

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

OMB #0920-1262

Supporting Statement
Part A

REVISION

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CONTACT:

Cyprian Wejnert, PhD
Team Lead, Behavioral Surveillance Team
National Center for HIV, Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS US8-4
Atlanta, Georgia 30329
Phone: (404) 639-6055
Fax: (404) 639-8640
E-mail: DWY7@CDC.GOV

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- **Goals of the study:** The purpose of the National HIV Behavioral Surveillance among Transgender Women (NHBS-Trans) is to demonstrate the feasibility of a national surveillance system to obtain data on HIV risk behaviors, gaps, barriers to services and other experiences of transgender (trans) women with emphasis on racial and ethnic minority populations in up to 14 U.S. cities with high burden of HIV.
- **Intended use:** This project seeks to assess the acceptability, feasibility and performance of National HIV Behavioral Surveillance (NHBS) data collection behavioral assessment instruments, sampling and recruitment methods among transgender women.
- **Methods to be used to collect data:** This 3-year project will use statistical methodologies appropriate for sampling hard-to-reach or hidden populations. A one-on-one, CAPI-based survey will be administered by trained interviewers for each respondent.
- **The subpopulation to be studied:** Adult transgender women in up to 14 U.S. cities with high prevalence of HIV.
- **How data will be analyzed:** Quantitative analysis of data using SAS. Quantitative analysis of procedural data using SAS, including recruitment rates, recruitment refusals, willingness to consent to HIV testing, receipt rate of testing results, and process monitoring data. Descriptive statistics and multivariable analyses to assess: 1) prevalence and awareness of HIV infection, 2) risk behaviors for HIV transmission, 3) receipt of HIV prevention services.

73.

74. **A. JUSTIFICATION**

75.

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

77.

78. The Division of HIV Prevention (DHP) of the Centers for Disease Control and Prevention (CDC) requests a 3-year revision of the currently approved Barriers and Facilitators to Expanding the NHBS to Conduct HIV Behavioral Surveillance Among Transgender Women (NHBS-Trans) (OMB# 0920-1262, expiration 04/30/2022). NHBS-Trans is modeled after National HIV Behavioral Surveillance (NHBS) (OMB# 0920-0770, exp. 01/31/2023). 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 heterosexually active persons at increased risk for HIV. Like transgender (trans) 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.

79.

80. This project seeks to examine revisions to the initial data collection in 2019-2020 to further assess feasibility of an ongoing surveillance system for trans women. Based on completion of data collection in 2019-2020, evaluation of the previous efforts, and updates in scientific literature, the following revisions to the information collection request have been made: project activities and methods have expanded to allow for remote variants of our in-person methods, such as interview by videoconference or phone; the number of project areas participating in NHBS-Trans will increase (from 9 to up to 14) and the number of respondents recruited per project area will increase from 200 to 300; revisions were made to the eligibility screener and behavioral assessment. (For a detailed description, see **Attachment 3**) If revisions to this project are successful, these findings may be used to justify a future expansion of NHBS to include trans women.

81.

82. Collection of HIV surveillance data is regulated by Title III - General Powers and Duties of Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

83.

84.

85. A.2 - PURPOSE AND USE OF THE INFORMATION COLLECTION

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87.

Trans women are at high risk for HIV infection. A recent meta-analysis indicates an overall laboratory-confirmed estimated prevalence of HIV infection of 14.1% (95% CI = 8.7%, 22.2%); self-reported infection was 21.0% (95% CI = 15.9%, 27.2%) (Becasen, Denard, Mullins, Higa & Sipe, 2018). In this systematic review, 88 studies met the review inclusion criteria, a list of which can be found in the citation mentioned above. These high estimates highlight the need for robust, multi-site data on this population. Factors contributing to the disproportionate burden of HIV among trans women include condomless sex, survival sex, injection drug use, hormone and silicone injection, unstable housing, and depression and anxiety (Becasen et al., 2018; Budge, Adelson & Howard, 2013; Brennan, Kuhns, Johnson, Belzer, Wilson & Garofalo, 2012). In addition, trans 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). Bio-behavioral surveillance among trans women is a critical element in understanding and reducing the disproportionately high burden of HIV among trans women, particularly trans women of color. High-quality data collected through rigorous means are necessary to improve the understanding of prevalent risk factors and prevention

needs in order to meet the goals set forth in the End the HIV Epidemic initiative (<https://www.cdc.gov/endliv/index.html>).

88.

89. While several limited studies of HIV risk and prevalence have been conducted with trans women, no ongoing public health surveillance system has focused on trans women. Most surveillance systems either exclude trans respondents or include too few respondents to draw meaningful conclusions that are specific to trans experiences. NHBS-Trans successfully surveyed over 1,600 trans women in 2019-2020 and found that 42% of trans women surveyed have HIV (CDC, 2021). It also revealed 62% of Black/African American trans women and 35% of Hispanic/Latina trans women surveyed have HIV. These findings demonstrate the pressing need to scale-up HIV prevention strategies and to address social and structural factors such as stigma, discrimination, inadequate employment, unstable housing, and limited access to gender affirming services which contribute to health disparities.

90.

91. Ongoing surveillance of HIV risk behaviors, gaps and barriers to services, and other experiences of trans 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. Expansion of NHBS to include trans women could address a critical need by 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. NHBS-Trans has identified best practices for local and national HIV behavioral surveillance among minority trans women and collected baseline data on HIV prevalence and factors associated with HIV among trans women. Additional project efforts will aid in refining methodologies, testing expansion of activities to a larger sample, and assessing revisions to data collection instruments.

92.

93. **A.2.a - STUDY OVERVIEW**

94.

95. This project 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 project will assess the feasibility of data collection methodologies to obtain data on HIV risk behaviors, gaps and barriers to services, and other experiences of trans women within

racial and ethnic minority populations in up to 14 U.S. cities with high burden of HIV.

96.

97. NHBS-Trans project areas comprise the state and local health departments with the highest HIV prevalence, limiting eligibility to one metropolitan statistical area (MSA) or Division per health department jurisdiction. The information collection described in this request is 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).

98.

99. Data collection activities for NHBS-Trans include eligibility screening (**Attachment 4a**), the behavioral assessment (**Attachment 4b**), and the recruiter debriefing (**Attachment 4c**); HIV testing will also be conducted. Respondent-driven sampling (RDS), a type of chain referral sampling, will be used for an interviewer-administered, face-to-face or remote, computer-assisted behavioral assessment. Except for a few initial ("seed") recruits, persons will be recruited by peers for participation. After the behavioral assessment, the interviewer will train the respondent to recruit up to five of their peers. The recruiter will be offered a small incentive for each person recruited. After recruiting, they will be debriefed using a computer-assisted, interviewer-administered recruiter debriefing (**Attachment 4c**). This instrument collects information about those who refused recruitment attempts. Each of these data collection instruments is also available in Spanish (**Attachments 5a-c**). These methods are explained in more detail in Part B.

100.

101.

NHBS-Trans collects data through face-to-face or remote interviews. A short screening to assess various eligibility criteria and limited demographics will be administered to those recruited by peers for participation in NHBS-Trans (**Attachment 4a**). If the respondent is eligible for the assessment and consents to a behavioral assessment, the interviewer will administer the behavioral assessment. The data collected from the behavioral assessment will include self-reported demographics, sex and substance use behaviors, access to health care, HIV testing patterns, and exposure to and use of HIV prevention services. In addition to these factors directly associated with HIV transmission, the instrument includes topics relevant to the life experience, health, and well-being of trans women (gender affirmation, experiences of discrimination, access to transgender competent health care, and suicidality) (**Attachment 4b**). 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 stakeholders and subject matter experts indicated that these topics are necessary for the success

of the project because many trans women view external interest in the trans community as only interest 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 trans women would reinforce this view, damaging community rapport with the health departments and alienating potential respondents.

102.

103.

To identify and address the data collection methodological issues, CDC will conduct continuous monitoring of data collection efforts in each project area 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 project area 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 project areas 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 trans women.

104.

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

106.

107.

Behavioral assessment data will be collected on password-protected encrypted portable computers using electronic data collection software. Provision of electronic data collection software will help to reduce the burden of data collection on project areas conducting NHBS-Trans. An evaluation of supplemental surveillance data using electronic data collection has shown a reduction in the duration of the behavioral assessment by up to 20%.

108.

109.

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 respondent's interactions with field staff, data can be called up efficiently through use of search terms, such as by coupon number.

110.

111.

The purpose of the Data Coordinating Center (DCC) 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 streamline the data collection and management process.

112.

113.

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

115.

116. We reviewed currently funded programs including a search on Reginfo.gov 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 trans women, age 18 and older. Although NHBS (OMB# 0920-0770, exp. 01/31/2023) collects similar data elements as are being proposed for NHBS-Trans, NHBS currently only monitors adult men who have sex with men (MSM cycle), persons who inject drugs (PWID cycle) and heterosexually active persons at increased risk for HIV (HET cycle). Trans persons are not eligible to participate in the MSM or HET cycles. Trans persons are eligible to participate in the PWID cycle but are not present in sufficient numbers to conduct analysis; approximately 50 trans persons (out of approximately 10,000 respondents in applicable cycles) have participated in each of the last five PWID cycles. Similarly, the Medical Monitoring Project (OMB# 0920-0740, exp. 05/31/2024) collects similar data elements, but data collection is limited to individuals with HIV and overall numbers of trans women in MMP samples are low (only 78 (1.8%) out of 4,050 participants in the 2018 cycle) (CDC, 2020). The previous cycle of NHBS-Trans has demonstrated that the NHBS framework is well suited for behavioral surveillance of trans women.

117.

118.

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

120.

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

122.

123.

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

125.

126. The proposed project involves a one-time data collection.

127.

128. There are no legal obstacles to reducing burden.

129.

130.

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

132.

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

134.

135.

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

137.

138. A 60-day Notice to solicit public comments was published in the Federal Register on 11/02/2021, Volume 86, Number 209, Page Number 60463 (**Attachment 2**). Public comments can be found in **Attachment 2a**. One commenter submitted more than one comment but was overall supportive. The other commenter submitted a negative comment, but it was not specific to this data collection effort and no changes were made as a result of this comment. 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.

139.

140. A consultation with external experts and stakeholders from state and local health departments and community-based organizations in NHBS-Trans project areas was conducted in December 2019. During this meeting, over 20 representatives from state and city health departments and community-based organizations provided feedback and consulted on NHBS-Trans operations, the behavioral assessment, key areas of interest, analysis strategies, and dissemination plans. There were no major unresolved problems identified during the meeting. Feedback to improve data collection methods and operations was received and incorporated into the current proposal.

141.

142. Additional consultation occurred with subject-matter experts after the conclusion of the previous data collection to obtain feedback on necessary revisions to the data collection instruments. Consults included Marissa Miller and members of Trans Solutions Consulting (<http://www.transolutionscenter.org>), as well as Cecilia Gentili and members of Trans Equity Consulting (<http://www.transequityconsulting.com>). Changes to the instrument are further described in Section A.15 and **Attachment 3**.

143.

144.

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

146.

147. Incentives are used in NHBS-Trans, as the project seeks to conduct surveys with a hard-to-reach and highly selective population and to ask them highly sensitive questions about issues such as sexual behavior and substance use (Kulka, 1995). Because on average the behavioral assessment takes 40 minutes to complete, to increase response rates, eligible persons are offered an incentive following participation. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest.

148.

149. Respondents are given \$20-\$50 for completing the behavioral assessment, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g., cost of living), and previous research experience. Respondents may receive incentives in-person (cash, physical gift card, etc.) or electronically (Venmo, PayPal, email, text, etc.) In most project areas, respondents receive \$25 in cash. Respondents who agree to HIV testing are offered an additional incentive. Respondents who give a specimen for HIV testing are given \$10-\$50 for participation, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g., cost of living), and previous research experience. In most project areas, respondents receive \$25 in appreciation for providing a specimen for HIV testing.
- 150.
151. Incentives are provided to all respondents who complete the entire survey. Each project area will develop a protocol in consultation with their local IRB to determine appropriate incentive provision in the event that a respondent is unable to complete the entire survey for any reason.
- 152.
153. In the RDS methodology, respondents receive incentives for participating as a respondent and as 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 behavioral assessment and testing incentives, amount and form (cash, gift cards, cash cards, bus or subway tokens) are determined locally based on local regulations, city characteristics (e.g., cost of living), and previous research experience. In most project areas, respondents receive \$10 in appreciation for recruitment.
- 154.
155. 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...".
- 156.
157. 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.

158.

159.

Incentives have been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance among Transgender Women (OMB 0920-1262, exp. 4/30/2022), National HIV Behavioral Surveillance (OMB 0920-0770, exp. 01/31/2023), the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), and the Medical Monitoring Project (OMB 0920-0740, exp. 05/31/2024) all of which ask questions similar to those in NHBS-Trans and have a similar length of time for completing the behavioral assessment. In these other projects, incentives were used to help increase participation rates; respondents 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). Trans 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.

160.

161.

162.

[A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents](#)

163.

164.

The CDC Privacy Officer has assessed this package for applicability of 5 U.S.C. § 552a and determined that the Privacy Act does apply to the overall information collection (**Attachment 6**). This activity is covered under the Privacy Act System of Records Notice (SORN) #09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community. The NHBS-Trans behavioral assessment and optional HIV testing are anonymous.

165.

166.

The only personally identifiable information (PII) included in the data is the respondent's date of birth. The date of birth is collected during eligibility screening (**Attachment 4a**). Full date

of birth is collected for two reasons: to ensure respondents meet the eligibility criteria for participation in the assessment and for the purpose of identifying potential duplicate records or respondents who have participated more than once per cycle. Records that have the exact same date of birth will be compared on date of survey and other demographic information such as race, education, and zip code; determinations of whether a record is a duplicate or a respondent has already participated during the cycle will be made based on how closely this information matches. Full date of birth will be sent to CDC but would only be available to CDC staff overseeing data collection (i.e., date of birth is not maintained in analysis datasets). Data collected through NHBS-Trans, while sensitive, are not personally identifying. PII is NOT included in the data collection (**Attachment 6**). 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.

167.

168. For respondents' convenience or benefit, respondents may have the option to provide contact information to project staff on a voluntary basis. Examples of respondents providing contact information for convenience include but are not limited to: providing a phone number for phone text reminders of behavioral assessment appointments; providing payment information (e.g., Venmo, PayPal) so incentives can be provided electronically; providing an email address to facilitate videoconference interviews; or providing an address to receive self-collection or self-testing kits via mail. Examples of respondents providing contact information for respondent benefit include but are not limited to: providing telephone contact information so that project staff can call respondents when their HIV (or additional testing offered) test results are ready; providing contact information to help respondents with linkage to HIV care or other services (e.g., PrEP, housing, legal, substance use disorder treatment) they may need. Provision of contact information will be optional. In all cases, respondents also will be provided information and instructions for how to participate fully without providing contact information (e.g., respondents can participate in-person or call the project (rather than be called by the project) for behavioral assessment, linkage to services, or test results). In all cases, respondent contact information will not be linked or linkable to the respondent's behavioral assessment responses. Contact information will be stored and secured locally and never shared with CDC. Contact information will be destroyed by the end of the data collection.

169.

170. NHBS-Trans is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 7**). The Assurance provides the highest level of legal confidentiality protections to data housed at CDC. 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.
- 171.
172. The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all respondents 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).
- 173.
174. The NHBS-Trans behavioral assessment 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).
- 175.
176. A number of required protections will ensure the security of the data on the data collection computers. The portable computers will be used solely for NHBS-Trans data collection activities. NHBS-Trans data will be encrypted when stored on a portable computer. Computers will be protected using a coded password only known by authorized NHBS-Trans project staff. NHBS-Trans data will be deleted from the portable computers after they are uploaded to the main secured database. The portable 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 portable computers will be locked in a drawer or an office.

177.

178. 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/PCSIDataSecurityGuidelines.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 are required to attend annual confidentiality training, to sign a Nondisclosure Agreement (**Attachment 8**), 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.

179.

180. CDC awarded a contract in 2016 to maintain a Data Coordinating Center (DCC). The DCC manages a data portal system, which contains secure file data servers where NHBS-Trans data are transmitted and stored. The DCC uses the secure data transfer algorithm, FIPS 140-2 (Federal Information Processing Standards Publication). The data transfer methodology is compliant with the guidelines set forth in OMB memorandum M-0404 (E-Authentication Guidance for Federal Agencies) as well as with OMB, HHS, and CDC Security Assessment and Authorization (SA&A) Guidelines outlined in NIST SP 800-37 (Guide for the SA&A of Federal Information Systems). The DCC has received Authority to Operate (OAT) through the SA&A process (**Attachment 9**). In addition to the technical requirements listed above, data management processes are in compliance with *The Guidelines for HIV/AIDS Surveillance - Security and Confidentiality*. (www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf)

181.

182.

183. [A.11. Institutional Review Board \(IRB\) and Justification for Sensitive Questions](#)

184.

185. [IRB Approval](#)

- 186.
187. The NCHHSTP Project Determination form for NHBS-Trans (**Attachment 10**) was originally approved on September 6, 2017 and was amended on September 13, 2021. The project was granted “non-research” status, as the primary intent is a routine disease surveillance activity. As the project determination for “non-research” status was approved, the protocol will not be reviewed by CDC’s IRB. Each participating project area will be required to obtain local IRB approval before data collection, in accordance with their local guidelines.
- 188.
189. The informed consent process for respondents may be fulfilled by obtaining oral consent. All project areas 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 behavioral assessment, HIV testing, and other testing activities, if applicable. Respondents may elect to complete the behavioral assessment and not be tested; however, they may not be tested without completing the behavioral assessment (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.
- 190.
191. Sensitive Questions
- 192.
193. 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 status, medical history, sexual practices, and alcohol and drug use, which NHBS-Trans has been approved to collect. This data collection also includes 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 harassment, and experience of stigma and discrimination.
- 194.
195. The target population for this project includes only transgender or transfeminine respondents, with exclusion criteria designed to exclude respondents who are not transgender or transfeminine. Accordingly, we’ve included 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. Respondents who report being assigned male sex at birth and a non-masculine gender

identity will be eligible to participate. The check-all-that-apply measure of gender has been well-received by community members who feel their true identity can be reflected using more than one response option.

196.

197. Although the information requested from respondents is highly sensitive, the goals of NHBS-Trans cannot be accomplished without its collection. The data are used to understand barriers to engaging in protective behaviors and to using HIV prevention services. The data are also used to enhance HIV prevention programs designed to reduce high risk behaviors in persons most likely to acquire or transmit HIV.

198.

199. 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:

200.

- Nearly all questions allow for responses of “don’t know” or “refuse to answer.”
- Consent scripts make it clear that the behavioral assessment 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 survey.
- The behavioral assessment 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 privacy and confidentiality of the data will be reiterated.
- The use of 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.
- Many sensitive questions were developed in consultation with community members to identify most appropriate wording and placement.

201.

All behavioral assessments will be conducted by trained field staff in a private location during established operating hours at local field site locations or remotely. Remote behavioral assessments will not proceed if the respondent’s privacy cannot be ensured. Interviewers will be trained to administer the consent script and all behavioral assessment questions by reading each item verbatim, thus ensuring that all respondents receive

the same information for the consent and each question. No behavioral assessments will be conducted without the verbal assent of the respondent.

202.

203. Social security numbers will not be collected from respondents.

204.

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

206.

207.

208. A.12. Estimates of Annualized Burden Hours and Costs

209.

210. *A.12.a Estimated Annualized Burden Hours*

211.

212. The estimate of annualized burden hours for this data collection is 1,108 hours; details are provided in exhibit A.12.a. Each year for three years, we expect 1,540 individuals (total 4,620) to participate in the eligibility screener, which is expected to take 5 minutes per respondent. For the behavioral assessment, we expect 1,400 eligible and consenting individuals to participate per year (total 4,200), which is expected to take 40 minutes per respondent on average.

213.

214. RDS will occur in up to 14 project areas. At each project area, approximately 110 individuals per year (1,540 total per year) will present themselves at a field location for eligibility screening. We estimate that it will take 5 minutes to complete the eligibility screener and that 10% of respondents will be either not interested in completing the behavioral assessment or will be ineligible after completing the screener, yielding 100 eligible respondents per project area, per year (1,400 total). We estimate that it will take 40 minutes for each respondent to complete the behavioral assessment.

215.

216. We estimate that 100 respondents per project area (1,400 total) will complete the recruiter debriefing form 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.

217.

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

219.

220. **Exhibit A.12.a Estimate of Annualized Burden Hours**

221. Type of Respondent	222. Form Name	223. Number of Respondents	226. Number of Responses per Respondent	230. Average Burden per Response	233. Total Response Burden (Hours)
237. Transgender Women, >18 years old	238. (Attachment 5a,6a) Eligibility Screener	239. 1,540	240. 1	241. 5/60	242. 128
243. Eligible and consenting respondents	244. (Attachment 5b,6b) NHBS-Trans Behavioral Assessment	245. 1,400	246. 1	247. 40/60	248. 933
249. Peer Recruiters	250. (Attachment 5c,6c) Recruiter Debriefing Form	251. 1,400	252. 1	253. 2/60	254. 47
255. Total	256.	257.	258.	259.	260. 1,108

261.
262.

263. **A.12.b Estimated Annualized Costs**

264.

265. The annualized cost to respondents for the burden hours is estimated to be \$27,265; details are provided in Exhibit A.12.b. The estimates of hourly wages were obtained from the Department of Labor (U.S. Bureau of Labor Statistics Wage Data <https://www.bls.gov/cps/cpsaat39.htm>).

266. **Exhibit A.12.b. Annualized Cost to Respondents**

267. Type of Respondent	268. Form Name	269. Number of Respondents	270. 271.	272. Number of Responses per Respondent	273. 274. 275.	276. Average Burden per Response	277. 278.	279. Average Hourly Wage	280. 281. Total Cost	282.
283. Transgender Women, >18 years old	284. (Att 5a,6a) Eligibility Screener	285. 1,540		286. 1	287. 5/60	288. \$24.60	289. \$31.57			
290. Eligible and consenting respondents	291. (Att 5b,6b) NHBS-Trans Behavioral Assessment	292. 1,400		293. 1	294. 40/60	295. \$24.60	296. \$22.96			
297. Peer Recruiters	298. (Att 5c,6c) Recruiter Debriefing Form	299. 1,400		300. 1	301. 2/60	302. \$24.60	303. \$11.48			
304. Total	305.	306.		307.	308.	309.	310. \$27,265			

311.

312.

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

314.

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

316.

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

318.

319. The annualized cost of this project is estimated to be \$2,772,886.

320.

321. **Exhibit 14.a Estimated Cost to the Government**

322.

323. Expense Type	324. Expense Explanation	325. 326. Annual Costs (dollars)
327. Direct Costs to the Federal Government	328. NHBS-Trans: Personnel 329. Epidemiologist-14 1 @ 35% \$42,828 330. Epidemiologist-13 2 @ 50% \$103,550 331. Epidemiologist-12 1 @ 50% \$43,541 332.	333. \$189,919 334.
335.	336. Cooperative agreement funds to project areas	337. \$2,166,667
338. Contractor and Other Expenses	339. Contracted Questionnaire Programming 342. Data Coordinating Center (CDC Contractor for data collection) 5% 345. ORISE Fellow 1 @ 50% 348. Scientific Data Analyst 1 @ 50% 351. Travel (14 trips*\$1,200) 354. Meetings and Trainings 357. Printing	340. \$155,000 343. \$163,000 346. \$30,000 349. \$50,000 352. \$16,800 355. \$1,000 358. \$500
359.	360. TOTAL COST TO THE GOVERNMENT	361. \$2,772,886 362. 363.

364.

365. 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.

366.

367. Data for NHBS-Trans are compiled by project area staff and sent via secure network to a central processing location, called the Data Coordinating Center (DCC). The DCC will be funded through a separate contract. The purpose of the DCC is to receive data from data managers at local project areas, track the progress of the data, and distribute monthly monitoring reports to project area staff. The DCC will process all data sent from local project areas and produce a clean, final data set for use by CDC and each project area at the completion of each data collection cycle.

368.

369. 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).

370.

371.

372. [A.15. Explanation for Program Changes or Adjustments](#)

373.

374.

In order to overcome challenges related to in-person participation, NHBS-Trans methods were revised to include remote variants of our in-person methods. The underlying methods remain unchanged. The changes are as follows:

- Recruitment methods were changed to include remote recruitment via electronic communication platforms (e.g., text messages, phone calls) in addition to in-person recruitment.
- Interview methods were changed to include remote interviews by videoconference or phone in addition to in-person interviews.
- For respondents' convenience or benefit, respondents may have the option to provide contact information to project staff on a voluntary basis. Examples of respondents providing contact information for convenience include but are not limited to: providing a phone number for phone text reminders of behavioral assessment appointments; providing payment information (e.g., Venmo, PayPal) so incentives can be provided electronically; providing an email address to facilitate videoconference behavioral assessments; or providing an address to receive self-collection or self-testing kits via mail. Examples of respondents providing contact information for respondent benefit include but are not limited to: providing telephone contact information so that project staff can call respondents when their HIV (or additional testing offered) test results are ready; providing contact information to help respondents with linkage to HIV care or other services (e.g., PrEP, housing, legal, substance use disorder treatment) they may need. Provision of contact information will be optional. In all cases, respondents also will be provided information and instructions for how to participate fully without providing contact information (e.g., respondents can participate in-person or call the project (rather than be called by the project) for behavioral assessment, linkage to services, or test results). In all cases, respondent contact information will not be linked or linkable to the respondent's behavioral assessment responses. Contact information will be stored and secured locally and never shared with CDC. Because of this change, the model consent form has been updated to remove the word "anonymous" (**Attachment 11**).

375.

376. The number of project areas participating in NHBS-Trans will increase (from 9 to up to 14). The number of expected respondents per project area will also increase (from 200 to 300). For respondent-driven sampling (RDS) methods and resulting network analysis upon which NHBS-Trans is established, a minimum sample size of 300 socially interconnected respondents per project area is required. The sample size must also be sufficient within project areas to support meaningful analysis of trans subpopulations in each participating MSA. These increases will also allow for greater geographic representation both within each MSA and nationally.

377.

378. The following revisions were made to the eligibility screener and behavioral assessment of the OMB-approved project 0920-1262: (For detailed description, see **Attachment 3**)

- Revision of the eligibility screener: Modifications made to questions to aid in identification of previous respondents and reduce burden on interviewers.
- Addition of high priority topics to the behavioral assessment: A number of high priority topics were identified that were either omitted from the previous survey or required updates including questions on discrimination, gender affirmation, and PrEP.
- Deletion of lower priority topics from behavioral assessment: To reduce burden, items measuring low priority or repetitive content were deleted.
- Measurement improvements in the behavioral assessment: All items were reviewed for data quality, cognitive ease, and interview flow. Improvements (additions, deletions, and modifications) were made where possible.
- Changes to reduce repetitive language and improve interview flow in the behavioral assessment: Wording of introductory text and questions was modified to reduce repetitive language and information read to respondents. Location of some items was changed to improve flow and respondent experience.

379.

380.

381. [A.16. Plans for Tabulation and Publication and Project Time Schedule](#)

382.

383. All data collection and analysis will be completed during the 36-month period after OMB approval. The following is a brief overview of the NHBS-Trans Timeline.

384.

385. **Exhibit 16.a Project Time Schedule**

386.

387. Activity	389. Time Schedule
391. Interviewer training	392. One month after OMB approval

387.		389.	
388.	Activity	390.	Time Schedule
393.	Interviewing respondents	394.	2-24 months after OMB approval
395.	Data management	396.	2-24 months after OMB approval
397.	Evaluation of data collection	398.	24-36 months after OMB approval
399.	Data quality assessment and analysis	400.	24-36 months after OMB approval
401.	Publication of NHBS-Trans data	402.	36 months after OMB approval

403.

404. Data from NHBS-Trans will inform prevention programs services and increase existing knowledge in the behaviors that lead to acquisition of HIV. See **Attachment 12** for sample analysis tables.

405.

406. Most of the results are expected to be useful at the local level, while other results will be more meaningful aggregated across project areas. Each participating project area has responsibility for the release of local data. CDC has primary responsibility for the release of data aggregated from all geographic areas. These data are distributed to the participating agencies, researchers, policy makers and other interested parties through presentations at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars.

407.

408. Community members will continue to be informed of NHBS-Trans findings through multiple conduits of information. Aggregate data results will be released through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, and presentations to local HIV Service Organizations and community planning bodies and at local conferences and workshops.

409.

410.

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

412.

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

414.

415.

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

417.

418. There are no exceptions to the certification.

419.

420.

421. **REFERENCES**

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