment	After OMB Approval
Data Collection	1-4 months after OMB Approval
Data analysis finalized and report drafted	5-7 months after OMB Approval
Final data set and final report submitted to CDC	8 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation, which will be made publicly available within 30 months of the end of data collection.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

We do not seek approval to eliminate the expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exemptions to the certification.

## References:

- Baral, S., Logie, C. H., Grosso, A., Wirtz, A. L., & Beyrer, C. (2013). Modified social ecological model: a tool to guide the assessment of the risks and risk contexts of HIV epidemics. *BMC Public Health* , 13 (482), 1-8.
- Bockting, W. O., Robinson, B. E., & Rosser, B. R. (1998). Transgender HIV Prevention: A qualitative needs assessment. *AIDS Care* , 10, 505-526.
- Bockting, W., Robinson, B., Forberg, J., & Scheltema, K. (2005). Evaluation of a sexual health approach to reducing HIV/STD risk in the transgender community. *AIDS Care* , 17 (3), 289-303.
- Brennan, J., Kuhns, L. M., Johnson, A. K., Belzer, M., Wilson, E. C., & Garofalo, R. (2012). Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. *American Journal of Public Health* , 102 (9), 1751-1757.
- Crosby, R. A., & Pitts, N. L. (2007). Caught between different worlds: how transgendered women may be "forced" into risky sex. *Journal of Sex Research* , 44 (1), 43-48.
- Deutsch, M. B., Glidden, D. V., Sevelius, J., Keatley, J., McMahan, V., Guanira, J., et al. (2015). HIV pre-exposure prophylaxis in transgender women: A sub-group analysis of the iPrEx trial. *The Lancet* .
- Garofalo, R., Deleon, J., Osmer, E., Doll, M., & Harpe, G. (2006). Overlooked, misunderstood and at-risk: Exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *J Adolesc Health* , 38, 230-236.
- Garofalo, R., Johnson, A., Kuhns, L., Cotten, C., Joseph, H., & Margolis, A. (2012). Life Skills: Evaluation of a theory-driven behavioral HIV prevention intervention for young transgender women. *J Urban Health* , 89 (3), 419-31.
- Gelaude, D. J., Sovine, M. L., Swayzer, R. I., & Herbst, J. H. (2013). HIV Prevention Programs Delivered by Community-Based Organizations to Young Transgender PErsons of Color: Lessons Learned to Improve Future Program Implementation. *International Journal of Transgenderism* , 14, 127-139.
- Golub, S. A., Gamarel, K. E., Rendina, J., Surace, A., & Lelutiu-Weinberger, C. L. (2013). From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence among MSM and Transgender Women in New York City. *AIDS Patient Care and STDs* , 27 (4), 249-254.
- Herbst, J. H., Jacobs, E. D., Finlayson, T. J., McKleroy, V. S., Neumann, M. S., & Crepaz, N. (2008). Estimating HIV Prevalence and Risk Bheaviors of Transgender Person in the United States: A Systematic Review. *AIDS Behavior* , 12 (1), 1-17.
- Kosenko, K. A. (2011). Contextual influences on sexual risk-taking in the transgender community. *Journal of Sex Research* , 48 (2-3), 285-296.

Lombardi, E., Wilchins, R. A., Priesing, D., & Malouf, D. (2001). Gender violence: transgender experiences with violence and discrimination. *J Homosex* , 42 (1), 89-101.

Nemoto, T., Operario, D., Keatley, J., & Villegas, D. (2004). Social context of HIV risk behaviours among male-to-female transgenders of colour. *AIDS Care* , 16 (6), 724-35.

Nemoto, T., Operario, D., Keatley, J., Han, L., & Soma, T. (2004). HIV Risk Behaviors Among Male-to-Female Transgender Persons of Color in San Francisco. *American Journal of Public Health* , 94 (7), 1193-1199.

Nuttbrock, L., Bockting, W., Rosenblum, A., Hwahng, S., Mason, M., Macri, M., et al. (2013). Gender abuse, depressive symptoms, and HIV and other sexually transmitted infections among male-to-female transgender persons: a three year prospective study. *American Journal of Public Health* , 103 (2), 300-307.

Operario, D., & Nemoto, T. (2010). HIV in Transgender Communities: Syndemic Dynamics and the need for Multi-component Interventions. *Journal of Acquired Immune Deficiency Syndrome* , 15 (2), S91-S93.

Sevelius, J. M. (2013). Gender Affirmation: A framework for conceptualizing risk behavior among transgender women of color. *Sex Roles* , 68 (11-12), 675-689.

Sevelius, J. M., Patouhas, E., Keatley, J. G., & Johnson, M. O. (2014). Barriers and facilitators to engagement and retention in care among transgender women living with Human Immunodeficiency Virus. *Annals of Behavioral Medicine* , 47, 5-16.

Taylor, R., Bimbi, D., Joseph, H., Margolis, A., & Parsons, J. (2011). Girlfriends: Evaluation of an HIV-risk reduction intervention for adult transgender women. *AIDS Educ Prev* , 23 (5), 469-478.