Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (NHBS-Trans)

#0920-NEW

NEW Information Collection Request

April 23rd, 2019

Supporting Statement
Part A

CONTACT:

Cyprian Wejnert, PhD
Team Lead, Behavioral Surveillance Team
National Center for HIV, Hepatitis, STD and TB Prevention
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS E-46
Atlanta, Georgia 30333
Phone: (404) 639-6055
Fax: (404) 639-8640
E-mail: DWY7@CDC.GOV

Table of Contents

48.	7b		49. Recruiter Debriefing Form (Spanish)
50.	8	51.	Recommendations For Revising The National HIV Behavioral Surveillance Core Research Questionnaire For Use In A Future Study With Transgender Women
52.	9		53. Assurance of Confidentiality for HIV/AIDS Surveillance
54.	10		55. Agreement to Abide by Restrictions on Release of Surveillance Data
56.	11	57.	Model Consent for Survey Activities
58.	12	59.	Project Determination (Approved 9/6/2017)
60.	13	61.	Privacy Impact Assessment
62.	14		63. NHBS-Trans Survey Crosswalk

64.
65.

66.

- **Goals of the study:** The purpose of this pilot study is to demonstrate the feasibility of a national surveillance system to obtain data on HIV risk behaviors, gaps, barriers to service and other experiences of transgender (TG) women within racial and ethnic minority populations in 9 U.S. cities with high burden of HIV.
- **Intended use:** This pilot study seeks to assess the acceptability, feasibility and performance of National HIV Behavioral Surveillance (NHBS) instruments, sampling and recruitment methods among transgender women.
- **Methods to be used to collect data:** This 2-year project will pilot methods, best practices, and existing infrastructure from CDC's NHBS to collect data from transgender women. A one-on-one, CAPI-based pilot survey will be administered by trained interviewers for each participant.
- **The subpopulation to be studied:** 1,800 transgender women; 200 living in each of 9 MSAs (Atlanta, GA, Dallas, TX, Los Angeles, CA, New Orleans, LA, New York City, NY, Philadelphia, PA, San Francisco, CA, Seattle, WA or Washington, D.C.)
- **How data will be analyzed:** Quantitative analysis of 1,800 surveys using SAS. Quantitative analysis of grantee procedural data using SAS, including recruitment rates, recruitment refusals, willingness to consent to HIV and/or STI testing, receipt rate of testing results, and grantee process monitoring data.

67.

68. **A. JUSTIFICATION**

69.

70. **A.1 - CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY**

71.

72. The Division of HIV and AIDS Prevention of the Centers for Disease Control and Prevention (CDC) requests approval for a new data collection called Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (NHBS-Trans), to be conducted over the period of two years. This data collection effort is a new pilot study to examine the feasibility of extending the proven framework and goals of National HIV Behavioral Surveillance (NHBS) (OMB#: 0920-0770, exp. May 31, 2020) to transgender (TG) women. NHBS is CDC's ongoing surveillance system to assess HIV prevalence and factors associated with HIV among populations at high risk for HIV, including men who have sex with men (MSM), people who inject drugs (PWID), and heterosexuals at increased risk for HIV. Like TG women, these populations are all "hidden," meaning that they cannot be accessed through standard sampling methodologies because no sampling frame exists from which to recruit a sample. Hidden populations are typically characterized by being rare and/or stigmatized in the

general population. NHBS has a 15-year track record of successfully reaching and recruiting hidden populations. This project seeks to reduce cost and burden associated with developing a new surveillance system by piloting the application of the existing NHBS framework, mechanisms, and processes to reach TG women. The pilot study will provide methodological data which will answer a series of study design issues that impact the design and implementation of an ongoing surveillance system for TG women. If the pilot design and implementation are feasible, the pilot study may also provide baseline data to local communities on the health and HIV risk of TG women.

73. To properly test NHBS methodologies among this population, particularly the respondent-driven sampling (RDS) methods and resulting network analysis upon which NHBS cycles are established, a minimum sample size of 200 socially-interconnected participants per site is required. Core NHBS cycles require a sample size of 500, which is larger than needed for the purposes of this pilot study. Sample size must also be sufficient within sites to support meaningful analysis of TG subpopulations in each participating MSA. The outcomes of this pilot study may lead to additional information collection requests in the future. If NHBS methods can be feasibly applied with TG women, these findings may be used to justify a future expansion of NHBS to include TG women. If this pilot study indicates significant limits on the feasibility of NHBS methods with this population, these findings may be used to develop an alternative surveillance systems better suited to TG women.

74.

75. **A.2 – PURPOSE AND USE OF THE INFORMATION COLLECTION**

76.

77. Transgender (TG) women are at high risk for HIV infection. HIV prevalence estimates in this population have varied, ranging from 3% to 60% for self-reported HIV infection; 16% to 68% for laboratory-confirmed HIV infection (Herbst, Jacobs, Finlayson, McKleroy, Neumann & Crepaz, 2008). In this systematic review, 29 studies met the review inclusion criteria, a list of which can be found in the citation mentioned above. The broad range in estimates is primarily due to the differences in sampling designs and geographic variation in study sites within the U.S. and highlights the need for robust, multi-site data on this population. Compared with white TG women, HIV prevalence estimates are higher among African American or black (hereafter referred to as black) TG women (Herbst et al., 2008). Factors contributing to HIV infection among TG women include condomless sex, survival sex, injection drug use, hormone and silicone injection, unstable housing, and depression and anxiety (Herbst et al., 2008; Budge, Adelson & Howard, 2013; Brennan, Kuhns, Johnson, Belzer, Wilson & Garofalo, 2012). In addition, TG women often face barriers to healthcare, including lack of health insurance and culturally competent healthcare

providers, that can increase risk for HIV and hinder HIV treatment (Mizuno, Frazier, Huang & Skarbinski, 2015). The establishment of a national HIV behavioral surveillance system for TG women is therefore an important initial step to understanding and reducing the disproportionately high burden of HIV on TG women, particularly TG women of color. High-quality data collected through rigorous means are needed to better understand prevalent risk factors and prevention needs in order to meet the goals set forth in the End the HIV Epidemic initiative.

78.

79. While several limited studies of HIV risk and prevalence have been conducted with TG women, no public health surveillance system has focused on TG women. Little is known about how to design a multi-site surveillance system for TG women that can function across the varied demographic and cultural demarcations observed from site to site. Most surveillance systems either exclude TG participants, or include too few participants to draw meaningful conclusions that are specific to TG experiences. Testing the feasibility of a multi-site surveillance system for TG women is an important step in monitoring not only the prevalence of HIV among TG women, but also behavioral and environmental HIV risk factors that contribute to the disproportionately high prevalence of HIV within this population, particularly among TG women of color.

80.

81. Ongoing surveillance of HIV risk behaviors, gaps and barriers to services, and other experiences of TG women within racial and ethnic minority populations is particularly important to local, state, and federal public health programs. It helps these groups identify areas for community-level interventions, track the progress of communities in implementing change, and evaluate interventions that seek to reduce HIV risk factors and increase engagement in HIV prevention and care. CDC's current HIV behavioral surveillance efforts mainly focus on groups at higher risk for HIV, including men who have sex with men, people who inject drugs, and heterosexuals at increased risk for HIV, as well as people living with HIV. However, the proposed data collection extends the breadth of NHBS's behavioral surveillance activities and fills a critical gap by determining the feasibility of a surveillance system for reaching TG women and collecting quality data from this underserved population, for whom prevalence of HIV may exceed that of other high-risk groups already covered by HIV surveillance. The proposed NHBS-Trans project would establish best practices for local and national HIV behavioral surveillance among minority TG women and, if successful, provide limited baseline data on HIV prevalence and factors associated with HIV among TG women.

82.

83. *Efforts in assessing the programmatic and surveillance needs of U.S. transgender women.* This effort to develop a surveillance system to measure HIV risk behaviors, gaps and barriers to

services, and other experiences of TG women within racial and ethnic minority populations, is influenced by previous work conducted by NIH on recommended research opportunities, methodologies and measurements to engage TG women in the United States (IOM, 2011). This previous effort identified limitations and gaps in the existing pool of TG-focused studies, suggesting future efforts should aim to address limitations including: collecting further data towards a standardized measure of gender identity in federal surveys; determining the feasibility of collecting probability samples with sufficient subgroup participation to produce meaningful subgroup estimates; and developing a national sampling strategy that can describe the needs of U.S. TG women. In particular, the lack of national-level probability sampling among TG women was cited as an obstacle for the advancement of TG health in the United States. However, at this time, there are no established Federal guidelines for collecting information from TG women. In the proposed data collection, CDC seeks to inform this challenge by determining the feasibility of applying NHBS methods—a set of methodologies developed to systematically assess HIV risk behaviors, gaps and barriers to services among hidden or stigmatized populations across multiple cities—to TG women.

A.2.b - STUDY OVERVIEW

The pilot study has been designed to demonstrate the feasibility of a national surveillance system to produce local and aggregate estimates by incorporating methods to optimize both response rates and completeness of data. It will also identify implementation barriers and possible solutions for overcoming them in a systematic way. This pilot study will assess the feasibility of a survey and supporting data collection methodologies to obtain data on HIV risk behaviors, gaps and barriers to services, and other experiences of TG women within racial and ethnic minority populations in 9 U.S. cities with high burden of HIV. The following are the specific methodological objectives of the pilot study:

- **Objective 1**: Assess the feasibility of existing NHBS sampling methods, mechanisms, and processes to recruit TG women for HIV surveillance across diverse cities.
- **Objective 2**: Assess the acceptability and feasibility of a full-length interview focusing on sensitive topics associated with HIV infection (sex, drug use, stigma, etc.) among TG women.
- **Objective 3**: Test performance, acceptability, and effectiveness of measuring gender identity and sex at birth as eligibility criteria for behavioral surveillance among transgender populations, and other gender-diverse populations.

Objective 4: Provide critically needed, preliminary data on HIV associated risk and prevention behaviors, including HIV prevalence, as well as on the lived experience of TG women in 9 cities for public health use at the local and national levels.

Objective 1: The pilot study tests the implementation of the NHBS study protocol to recruit a hidden population using respondent-driven sampling (RDS) when minimally adapted for TG participants. The pilot will include 9 metropolitan statistical areas (MSAs) in 8 states -- Atlanta, GA, Dallas, TX, Los Angeles, CA, New Orleans, LA, New York City, NY, Philadelphia, PA, San Francisco, CA, Seattle, WA, and Washington, D.C. These MSAs are regionally and demographically diverse. Because TG communities vary in population size and demography, conducting the pilot in multiple, diverse cities is critical to assessing feasibility for a national system. To identify and address the data collection methodological issues, CDC will conduct continuous monitoring of data collection efforts in each grantee site, to check whether process indicators—such as screening rates, eligibility rates, survey completion rates, recruitment diagnostics, and, willingness to undergo HIV testing—indicate significant gaps or barriers to recruitment. A CDC project officer will be assigned to each grantee to monitor data collection efforts. CDC project officers will meet weekly to discuss challenges, successes, and strategies to address challenges. When needed, CDC will direct grantee sites to adjust their operations to address data collection problems. Operational indicators (screening rates, eligibility rates, survey completion rates, recruitment diagnostics, data quality) will be assessed using the final data at the local and national levels to develop lessons learned, best practices, and recommendations to inform future surveillance efforts among TG women.

Objective 2: The length and content of a typical behavioral surveillance questionnaire among populations at risk for HIV can be barriers to participation. Assessing the acceptability and feasibility of a full-length interview is critical to a complete evaluation of the pilot. The transmission routes of HIV are inherently sensitive and require detailed information of sexual and drug use behaviors as well as access to and receipt of healthcare and other prevention services. Further, the challenges of recruiting hidden populations and the complex social, economic, and cultural contexts associated with certain risk behaviors require context information that precludes short surveys. The NHBS-Trans Interview (**Attachment 6a [English] & 6b [Spanish]**) includes 268 items that cover standard HIV associated topics included in NHBS as well as items that are specific to the experiences of TG women. The NHBS-Trans instrument was developed starting with the NHBS

instrument. Items requiring edits were identified (e.g., sexual behavior questions that assume genitalia based on gender). A contractor conducted a literature review to identify all TG specific surveys or survey items. The literature review resulted in identification of 170 articles and 24 individual survey instruments. All identified, publically available items were considered for inclusion based on expert review and relevance to HIV. A community advisory board (CAB) made up of less than 9 national TG experts representing all regions of the U.S. provided feedback on the items and content. Of 150 constructs included in the survey, 97 were sourced from OMB-approved data collection instruments (National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2020) and the Medical Monitoring Project (OMB 0920-0740, exp. 06/30/2021)). The source of an additional 29 constructs were academic research studies (not federal collections) including The Fenway Health Patient Survey, Atlanta Homelessness Youth Count and Needs Assessment, Transgender Veteran Survey, TransPulse Provincial Survey, Los Angeles Transgender Health Survey, Transgender Empowerment and Community Health survey, American Men's Internet Survey, and Project STRONG. Two validated scales are included in the study: Multidimensional Scale of Perceived Social Support (MSPSS) and the Transgender Congruence Scale (TCS). The remaining 22 constructs are a combination of modified survey items from National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2020) or new survey items included at the direction of the CAB, identified as priority constructs to obtain a complete picture of HIV risk and prevention behaviors. A number of constructs that fall in this category required minor modification in order to use language appropriate for a population of TG women. Please note, the number of constructs does not match up to the total number of the questions due to some constructs being comprised of multiple survey items. For example, the Kessler Psychological Distress Scale (K6) is listed as a single construct but is comprised of 6 survey items. A detailed list of constructs and their source can be found in the table included in Attachment 8 on pages 10-22. New and potentially challenging items were cognitively tested by 8 TG women recruited from 3 U.S. cities. The hidden stigmatized nature of TG women prevented recruitment of more participants for the CAB and cognitive testing. Identities of CAB and cognitive testing participants were intentionally withheld from CDC. A recommended survey instrument was then provided to CDC along with a detailed report of these activities (**Attachment 8**). The recommended survey instrument included 408 items and was estimated to take 60 minutes to complete. CDC reduced the final instrument to 268 items and 40 minutes in order to reduce participant burden. Prior experience from the implementation of National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2020) has shown that 60 minutes places undue burden on participants and may increase nonresponse when the survey instrument contains questions of a sensitive nature. The

main assessment used in the reduction of questions and shortening of the instrument was each construct's and measure's relation to HIV risk and transmission. It was a priority for validated scales to remain intact and to minimize the use of measures that had not been previously included on OMB-approved survey instruments. It was also necessary to consider the level of detail that could be collected on a given topic. For example, sexual behavior questions were limited to those most likely to contribute to HIV transmission and rather than ask about the last 5 sexual partners, questions were limited to the last 3 sexual partners. Although many survey items that were ultimately cut for time may collect important data, the priority was to avoid overburdening the participants.

101.

102. In addition to factors directly associated with HIV transmission (sexual behavior, drug use, HIV testing, healthcare access, etc.) the instrument includes topics relevant to life experience, health, and well-being of TG women (discrimination in work and housing, access to transgender competent health care, suicidality and self-harm). These topics are important for understanding the context within which HIV risk behaviors occur and the barriers to HIV prevention and treatment. Further, feedback from TG experts and the CAB strongly indicated that these topics are necessary for the success of the project because many TG women view external interest in the TG community as only interested in their sexual behavior. A survey primarily focusing on sex and drug use behaviors, without soliciting information about other health topics and experiences important to TG women would reinforce this view, damaging community rapport with the local health department and alienating potential participants.

103.

104. During the development of the recommended survey instrument, new and potentially challenging items were cognitively tested by 8 TG women recruited from 3 U.S. cities. All persons gave positive feedback about the survey, voicing their appreciation that this topic is being researched. Some participants expressed embarrassment regarding the more personal and sensitive questions regarding the number of sex partners. In the final survey instrument, it is reiterated that participants do not have to answer any questions that make them feel uncomfortable. Overall, participants were well-versed in issues related to the transgender community, and were able to understand the various types of gender identity, sexual identity, and sexual intercourse definitions referenced throughout the survey.

105.

106. The contents of the final interview survey are summarized in a crosswalk document, linking each section of the survey to the project's programmatic and research objectives (**Attachment 14**). As described previously, the majority of the NHBS-Trans survey instrument is composed of unmodified sections of the Core Round 5

NHBS survey instrument (OMB No. 0920-0770, exp. 5/31/2020). Some sections from the Core Round 5 NHBS survey were modified to better accommodate transgender participants, based on the recommendations of our consulting contractors and community advisors. Finally, five Trans-specific sections were added at the suggestion of our consulting contractors and community advisory board, as these sections collect information specifically relevant to HIV risk among transgender populations (Gender Identity, Medical Gender Affirmation, Other Injections, Discrimination and Abuse & Harassment). The first 3 rows of the crosswalk document indicate which sections are entirely unmodified from Core NHBS, which have been modified per recommendations, and which sections were adapted from other transgender research projects. The remaining rows indicate which sections of the survey address our project objectives.

107.

108. **Objective 3**: There is not a standardized measure of gender identity currently recommended for federal surveys. Measurement of gender identity in the general population is complicated by the competing need to accurately capture a complex and nuanced topic among transgender persons while also remaining clear and understandable to cisgender persons (i.e., people who are not transgender) who may have no awareness or concept of gender beyond physical anatomy.

109.

110. Several studies have examined the comprehensibility and acceptability of transgender-inclusive gender identity measures among subjects who do not identify as transgender. For the general population, gender identity is typically measured using two items: 1) a measure of physical sex at birth and 2) a 3 or 4 category measure of gender identity that includes “male”, “female”, and either a catch all “transgender” category or masculine and feminine versions of “transgender.” However, transgender-identified respondents report difficulty indicating their gender identity accurately when presented with response options that don’t adequately differentiate between TG subgroups (Reisner, Conron, Tardiff, Jarvi, Gordon & Austin, 2014).

111.

112. While this project utilizes the common 2-step format, the gender identity question provides 5 check-all-that-apply response categories, including an “other – specify” option for write-in responses.

113. Some have suggested that more-inclusive gender identity response options may be incomprehensible or unacceptable to general populations.

114. However, while transgender-identified respondents are more likely than non-transgender counterparts to accept and understand these questions, the majority of cisgender respondents indicated their ability to comprehend transgender-inclusive gender identity measures, with no significant impact on the veracity of their

responses or the acceptability of the survey items (Martinez, Henderson & Luck, 2016; Reisner et al., 2014; Cahill, Singal & Grasso, 2014).

The target population for this project includes only transgender participants, with exclusion criteria designed to exclude participants who are not transgender. Accordingly, we've selected a measure of gender identity that best reflects the lived experience of our target population, one which measures gender identity in a way that acknowledges that gender identity need not be static, singular, or simple.

Any participants who report being male sex at birth and a non-masculine gender identity will be eligible to participate. Feedback from the CAB and our grantees with direct knowledge of their local transgender communities suggest that gender identity may be highly sensitive and regional, but little data are available to inform how these differences might be standardized. The check-all-that-apply measure of gender will provide critical data on how TG women report gender identity on surveys and which subgroups of TG women would be included using simpler gender identity measures. More importantly, the assessment will inform inclusion in future surveillance of TG women based on HIV risk. Feedback from the CAB and our grantees with direct knowledge of their local transgender communities suggested many TG women may not identity as such, but instead identify as "gender queer" or "non-binary" or another identity. What was not clear from this feedback, or from the literature, is whether the HIV risk associated with being a TG woman also applies to these other genders. Analysis of the project data will include an assessment of gender measurement and recommendations for gender inclusion for future surveillance based on HIV risk.

Objective 4: Data on factors associated with HIV among TG women are limited for a number of reasons.

1) TG persons make up an estimated 0.6% of the general population (Flores, Herman, Gates & Brown, 2016) and are not numerous enough in most data sets focusing on broader populations for meaningful analysis.

2) Data systems designed for other populations may omit information critical to addressing TG-specific social, economic, and biological circumstances, such as gender identity and expression, sex behavior, stigma, discrimination, abuse, and social support from friends and family.

3) Many standard data collection forms lack appropriate ways to distinguish TG persons from cisgender males and females (http://www.transhealth.ucsf.edu/trans?page=lib-data-collection).

4) Data about the sexual risk behaviors of TG persons, such as condomless vaginal and anal sex, are not easily captured in typical behavioral surveys because sexual behaviors are inherently linked to genitalia, which is often assumed from participant gender.

Depending on the data quality and a full understanding of the limitations and potential biases, these data may provide important baseline information locally and nationally to help inform HIV prevention efforts among TG women. While the primary goals of the project are to pilot methods and implementation, the project is anticipated to be successful and provides a strong opportunity to conduct limited analysis and while further surveillance enhancements are developed.

Geographic Locations: NHBS-Trans activities were included as part of the existing NHBS cooperative agreement (RFA-PS16-1601). Of the 22 funded NHBS health departments, 13 applied to participate in NHBS-Trans. Those applications were reviewed and scored by a CDC objective review panel based on the applicants' previous experience with surveillance or research activities among TG women, ability to partner with organizations serving TG women, and ability to meet sample size, including the estimated number of TG women in the jurisdiction. Funding is available for the top 7 scoring applicants (i.e. the grantees) to conduct NHBS-Trans in the following cities:

- Atlanta, GA (grantee: Georgia Department of Public Health)
- Los Angeles, CA (grantee: Los Angeles County Department of Health)
- San Francisco, CA (grantee: San Francisco Department of Public Health)
- New Orleans, LA (grantee: Louisiana Office of Public Health)
- New York City, NY (grantee: New York City Department of Health and Mental Hygiene)
- Seattle, WA (grantee: Washington State Department of Health)
- Philadelphia, PA (grantee: Philadelphia Department of Public Health)

Two additional sites will participate with their own funds:

- Dallas, TX
- Washington, D.C.

Together these 9 cities accounted for over 33% of all persons living with HIV at year end 2014 in large (>500,000 residents)

U.S. MSAs (CDC, 2016). The 9 cities provide diversity in terms of geographic representation, including 4 cities (Atlanta, Dallas, New Orleans, and Washington, D.C.) in the south.

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

Interview data will be collected on password-protected encrypted portable computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland. Provision of electronic data collection software will help to reduce the burden of data collection on grantees conducting NHBS-Trans. An evaluation of supplemental surveillance data using electronic data collection has shown a reduction in the duration of the interview by up to 20%.

Data linking recruiters and recruits for RDS will be tracked using a coupon manager computer program, called “Respondent Driven Sampling Coupon Manager” (RDSCM). The RDSCM program reduces the time and effort to validate coupons and track payments of incentives. During a participant’s visits to the field site, data can be called up efficiently through use of search terms, such as by coupon number.

The purpose of the Data Coordinating Center (DCC), managed by ICF through a contract with CDC, is to implement a data management system to provide NHBS-Trans project areas with a secure web-based data portal system through which project areas can easily submit data to CDC, revise submitted data sets, and receive final data from CDC. This will help reduce project management burden at the project area and streamlines the data collection and management process.

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

We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects or maintains data on HIV risk behavior data from Transgender women, age 18 and older. Although NHBS (OMB# 0920-0770, exp. May 31, 2020)collects similar data elements as are being proposed for NHBS-Trans, NHBS currently only monitors adult men who have sex with men (MSM cycle), injection drug users (IDU cycle) and heterosexuals at increased risk for HIV (HET cycle). Transgender persons are not eligible to participant in the MSM or HET cycles. Transgender persons are eligible to participant in the IDU cycle, but are not present in sufficient numbers to conduct analysis; approximately 50 transgender persons (out of approximately 10,000 participants)

have participated in each of the last five IDU cycles. The information collected through NHBS-Trans will be used to determine whether the NHBS framework is well suited for behavioral surveillance of TG women.

151.

152. **A.5. Impact on Small Businesses and Other Small Entities**

153.

154. No small businesses will be involved in this data collection effort.

155.

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

157.

158. The proposed project involves a one-time data collection. There are no legal obstacles to reducing burden.

159.

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

161.

162. This request fully complies with the regulation 5 CFR 1320.5.

163.

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

165.

166. A Notice to solicit public comments was published in the Federal Register on 05/29/2018, Volume 83, Number 103, Page Number 24478 (**Attachment 2)**. No public comments were received. The Notice was titled “National HIV Surveillance System Among Transgender Women (NHBS-Trans).” In this information collection request CDC has revised the title to more clearly align with project aims.

167.

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

169.

170. Participants will be given an incentive of no more than $25 in cash for participation in the interview and $25 for taking a voluntary HIV test; the specific amount will be determined by grantees based on local standards. If local regulations prohibit cash incentives, equivalents may be offered in the form of gift certificates, cash cards, or bus or subway fare. Incentives are provided to all participants who complete the entire survey. Each grantee will develop protocol in consultation with their local IRB to determine appropriate incentive provision in the event that a participant is unable to complete the entire survey for any reason.

171.

172. In the RDS methodology, participants receive incentives for participating as a respondent and a reward for successfully recruiting one or more of their peers. Recruiter rewards are approximately $10 for each of up to five peer referrals, which is standard for RDS studies (Heckathorn, Semaan ,Broadhead & Hughes,

2002; Ramirez-Valles, Heckathorn, Vazquez, Diaz & Carlson, 2005; Wang, Carlson, Falck, Siegal, Rahman & Li, 2005). As with the interview and testing incentives, if local regulations prohibit providing cash, an equivalent incentive may be offered in the form of gift certificates or cash cards.

173.

174. In his memorandum for the President's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…" The maximum incentive level a participant could receive for participation in the interview, optional HIV testing, and RDS recruitment activities is $100.

175.

176. The use of incentives for participation in NHBS-Trans is appropriate because the project seeks to conduct surveys with a hard-to-reach and highly selective population and asks participants highly sensitive questions about issues such as sexual behavior and substance use (Kulka, 1995). Because the interview takes approximately 40 minutes to complete, to increase response rates, eligible persons are offered an incentive to participate. We require a sample size of 200 per city to perform an adequate assessment of the RDS methodology, which relies on peer-to-peer recruitment, and because the demographic composition of transgender populations varies both within and across grantee sites, suggesting that acceptability of the survey may vary similarly within the target population.

177.

178. The need for and amount of the incentives are based, in part, on the fact that other, similar projects that ask HIV risk behavior questions in the participating areas offer similar incentives. Thus, NHBS-Trans would be competing with local researchers who do offer incentives. Persons at risk for HIV infection have frequently been the focus of health-related data collections, in which incentives are the norm (MacKellar, Valleroy & Secura et al., 2005; Thiede, Jenkins & Carey et al., 2009). Providing incentives to NHBS-Trans respondents is critical to achieve acceptable response rates.

179.

180. Incentives have been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2020), the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), and the Medical Monitoring Project (OMB 0920-0740, exp. 06/30/2021) all

of which ask questions similar to those in NHBS-Trans and have a similar length of time for completing the interview. In these other projects, incentives were used to help increase participation rates; participants received an incentive of approximately $25, to be provided when they completed the survey. Other studies have also found that incentives modestly improve response rates (Shaw, Beebe, Jensen & Adlis, 2001). Transgender women are a hard-to-reach population for whom such incentives are crucial, particularly given the sensitive nature of questions about HIV and sexual behavior. Through analysis of nonresponse during the course of study implementation, staff will work to identify optimal incentive levels for use in this population. This will also inform overall feasibility of the proposed data collection.

181.

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

183.

184. The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a (**Attachment 13**). The Privacy Act is not applicable because PII is not being collected under this CDC funded activity. The NHBS-Trans interview and optional HIV testing are anonymous (neither names nor social security numbers are collected).

185.

186. Data that will be collected through NHBS-Trans, while sensitive, are not personally identifying. Personally identifiable information (PII) is NOT included in the data collection (**Attachments 5-7**). Private identifiable information used locally to validate coupons will be stored separately from collected data. Project areas will not transmit local validation information to CDC, nor will CDC staff have access to it. Data collected through NHBS-Trans, both locally and at CDC, will be stored and accessed by a study identification number.

187.

188. NHBS-Trans is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 9**). The Assurance provides the highest level of legal confidentiality protection to the individual persons who are the subjects of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to

individual respondents. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent’s death.

189.

190. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the document “Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs” available at (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf).

191.

192. The NHBS-Trans interview will be conducted by trained NHBS-Trans staff in a private location where the questions and responses cannot be overheard by others. NHBS-Trans data will be transmitted to CDC via the secure system described above known as the DCC. Encryption security for all NHBS-Trans data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document “Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines” for further information (www.cdc.gov/hiv/surveillance.htm).

193.

194. A number of required protections ensure the security of the data on the data collection computers. The tablet computers and laptop computers will be used solely for NHBS-Trans data collection activities. NHBS-Trans data will be encrypted when stored on a tablet device or laptop. Computers will be protected by using a coded password only known by authorized NHBS-Trans project staff. NHBS-Trans data will be deleted from the laptop computers after they are uploaded to the main secured database. The tablet and laptop computers must be kept with the staff at all times in the field; the computers will be collected and secured by the field supervisor after return to the local NHBS-Trans office. When not in use in the field, the computers are to be locked in a drawer or an office.

195.

196. NHBS-Trans interviewers and data managers will undergo annual security and confidentiality training consistent with the guidelines set forth in the document (“Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs” available at www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuide

lines.pdf. CDC's Office of Financial Resources will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement, and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements with state and local health departments reference the Assurance of Confidentiality as a condition of award.

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

IRB Approval

The NCHHSTP Project Determination form for NHBS-Trans (**Attachment 12**) was approved on September 6th, 2017. The project was granted "non-research" status, as the primary intent is to inform routine disease surveillance by assessing whether NHBS outreach, recruitment, and data collection methods are effective in this population. As the project determination for "non-research" status was approved, the protocol will not be reviewed by CDC's IRB. Each participating health department will be required to obtain local IRB approval before data collection, in accordance with their local guidelines.

The informed consent process for respondents may be fulfilled by obtaining oral consent. All sites must obtain consent for all activities. Model consent forms are included in **Attachment 11**. These forms may be modified as required by a project area IRB. Consent must be obtained separately for the interview, STI testing and HIV testing. Participants may elect to complete the interview and not be tested; however, they may not be tested without completing the interview (those persons who only want an HIV test may be given information on where to seek an HIV test elsewhere). Respondents will be informed that data collected from them for NHBS-Trans will be kept private and secure and that the data will be reported in aggregate format.

Sensitive Questions

HIV can be transmitted from person to person through sexual contact and the sharing of HIV contaminated needles and syringes. In addition, HIV-infected persons with higher HIV viral loads may

be at increased risk of transmitting the virus to others. These modes of transmission necessitate the collection of sensitive data regarding HIV/AIDS status, medical history, sexual orientation, sexual practices, and alcohol and drug use, which NHBS has been approved to collect. Accordingly, the proposed project will also collect these data. As with NHBS' data collection, this data collection will also request sensitive information relating to STD and HIV diagnosis and testing, mental health conditions such as depression, history of suicide attempt, incarceration history, alcohol and drug use, experience of violence and bullying, and experience of stigma and discrimination.

210.

211. Although the information requested from participants is highly sensitive, the purposes of NHBS-Trans cannot be accomplished without their collection. Collection of the data will be used to determine

212. whether participants are willing to answer sensitive questions and whether their responses yield useful information.

213.

214. The context in which questions are asked helps to overcome their potential sensitivity. There are several steps taken in NHBS-Trans to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

215.

- Nearly all questions allow for responses of "don't know" or "refuse to answer."
- Consent scripts make it clear that the interview is sponsored by CDC and the local health department and that the information will be put to important uses.
- Toll-free phone numbers will be provided in case the respondent has questions about the study.
- The interview is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for information is explained.
- Assurances about the anonymity, privacy, and confidentiality of the data will be reiterated.
- The use of handheld or portable computers for data collection addresses concerns the respondent might have about privacy (that others can see their answers).
- If at any point respondents feel uncomfortable, they may skip any questions or stop the survey altogether.

216. All interviews will be conducted by trained field staff in a private location during established operating hours at local field site locations. Interviewers will be trained to administer the consent script and all interview questions by reading each

item verbatim, thus ensuring that all respondents receive the same information for the consent and each question. No interviews will be conducted without the verbal assent of the respondent.

Social security numbers, names, or addresses will not be collected from respondents.

No data will be collected from agencies regarding their policies, performance data or other practices.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. Estimated Annualized Burden Hours

The estimate of annualized burden hours for this sub collection is 713 hours; details are provided in exhibit A.12.A. Each year for two years, we expect 990 individuals (total 1,980) to participate in the eligibility screener, which is expected to take 5 minutes per participant. For the interview, we expect 900 eligible and consenting individuals to participate per year (total 1,800), which is expected to take 40 minutes per participant on average.

RDS will occur at all 9 sites. At each site, approximately 110 individuals per year (990 total per year) will present themselves at a field location for eligibility screening. We estimate that it will take five minutes to complete the screener and that 10% of respondents will be either not interested in completing the interview or will be ineligible after completing the screener, yielding 100 eligible respondents per site, per year (900 total). We estimate that it will take 40 minutes for each respondent to complete the interview.

We estimate that 100 respondents per site (900 total) will complete the recruitment debriefing instrument each year, which will take 2 minutes per respondent. These estimates cover the time that each respondent will spend communicating with the project staff and answering questions.

Because HIV testing is a clinical procedure, it is not included in the burden estimates.

Exhibit A.12.A Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Minutes Per Response	Total Response Burden (Hours)
Transgender Women, >18 years old	(Att 5a,b) Eligibility Screener	990	1	5/60	83
Eligible and consenting participants	(Att 6a,b) NHBS-Trans Interview	900	1	40/60	600
Peer Recruiters	(Att 7a,b) Recruiter Debriefing Form	900	1	2/60	30
Total					**713**

A.12.B. Estimated Annualized Costs

The annualized cost to respondents for the burden hours is estimated to be $16,192; details are provided in Exhibit A.12.B. The estimates of hourly wages were obtained from the Department of labor (Bureau of Labor Statistics Wage Data (http://www.bls.gov/news.release/pdf/ecec.pdf).

Exhibit A.12.B. Annualized Cost to Respondents

Activity	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
(Att 5a,b) Eligibility Screener	83	$22.71	$1,885

291.	(Att 6a,b) NHBS-Trans Interview	292. 600	293. $22.71	294. $13,626
295.	(Att 7a,b) Recruiter Debriefing Form	296. 30	297. $22.71	298. $681
299.	**Total**	300.	301.	302. **$16,192**

303.

304.

305. **A.13.Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

306.

307. There are no other costs to respondents or record keepers with this proposed collection of information.

308.

309.

310. **A.14.Annualized Cost to the Federal Government**

311.

312. The annualized cost of this project is estimated to be $2,275,529.

313.

314. **Exhibit 14.A Estimated Cost to the Government**

315.

316. **Expense Type**	317. **Expense Explanation**	318. 319. **Annual Costs (dollars)**
320. Direct Costs to the Federal Government	321. NHBS-Trans: Personnel 322. Epidemiologist-14 1@ 35% 323. Epidemiologist-13 2 @ 50% each 324. Epidemiologist-12 1 @ 50% 325.	326. $43,000 327. $102,000 328. $45,000
	330. Cooperative agreement funds to project areas	331. $1,666,969
332. Contractor and Other Expenses	333. Contracted Questionnaire Programming	334. $135,660
	336. Data Coordinating Center (CDC Contractor for data collection) 10%	337. $193,000
	339. ORISE Fellow 1 @ 50%	340. $30,000
	342. Scientific Data Analyst 1 @ 50%	343. $50,000
	345. Travel (7 trips*$1,200)	346. $8,400
	348. Meetings and Trainings	349. $1,000

	Printing	$500
	TOTAL COST TO THE GOVERNMENT	$2,275,529.

The personnel hired specifically to conduct the NHBS-Trans data collection consists of .5 ORISE Fellow and .5 Scientific Data Analyst contractor. Travel is related to providing technical assistance and conducting site visits.

The information collection described in this request will be funded through cooperative agreements with state and local health departments (CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments).

A.15. Explanation for Program Changes or Adjustments

Not applicable – this is a new request.

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

All data collection will be completed during the 24-month period after OMB approval. Data analysis will occur within 36 months of OMB approval. The following is a brief overview of the NHBS-Trans Timeline.

Exhibit 16.A Project Time Schedule

Activity	**Time Schedule**
Interviewer training	One month after OMB approval
Interviewing participants	2–24 months after OMB approval
Data management	2–24 months after OMB approval
Evaluation of pilot methods	24-36 months after OMB approval
Data quality assessment and analysis	24-36 months after OMB approval
Production of report	36 months after OMB approval

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

The OMB Expiration Date will be displayed. No exception is requested.

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

There are no exceptions to the certification.

REFERENCES

Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, Garofalo R, with the Adolescent Medicine Trials Network for HIV/AIDS Interventions. Syndemic theory and HIV-related risk among young TG women: the role of multiple, co-occurring health problems and social marginalization. Am J Public Health. 2012 Sep; 102:1751-1757

Budge SL, Adelson JL, Howard KA. Anxiety and depression in TG individuals: the roles of transition status, loss, social support, and coping. J Consult Clin Psychol. 2013; 81:545-557

Cahill S, Singal R, Grasso C, King D, Mayer K, Baker K & Makadon H. 2014. “Do Ask, Do Tell: High Levels of Acceptability by Patients of Routine Collection of Sexual Orientation and Gender Identity in Four Diverse American Community Health Centers.” PLoS One 9: e107104.

CDC. HIV Surveillance Report, 2015. Vol. 27, published 2016

Flores AR, Herman JL, Gates GJ, Brown TNT. 2016. How many adults identify as TG in the U.S.? Los Angeles, CA: The Williams Institute, UCLA. 2016

Heckathorn D, Semaan S, Broadhead R & Hughes J. Extensions of respondent-driven sampling: a new approach to the study of injection drug users aged 18-25. AIDS and Behavior 2002; 6(1):55-67.

Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS & Crepaz N, with the HIV/AIDS Prevention Research Synthesis Team. Estimating HIV prevalence and risk behaviors of transgender persons in the US: a systematic review. AIDS Behav. 2008; 12:1-1

Institute of Medicine. 2011. The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding. Washington, DC: The National Academies Press. https://doi.org/10.17226/13128.

Kulka R. The use of incentives to survey "hard to reach" respondents:a brief review of empirical research and current research practice. Seminar on New Directions in Statistical Methodology, 1995 #23, 256-289. 1995. FCSM Statistical Policy Working Papers. Ref Type: Report

413. MacKellar D, Valleroy L, Secura G, Behel S., Bingham T, Celentano D, Koblin B, LaLota M, McFarland W, Shehan D, Thiede H, Torian , Janssen R ; for the Young Men's Survey Study Group. Unrecognized HIV Infection, Risk Behaviors, and Perceptions of Risk Among Young Men Who Have Sex With Men: Opportunities for Advancing HIV Prevention in the Third Decade of HIV/AIDS. JAIDS 2005; 38(5):603-614

414. Martinez M, Henderson A, and Luck J. 2016. “Cognitive Pretesting of the National Crime Victimization Survey Supplemental Victimization Survey.” U.S. Census Bureau (unpublished report)

415. Mizuno Y, Frazier EL, Huang P & Skarbinski J. Characteristics of TG women living with HIV receiving medical care in the U.S. LGBT Health. 2015; 2, 228-234

416. Ramirez-Valles J, Heckathorn D, Vazquez R, Diaz RM, Carlson R. From networks to populations: The development and application of respondent-driven sampling among IDUs and Latino gay men. AIDS and Behavior 2005; 9(4):387-402.

417. Reisner SL, Conron KJ, Tardiff LA, Jarvi S, Gordon AR, Austin SB. 2014. “Monitoring the Health of Transgender and Other Gender Minority Populations: Validity of Natal Sex and Gender Identity in a U.S. National Cohort of Young Adults.” BMC Public Health 14: 1224.

418. Shaw MJ, Beebe TJ, Jensen HL, Adlis SA. The use of monetary incentives in a community survey: impact on response rates, data quality, and cost. Health Serv Res. 2001 February; 35(6): 1339–1346.

419. Thiede H, Jenkins RA, Carey JW, Hutcheson R, Thomas KK, Stall RD, White E, Allen I, Mejia R, Golden MR. Determinants of Recent HIV Infection Among Seattle-Area Men Who Have Sex with Men. American Journal of Public Health: April 2009, Vol. 99, No. S1, pp. S157-S164.

420. Wang J, Carlson R, Falck R, Siegal H, Rahman A, Li L. Respondent-driven sampling to recruit MDMA users: a methodological assessment. Drug and Alcohol Dependence 2005; 78(5):147-157.

421.

422.