

Transgender HIV Behavioral Survey

**OMB 0920-0794
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Contact Information:

Teresa Finlayson, PhD MPH
Behavioral and Clinical Surveillance Branch
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road (MS E-46)
Atlanta, GA 30333
Voice: 404.639.2083
Fax: 404 639 8640
Email: TFinlayson@cdc.gov

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention request approval for a reinstatement with change. We are requesting a 3-year extension for the previously approved Transgender Behavioral Survey (OMB No. 0920-0794, expired December 31, 2010). The data collection instruments have been shortened, and a peer recruiter debriefing instrument has been added. Changes to the text in the previously approved data collection instruments are outlined in **(Attachments 9 and 10)**. The previously approved project was a pilot. The purpose of the proposed data collection is to collect information about HIV risk behaviors from transgender persons at risk of acquiring HIV, which are used to interpret changes in numbers of new diagnoses of HIV infection. The project activities and methods will remain the same as in the previously approved information collection request.

The following changes were made to the OMB approved project 0920-0794:

- Increased the sample size from 100 to 200 respondents in each participating area;
- Increased the number of project areas conducting the survey from 4 to 5;
- Broadened eligibility criteria to include all races/ethnicities;
- Provide a Spanish version for monolingual Spanish speakers;
- Switched the format of the interview from an audio-computer assisted self interview (ACASI) conducted on a laptop to a computer-assisted personal interview conducted on a handheld computer;
- Renumbered the eligibility screener and behavioral assessment questionnaire and providing headers for each session;
- Modified the eligibility screener instrument:
 - Deleted 2 questions used to assess a transgender identity;
 - Moved 1 network question to the beginning of the behavioral assessment instrument; and
 - Deleted 6 network questions assessing race of persons in social networks
- Modified the behavioral assessment:
 - Deleted 129 questions;
 - Added 77 new questions;
 - Modified the wording of 63 existing questions; and
 - Added flashcards to 26 existing questions (**Attachment 3d**).
- Added a peer recruitment debriefing instrument.

Background

The National HIV/AIDS Strategy for the United States describes a nationally coordinated effort to reduce HIV infections. Specifically, the strategy calls for a nationally coordinated effort of HIV programs across the federal government and between the federal government and state and local governments (ONAP, 2010). One step to achieving this coordinated response is to develop improved mechanisms to monitor and report on progress toward achieving the goals of the national strategy.

This effort is not novel -- previously, CDC's HIV Prevention Strategic Plan had established several goals to reduce the annual number of new HIV infections in the United States, including strengthening the national capacity to monitor the HIV epidemic. The plan specifically called for more information about the HIV risk behaviors and prevention experiences of transgender persons, a population vulnerable to HIV infection. A meta-analysis of findings from published surveys among transgender persons reported high prevalence (weighted mean 27.7%: CI: 24.8-30.6%) of HIV infection among male-to-female transgender persons (Herbst et al., 2007). Consistent with this prevalence data are findings that also indicate high rates of new infections (3.4 to 7.8 new infections per 100 persons) among male-to-female transgender persons (Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Simon, Reback, & Bemis, 2000).

Historically, the HIV epidemic in the United States was monitored primarily by tracking cases of HIV infection and AIDS. However, as many years may pass between HIV infection and HIV diagnosis, case surveillance does not reflect recent trends in the behaviors that fuel the epidemic. Therefore, ongoing, systematic collection of behaviors related to HIV infection is an important component of an integrated surveillance system. An integrated surveillance system is more effective in directing and evaluating prevention efforts conducted to reduce the annual number of new infections.

To strengthen the national capacity to monitor the epidemic among vulnerable populations, CDC developed the National HIV Behavioral Surveillance (NHBS) system to monitor risk behaviors and prevention experiences. NHBS allows CDC, through partnerships with health departments, to obtain these HIV-related behavioral data from groups vulnerable to the HIV epidemic, including men who have sex with men, injection drug users, and high-risk heterosexuals. However, the system is not designed to collect behavioral data among transgender persons.

Current surveillance systems do not adequately monitor the epidemic among transgender persons for several reasons. First, current questions assessing gender identity in these systems are not adequate to identify transgender persons. Second, typical HIV risk assessments do not capture all the potential risks experienced by transgender persons, such as those related to hormone and silicone injections. In addition, questions assessing risky sexual behaviors may or may not apply to transgender persons, depending on their physical sexual characteristics.

Because transgender persons are members of a stigmatized group, they may hide their transgender identity, making it difficult to recruit a broad sample from this group. Therefore, the previously approved information collection was conducted to pilot a method for identifying transgender persons, a questionnaire to accurately capture their risk behaviors, and a sampling

methodology. Specifically, CDC developed an eligibility screener, and behavioral questionnaire, and tested sampling and recruitment methods for recruiting transgender persons. Based on the need for behavioral data to guide HIV prevention among transgender persons and the successful experience with the previously approved pilot, this request seeks to reinstate 0920-0794, with changes to expand it demographically and geographically, and to improve the data collection instruments. The purpose of the behavioral assessment information collection is to characterize behaviors related to acquiring or transmitting HIV infection among male-to-female transgender persons, to inform prevention services for this population. The purpose of the peer recruitment debriefing (not included in the previously approved data collection) is to collect information about those who declined to participate when approached by a peer recruiter.

This request is authorized by Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a.(**Attachment 1**).

Privacy Impact Assessment

The previously approved data collection was assessed for privacy impact.

Overview of data collection system

Respondent Driven Sampling (RDS) will be used to recruit participants for interviewer-administered, face-to-face, computer-assisted interviews. Except for a few initial (“seed”) recruits, persons will be recruited by peers for participation in THBS. For each person recruited, a short computer-based eligibility screening survey will be administered by an interviewer to assess eligibility and collect limited demographic information (**Attachment 3a**). If the respondent is eligible for the survey and consents to an interview, the interviewer will administer the behavioral assessment (**Attachment 3b**). At the end of the interview, the interviewer will train the respondent to recruit up to five of her peers. She will be offered a small –token of appreciation for each person recruited. When she returns to the field site, she will be debriefed using a computer-assisted, interviewer-administered recruiter debriefing instrument (**Attachment 3c**). This instrument collects information about those who refused her recruitment attempts. Electronic data collected for THBS is maintained indefinitely at CDC. The survey is anonymous; no names or phone numbers are collected.

Items of information to be collected

Eligibility Screener

Data collected using the eligibility screener will include age (determined from date of birth), race/ethnicity, previous participation, county of residence and length of time residing there, gender at birth and gender identity (**Attachment 3a**). The only information in identifiable form that is collected using the eligibility screener form is the full date of birth. Date of birth is sent to CDC, but is not shared beyond the CDC team conducting the data collection (i.e., it is not included in analysis datasets).

Behavioral Assessment

Data collected for the behavioral assessment will include additional demographics not included on the screener (including income, homelessness), the number of transgender persons the respondent knows (or network size), health care visits and interactions with health care providers, sexual and substance use behaviors, hormone and silicone injection behaviors, HIV testing patterns and exposure to and use of HIV prevention services (**Attachment 3b**). No information in the identifiable form is collected using the behavioral assessment form.

Peer Recruitment Debriefing

The items in the peer recruitment debriefing instrument include the number of coupons the recruiter has distributed, whether anyone had refused the coupons, the race and ethnicity of those refusing coupons, and the reason for refusal (**Attachment 3c**).

In addition to the data collected in these three instruments, field staff collects physical marks or characteristics to identify an individual. Field staff also asks the following questions which are used to create a unique ID. This information, together with the physical marks or characteristics is used to identify previous participants to identify the person so that the correct recruiter is provided a token of appreciation for the recruitment efforts and to prevent subsequent interview data obtained from people who participated more than once in the survey from being added to the analysis dataset.

1. What are the 1st 2 letters of YOUR LAST name?
2. What is the 1st letter of YOUR FIRST name?
3. What is the 1st letter of YOUR MOTHER'S FIRST name?
4. In which MONTH were you born?
(Enter the 2-digit number corresponding to the month, e.g. 04 for April, 10 for October)
5. What are the LAST 2 digits of your YEAR of birth?
6. Do you consider yourself to be male, female, or transgender?
(Enter recruiter's gender: M=male, F=female, T=transgender)
7. What racial/ethnic group or groups do you consider yourself to be in?
(Enter recruiter's race/ethnicity: B= Black/African-American, H= Hispanic/Latina, W= White, A= Asian and O= Other)

(For example, the unique ID of a Black male, last name Smith, first name Joe, mother's first name Olivia, and born in November 1961 will look like this: SMJO1161MB)

The physical marks and unique ID are retained locally in a separate database; they are not sent to CDC; they are not linked to any responses. After the database containing behavioral assessment responses has been finalized, the local databases containing the physical marks and recruiter unique ID are destroyed following local procedures.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

The information collection system will not involve a web-based data collection method, nor will it host a website. There will be no websites or internet content directed at children under the age of 13 years.

2. Purpose of Use of the Information Collection

The primary purpose of the previously approved information collection was to test a transgender-specific survey instrument and sampling method. However, the data were also intended to be used to describe HIV risk behaviors among male-to-female transgender persons and guide HIV prevention efforts in the areas in which the data were collected.

The purpose of this request is to assess the prevalence of and trends in: 1) risk behaviors for HIV infection, 2) HIV testing behaviors, and 3) exposure to, use of, and impact of HIV prevention services among male-to-female transgender persons. The focus of THBS is on behaviors directly related to the acquisition or transmission of HIV infection and those that are amenable to intervention through prevention programs. The explicit ability to identify gaps in HIV prevention services is an important aspect of THBS. THBS will also serve as a mechanism for state and local health departments to monitor and report on progress toward achieving the goals in the National HIV/AIDS Strategy (Office of National AIDS Policy, 2010) by providing the prevalence of HIV risk behaviors and prevention experiences in the funded areas.

The focus of THBS is on behaviors directly related to the acquisition or transmission of HIV infection and those that are amenable to intervention through prevention programs. The explicit ability to identify gaps in HIV prevention services is an important aspect of THBS. In addition, the results of this data collection will be used to assess progress toward CDC's goals to increase the proportion of people who consistently engage in behaviors that reduce risk of HIV transmission or acquisition; and to monitor behaviors that increase the risk of HIV infection (among those who are not infected).

Privacy Impact Assessment

Information is being collected to 1) determine eligibility, 2) inform prevention efforts by providing information about the characteristics and HIV risk behaviors of male-to-female transgender persons, and 3) describe persons who refused to participate to facilitate non-response bias analysis.

THBS involves collecting information on the respondents' sexual or drug use behaviors that increase the risk for acquisition or transmission of HIV, hormone and silicone injection behaviors, and patterns of HIV testing. Although the information requested is sensitive, the purposes of this project cannot be accomplished without their collection. During the informed consent process, all participants will be told that they may decline to participate without penalty or if they agree to participate, they may refuse to answer any question. They will also be

informed that the data will be used to improve HIV prevention services for transgender persons in their area, and that only aggregated data will be released in published reports. Information in identifiable form (IIF) includes the respondent's date of birth. The date of birth is collected in the eligibility screener (**Attachment 3a**). It is used to determine age and assess whether a person participated previously. To identify previous participants, 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. Date of birth is sent to CDC. However, it is only available to the CDC staff that oversee NHBS data collection (i.e., is it not included in analysis datasets).

In addition to the respondent's date of birth, other information in identifiable form is collected to help local staff verify a person as a previous participant or recruiter. Specifically, the local staff will note any identifying physical marks or characteristics about the person and will also ask the person questions to create a unique "recruiter ID" (see section A.1 for specific questions). These data are collected so that state and local health department staff can identify a previous participant or confirm that a person presenting for the recruiter's reward is in fact a peer recruiter. To prevent subsequent interview data from people who participated more than once in the survey from being added to the analysis dataset, records from persons with the same date of birth are compared on date of survey and other demographic information such as race, education, and zip code. The local staff will also review the physical marks or characteristics reported for each record. Determinations about whether a record is a duplicate or a participant has previously taken the survey will be made based on how closely this information matches. To confirm a peer recruiter, field staff ask a series of questions, which are designed to elicit the same response from a person each time they are asked. Answers to the questions are concatenated to form a unique ID for the recruiter. The unique ID is stored in a database with the coupon numbers provided to the recruiter. When the recruiter returns to the field site for her tokens of appreciation, field staff will ask the series of questions to re-create the unique ID and subsequently use it to locate the recruitment record in the database containing the coupon numbers. They will also compare the person's physical marks and characteristics to those noted in the recruitment record of the coupon database. Both the physical marks and the recruiter's unique ID are stored locally in the database that houses the coupon numbers provided to the recruiter and the coupon number the recruiter received when she was recruited (submitted when she participated in the survey). The number on the coupon submitted for participation in the survey will become the respondent's survey ID.

Data collected through THBS are stored and accessed by a survey identification number. Date of birth is sent to CDC and stored with other sensitive information obtained in the eligibility screener and behavioral assessment forms. However, date of birth is not shared beyond the CDC team conducting the data collection (i.e., it is not included in analysis datasets). The physical marks and the recruiter ID are retained locally in a separate database; they are not sent to CDC nor are they linked to any responses. After the database containing responses to the behavioral assessment has been finalized, the local database containing the physical marks and recruiter ID are destroyed following local procedures. Other than date of birth, no information in identifiable format is shared with CDC. The sensitive information collected will not be linked to any other personally identifiable information and cannot be used to reveal the identity of any one person. The proposed data collection is expected to have little or no impact on the respondent's privacy.

An effect on the respondent's privacy is likely if there is a breach of confidentiality. Therefore, several precautions are in place to prevent information from being connected to the respondent. Data will be collected on password protected computers and will be encrypted. Encryption security for THBS data will meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). Interview data will be uploaded to password protected computers or data servers after 5-10 interviews are completed, thereby limiting the amount of data on each handheld computer. Only local THBS staff will have access to the password for the computer to which data will be uploaded. In the field, the physical marks and unique recruiter ID will be maintained on a different computer than the one on which behavioral data are maintained. The data will be transmitted to CDC through a secure data network. CDC will return each jurisdiction's clean, finalized data to the funded health department using a secure data network. Only the local public health agencies involved in data collection and the CDC will have access to the data. Each participating health department will only have access to their jurisdiction's data.

In addition, to control access to data collection equipment, the handheld and laptop computers used to collect and maintain data in the field will be secured at the end of the day by the field supervisor. When not in use in the field, the handheld computers will be kept in a locked drawer or office at the local agency implementing THBS. The local site Principal Investigator and the CDC project officer will be notified in the event that a computer (including handheld computers) containing THBS project data is lost or stolen. Adverse event reports will be filed if a computer containing THBS data is lost or stolen.

To ensure that these safeguards are implemented, all CDC and field staff (including interviewers) responsible for collecting or maintaining THBS data will complete security and confidentiality training and sign a statement indicating their understanding of security and confidentiality policies (**Attachment 5**). Data collected for this project are protected under a Federal assurance of confidentiality (**Attachment 6** for details). Should there be a breach of confidentiality, the reasons for the breach will be evaluated so that more stringent safeguards can be implemented.

3. Use of Improved Information Technology and Burden Reduction

For the previously approved data collection, eligible persons who consented to participate completed a self-administered questionnaire on a laptop computer loaded with audio, computer-assisted self-interview (ACASI) software. For this request, behavioral assessment data will continue to be collected electronically to minimize the burden to respondents and interviewers. However, the assessment will be administered by an interviewer, so that data collected for THBS can be compared with similar behavioral data collected from other populations through interview-administered questionnaires funded by CDC.

Interview data will be collected on password protected encrypted handheld computers using the Questionnaire Development Software (QDS), NOVA Research Company, Bethesda, Maryland. It is expected that 100% of interviews will be collected using electronic applications. All interviews will be conducted by trained local THBS staff.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the interview software, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide training to participating state and local health departments with detailed written instructions, on methods for conducting the interviews. CDC will require local THBS staff providing supervision on the project to monitor interviewers regularly. CDC will convene lessons learned meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure. Provision of electronic data collection software, training and technical assistance will help to reduce the burden on grantees conducting THBS.

Experience with using this information collection approach has shown an overall reduction in the duration of the interviews by up to 20% (reducing burden on the respondents); a decrease in the average number of interviewer errors per interview including errors due to incorrect skip patterns, out of range answers, and missing responses (from an average of 2.5 per interview to 0.3 per interview). Computer-assisted interviews also eliminate the need for data cleaning associated with data entry and the errors listed above, resulting in a reduction in the time between the last interview and the production of a final analysis dataset from approximately 6 months to approximately 1 month. As compared with a self-administered assessment, interviewer-administered behavioral assessment may result in improved respondent comprehension and reduce response time; potentially reducing burden on respondents. Also, the cost of data collection using handheld computers instead of paper data collection forms is also reduced despite the increased startup costs associated with purchasing the handheld computers and interview software. The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the handheld computer than paper.

Use of electronic data collection will help to reduce the burden on partner agencies. The reduced data collection time will result in a reduction in the time between the last interview and the production of a final analysis dataset. Automated edit checks and skip patterns will be built into the interview program used to collect the data, as a further quality control measure. Transfer of data collected electronically will eliminate the need for data entry of interview responses.

Data linking recruiters and recruits using RDS will be entered directly into a computer program, called "Coupon Manager." Entering data directly into the computer improves the efficiency of data collection as compared to using paper and then entering the data. The Coupon Manager program, which tracks the coupons distributed and returned, also reduces the time and effort to validate coupons and tracks payments of tokens of appreciation. During a participant's visits to the field site, data can be called up efficiently in the Coupon Manager program through the use of search terms, such as by coupon number, the recruiter's unique ID, or a physical mark. With logic checks and range values programmed in, the quality of the data is improved. Data from Coupon Manager linking recruiters and recruits is also used in analysis and weighting to produce adjusted estimates.

When the recruiter returns to the field site, the field staff will need to determine if the recruiter is due tokens of appreciation for recruiting peers for the survey. Therefore, they will ask the

recruiter the series of questions to create their unique ID, which will then be used to locate their recruitment record within the Coupon Manager program. This record will also include the recruiter's own survey ID, assigned when she completed the assessment, and which is used to link the data from the different data sources. Prior to providing the recruiter her tokens of appreciation, field staff will ask the recruiter the questions on the debriefing instrument. The responses to these questions will be maintained in a Microsoft Excel spreadsheet identified by the survey ID only (i.e., the recruiter ID will not be maintained in the spreadsheet with the responses to the debriefing questions).

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently-funded programs and did not identify potential areas of duplication. There are no known sources for HIV-related behavioral data from transgender persons available within the department or agency.

Within CDC, data elements from the following other HIV-related supplemental surveillance systems were reviewed:

- Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262) exp. 06/30/2004
- Medical Monitoring Project (MMP) (OMB-0920-0740) exp. 05/31/2012
- Never in Care (NIC) (OMB 0920-0748) exp. 08/31/2010
- National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770) exp. 03/31/2011

These existing information collections above cannot be modified, used partially, nor in aggregate format to satisfy the needs of the proposed project. SHAS was discontinued, and therefore does not meet the need for an ongoing data collection system to monitor changes in risk behaviors. MMP's target population includes transgender persons but only transgender persons who have been diagnosed with HIV and are receiving HIV medical care (not transgender persons who are at risk of acquiring HIV, the population of interest for this request). The Never in Care Project also includes only HIV-infected persons, including transgender persons (transgender persons of interest for this ICR, those who are at risk of HIV infection, are excluded). The National HIV Behavioral Surveillance System collects HIV risk behavior information, but not from transgender persons.

The Computer Retrieval of Information Scientific Projects (CRISP) database was searched for federally funded projects involving transgender populations. This search was updated using the RePORT Expenditures and Results (RePORTER) query tool. Six federally-funded research projects were identified in this recent query; four did not appear to collect behavioral data from transgender persons; two appeared to collect data from transgender persons. One is an internet survey designed to complement an internet HIV intervention focused on transgender persons; the other is a research study designed to examine the relationship characteristics influencing HIV infection among male-to-female transgender persons. The proposed data collection is designed to monitor risk behaviors for the purpose of directing prevention efforts (not to develop specific interventions). As such it requires the collection of information for monitoring various risk behaviors that may be associated with acquiring HIV infection or developing AIDS, as well as

experiences with prevention interventions. It is also designed to be conducted in multiple cities. Neither research project is expected to include all the questions of interest in this request as they both appear to be limited in scope (i.e., relate to an intervention evaluation or focused on examining relationship characteristics).

In addition, CDC established relationships with other federal stakeholders and consultants during the conception and development of national, integrated HIV surveillance system, for which THBS was piloted. In addition, a review of the medical and psychological literature databases was conducted to compile a list of persons who have conducted HIV-related research or community needs assessments among transgender populations in the United States and the nature of that research. Many of these individuals attended a consultation meeting for THBS in September 2006. The findings from the pilot were discussed with key stakeholders involved with data collection from the transgender community. To promote collection of data that can be used by multiple agencies, ongoing communications with these federal and non-governmental partners will continue for the duration of this project. Meetings with these federal stakeholders and consultants who are aware of data collection from transgender persons ensured that duplicate or similar data collection efforts do not exist.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

This request is for approval to collect data over a single 12-month period during the three years after approval. Participants interviewed for THBS are only eligible to participate once. Each person will be asked if they have been interviewed for the survey within the past year; those who indicate that they have already been interviewed within the past year will not be interviewed again. It is expected that conducting a behavioral survey among transgender persons every 3 years will be sufficient to track trends over time. Conducting the survey less frequently than every 3 years would not be advantageous because it would not permit monitoring of changes as frequently as needed to address these changes, and for the same reason, it would not meet the needs of the grantees collecting the data and planning groups that rely on the data for resource allocation.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

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

A 60-day notice to solicit public comments was published on November 2, 2010, volume 75, number 211, page numbers 67375-6. A copy of this publication is attached (**Attachment 2**). Four public comments were received. The response to these public comments is documented in (**Attachment 4**).

Several consultations were conducted with various scientists and public health practitioners outside the agency. The name, affiliation, and contact information for each consultant is included in Table 8.A. There were no problems that could not be resolved during the consultation.

In September 2006, CDC held a consultation with external researchers, who have conducted behavioral surveys among transgender populations. Key participants included: Walter Bockting, Dee Dee Chamblee, Viva DelGado, Robert Garofalo, Nina Kammerer, Joanne Keatley, Emilia Lombardi, Elizabeth Mediano, Nicole Pitts, Beatrice “Bean” Robinson, Ben Singer, Jessica Xavier. The purpose of this meeting was to obtain input on 1) strategies for assessing gender identity in eligibility screening surveys; 2) the key HIV-related behavioral indicators that should be included in the survey; 3) strategies for asking about sexual risk behaviors; and 4) the best sampling strategy for recruiting transgender persons. Some of these consultants were representatives of the transgender groups from which THBS data will be obtained. The discussion also focused on the utility of the information from the proposed data collection for developing HIV prevention programs.

During September through November 2006 Drs. Gretchen Kenegy, Christine Clements-Noelle, Sel Hwahng, and Larry Nuttbrock provided technical assistance in conducting health-related surveys among transgender persons. Dr. Clements-Noelle had previously used the proposed sampling strategy to recruit transgender persons for a survey. Among her observations was the need for incentives to increase referrals and to reaching an adequate response rate.

Between October 2006 and June 2009, CDC held regular conversations with Dr. Michael Burke, Dr. Kristina Peterson, and Ms. Victoria Albright of RTI, Inc regarding the development of the THBS eligibility screener, behavioral questionnaire, and sampling protocol.

In April 2007, CDC consulted with Dr. Stephanie Willson about testing the eligibility screener and questionnaire items.

In December 2007, CDC consulted with Drs. Lillian Lin, Christopher Johnson, and Doug Heckathorn to obtain advice on the sampling strategy, analytic methods and sample size.

In 2009, CDC analyzed the data from the pilot survey; In 2010, CDC consulted with Dr. Trista Bingham, Ms. Julie-Ann Carlos, Ms. Pam McCann, Mr. Nik Prachand, and Dr. Paige Padgett (who had been involved in conducting the pilot) to obtain their input on the findings. CDC also consulted with Dr. Cyprian Wejnert, an expert on respondent-driven sampling, about how to assess non-response in future proposed activities. Also in 2010, CDC consulted with Mr. Ejay Jack of the Presidential Advisory Council on HIV/AIDS to obtain input on the questionnaire.

Table 8.A Name, Affiliation, and contact information of Consultants

Consultant	Institutional Affiliation	City, State	Email
Victoria Albright, MA	RTI International	Research Triangle Park, NC	valbright@rti.org
Trista Bingham, PhD	Los Angeles County Health Department	Los Angeles, CA	tbingham@ph.lacounty.gov
Walter Bockting, PhD	University of Minnesota	Minneapolis, MI	bockt001@umn.edu
Michael Burke, PhD, MPH	RTI International	Washington DC	mburke@rti.org
Julie-Ann Carlos, MPH	Los Angeles County Health Department	Los Angeles, CA	jcarlos@ph.lacounty.gov
Dee Dee Chamblee	La Gender, Inc.	Atlanta, GA	deedeecham@yahoo.com
Kristen Clements-Noelle, PhD	University of Nevada - Reno	Reno, NV	clements@unr.edu
Viva DelGado, MPH	San Francisco Department of Public Health	San Francisco, CA	Viva_delgado@dph.sf.ca.us
Robert Garofalo, MD	Howard Brown Health Center	Chicago, IL	robgs@howardbrown.org
Doug Heckathorn, PhD	Cornell University	Ithaca, NY	douglas.heckathorn@cornell.edu
Sel Hwang, PhD	NDRI, Inc	New York, NY	sqw2864@nyu.edu
Ejay Jack	Presidential Advisory Council on HIV/AIDS (PACHA)	Omaha, NB	ejayjackmsw@gmail.com
Nina Kammerer, PhD	Brandeis University	Waltham, MA	kammerer@brandeis.edu
Joanne Keatley, MSW	Pacific AIDS Education and Training Center	San Francisco, CA	jkeatley@fcm.ucsf.edu
Gretchen Kenegy, PhD MSW	University of Illinois at Chicago	Chicago, IL	kenagy@uic.edu
Emilia Lombardi, PhD	University of Pittsburgh	Pittsburgh, PN	emilial@stophiv.pitt.edu
Pamela McCann	Chicago Department of Public Health	Chicago, IL	McCann_Pamela@cdph.org
Elizabeth Mediano	Asian Pacific AIDS Intervention Team	Los Angeles, CA	elizabethm@apaitonline.org
Larry Nuttbrock, PhD	NDRI, Inc	New York, NY	nuttbrock@ndri.org
Nik Prachand, MPH	Chicago Department of Public Health	Chicago, IL	prachand_nik@cdph.org
Paige Padgett, PhD	University of Texas	Houston, TX	Paige.M.Padgett@uth.tmc.edu
Nicole Pitts	Emory University	Atlanta, GA	nlpitts@sph.emory.edu
Beatrice "Bean" E. Robinson, Ph.D.	University of Minnesota Medical School	Minneapolis, MI	robin009@umn.edu
Ben Singer, PhD (c)	Rutgers University and Genderworks Consulting Company	New York, NY	bensinger@verizon.net
Jessica Xavier, MPH	Virginia Commonwealth University/Survey and Evaluation Research Laboratory	Richmond, VA	jessicax@earthlink.net

Consultant	Institutional Affiliation	City, State	Email
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Chris Johnson, PhD	Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention, Centers for Disease Control and Prevention	Atlanta, GA	CJohnson3@cdc.gov
Lillian Lin, PhD	Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention, Centers for Disease Control and Prevention	Atlanta, GA	LLin@cdc.gov
Vel McKleroy, MPH	Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention, Centers for Disease Control and Prevention	Atlanta, GA	VMckleroy@cdc.gov
Cyprian Wejnert, PhD	Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention, Centers for Disease Control and Prevention	Atlanta, GA	Cwejnert@cdc.gov
Stephanie J. Willson, Ph.D.	Questionnaire Design Research Laboratory, Office of Research and Methodology, National Center for Health Statistics, Centers for Disease Control and Prevention	Hyattsville, MD	SWillson@cdc.gov

9. Explanation of Any Payment or Gift to Respondents

THBS seeks to conduct surveys with hard-to-reach populations, because the interview will take approximately 45 minutes to complete, it is expected that paying respondents will increase response rates. We anticipate that increased response rates will lead to improved representativeness of the underlying population of interest.

Participants will be given \$25 in cash for their participation. If local regulations prohibit cash as a token of appreciation, an equivalent token of appreciation may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

A dual-incentive system is a standard part of the RDS methodology in which participants receive a token of appreciation for completing the survey and for recruiting their peers. To increase peer recruitment, additional tokens of appreciation will be provided to peer recruiters for each eligible recruit who completes the survey (the “recruiter reward”). Recruiter tokens of appreciation will

be \$10 for up to five peer recruits, which are standard for RDS studies (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2004). As with the survey tokens of appreciation, if local regulations prohibit cash as a token of appreciation, an equivalent token of appreciation may be offered in the form of gift certificates or cash cards.

The need for offering tokens of appreciation to respondents and the amount is based, in part, on that there are other, similar federally-funded research projects conducted among populations at increased risk for HIV infection that offer their participants \$25 for participation. Tokens of appreciation were used in other similar surveys conducted by CDC: SHAS (OMB 0920-0262, exp. 06/30/2004); MMP (OMB-0920-0740, exp. 05/31/2012); NIC (OMB 0920-0748, exp. 08/31/2010); and NHBS (OMB 0920-0770 exp 03/31/2011). These surveys are described in **A.4**. Each asks questions similar to those in the THBS behavioral assessment (but targets populations other than male-to-female transgender persons) and takes a similar length of time to complete. According to several consultants on this project, if THBS respondents are not paid comparable payments to the respondents of other similar behavioral surveys, participation will be low. Transgender persons will perceive the researchers to be unfair and as a result may not participate. In addition, recruiter rewards are necessary to ensure peer recruitment. Dr. Clements-Noelle attempted a respondent-driven survey among transgender persons without providing rewards to peer recruiters. Since recruiters in her survey were not motivated to recruit their peers without being provided some financial reward for doing so, she recommended providing the recruiter rewards to ensure peer recruitment. Thus, recruitment will suffer if THBS respondents are not paid for their participation and recruiting peers.

10. Assurance of Confidentiality Provided to Respondents

This section has been reviewed by ICRO, which determined that the Privacy Act does not apply, because the survey does not collect name, social security number (SSN), or other personally identifying information. Therefore, the data will not be retrievable by name, SSN, or other personal identifier. Full date of birth is collected for the purpose of identifying potential duplicate records or participants who have participated in the survey more than once. 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 participant has previously taken the survey will be made based on how closely this information matches. Full date of birth is sent to CDC, but is only available to the CDC staff overseeing THBS data collection in the field (i.e., date of birth is not maintained in analysis datasets). Because this is an anonymous survey, local field staff will collect both the respondent's physical marks and concatenated responses to a series of questions designed to form a unique ID. These data are collected and used by local staff to locate a person's coupon record and confirm that the person was a previous participant or a peer recruiter. They are not stored in a database with behavioral data. The physical marks and the unique recruiter ID are not shared with CDC and are destroyed after the behavioral assessment response dataset has been finalized, following local procedures for doing so. Data collected through THBS, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through THBS, while sensitive, are not personally identifying; these survey questions are described in Section 11.

In addition to limiting the amount of personally identifying information collected, THBS is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (**Attachment 6**). The Assurance provides the highest level of legal confidentiality protections to the individual persons who are the subject 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.

Privacy Impact Assessment

- A. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply.
- B. The interviewer-administered portion of the interview will be conducted by trained THBS staff in a private location where the questions and responses cannot be overheard by others. THBS data will be transmitted to CDC using a secure internet-based system that is used to transmit HIV/AIDS surveillance data to CDC. This system is referred to as the Secure Data Network (SDN). Databases submitted through the SDN must be encrypted before being sent to CDC. Encryption security for all THBS 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 (<http://www.cdc.gov/hiv/surveillance.htm>).

The following safeguards are applied to the data on computers used to collect data: 1) Computers are solely used for THBS data collection activities. 2) In the field, behavioral data are not maintained on the same computer as the one containing the unique recruiter ID or the respondent's physical marks; 3) THBS data are encrypted when stored on computers. 4) Computers are protected by using a coded password only known by authorized THBS project staff. 5) Computers are kept with staff at all times when in the field; 6) Computers are collected and secured by the field supervisor at the end of a recruitment event after the last interview. 7) When not in use in the field, computers are to be locked in a drawer or office.

THBS is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (**Attachment 6**). 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 CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (<http://www.cdc.gov/hiv/topics/surveillance/index.htm>) and are required to undergo security and confidentiality training. THBS interviewers and data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office 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 (**Attachment 5**) and to update their confidentiality agreements on an annual basis. CDC 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." Grants to state and local health departments will reference the Assurance of Confidentiality and require similar data security safeguards for health department staff and health department contractors as a condition of award. Any THBS data maintained at CDC that is released to persons other than study staff will not include full date of birth.

- C. The informed consent process for respondents may be fulfilled by obtaining oral consent from the respondent. All sites must obtain consent from respondents and document it using the consent questions at the end of the eligibility screener form on the handheld computer. An example of the consent document is included as **Attachment 7**. In conducting the proposed THBS survey, respondents will be informed that their data will be maintained in a strictly confidential manner and that the data will be reported in aggregate format. The confidentiality section of the consent form also explains to the respondent that no one except study staff at the specific participating agencies and CDC will have access to the survey data. Respondents will be advised that summary and not individual information will be shared in CDC reports and used to monitor changes in HIV risk behavior that can warn or explain trends in HIV infection among transgender individuals.

The approved Project Determination Form is provided in (**Attachment 8**). This form indicates that because CDC is not directly engaged with human subjects in connection with this project, the protocol will not be reviewed by CDC's IRB. However, each participating health department and any contracting agencies will be required to obtain IRB approval prior to data collection.

- D. The consent form also informs the respondent that participation in the survey is voluntary. All the questions in the eligibility screener, behavioral assessment, and recruiter debriefing instruments allow the respondent the option of refusing to provide a response.

11. Justification for Sensitive Questions

The collection of HIV/AIDS status itself is sensitive because of stigma associated with HIV infection. In addition, HIV can be transmitted from person to person through sexual contact and the sharing of HIV-contaminated needles and syringes. These modes of transmission necessitate the collection of sensitive data regarding medical history, sexual orientation, and sexual practices as well as alcohol and drug use. THBS data collection will also request sensitive information relating to race/ethnicity, health conditions such as sexually transmitted diseases and tuberculosis diagnoses, as well as recent incarceration history. Although the information requested is highly sensitive, the purposes of the THBS cannot be accomplished without their collection. Collection of these data will be used to understand barriers to HIV prevention, care and treatment and to describe the risk behaviors for acquiring HIV infection. These data will also be used to enhance HIV prevention programs designed to reduce high risk behaviors in persons most likely to acquire or transmit HIV.

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 consent of the respondent.

Social security numbers will not be collected from respondents.

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

12. Estimates of Annualized Burden Hours and Costs

Estimates of respondent burden for each data collection form are provided below. Approximately 1,100 individuals will be approached to participate in the THBS interview in a 12-month period. A screener will be used to determine eligibility by assessing the respondent's race/ethnicity, previous participation, county of residence and length of time residing there, gender at birth and gender identity. We estimate that it will take five minutes to complete the screener, totaling 92 hours per year. We anticipate that 10% of respondents will be either not interested in completing the behavioral assessment or will be ineligible after completing the screener. Approximately 1,000 individuals are expected to participate in the THBS behavioral assessment in a 12-month period. We estimate that it will take 40 minutes for each respondent to complete the interview. The average annual burden for the interview is estimated to be 667 hours. It is expected that about 60% (n= 600) of the persons interviewed will become peer recruiters. Of whom, about 500 will return for recruiter rewards. Therefore, we expect about 500 peer recruiters to be asked the questions included in the recruiter debriefing instrument. We estimate that the recruiter debriefing will take 2 minutes to complete, for a total annual burden of 17 hours. The total annual burden, including the screener, the behavioral assessment interview, and the recruiter debriefing is estimated to be 776 hours. These estimates cover the time that each respondent will spend communicating with the recruitment staff and answering interview questions.

The burden hours have changed from the previously approved data collection as follows;

The number of persons screened for eligibility increased by 850 and the time estimate for the screener did not change, so the burden hours associated with the screener increased by 72 hours. The number of persons to complete the behavioral assessment increased by 800, and the time estimated declined by 5 minutes, so the burden hours associated with the survey increased by 517 hours. The recruiter debriefing was not included in the previously approved data collection, and added 17 burden hours. The total number of burden hours increased by 605 burden hours.

Table 12.A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average burden per Response (in hours)	Total Burden hours
Persons Referred by Peer Recruiters	Screener	1,100	1	5/60	92
Eligible Transgender Persons	Behavioral assessment	1,000	1	40/60	667
Peer Recruiters	Recruiter debriefing	500	1	2/60	17
TOTAL		1,100			776

Table 12.B: Estimated Annualized Burden Costs

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average burden per Response (in hours)	Total burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Persons Referred by Peer Recruiters	Screener	1,100	1	5/60	92	\$19.07	\$1,754
Eligible Transgender Persons	Behavioral assessment	1,000	1	40/60	667	\$19.07	\$12,720
Peer Recruiters	Recruiter debriefing	500	1	2/60	17	\$19.07	\$324
TOTAL		1,100			776		\$14,798

In order to estimate the cost to the respondents, we used the preliminary estimate of the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls for 2010 available on the US Department of Labor website at <ftp://ftp.bls.gov/pub/suppl/empst.ceseeb2.txt>.

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

There are no other costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

Table 14.A. Estimated Annualized Costs to the Government

Expense Type	Government Related Expenses	Annual Costs (dollars)
Direct cost to the Federal Government		
	CDC Project Officer (GS-13, 1 FTE)	\$97,000
	CDC Public Health Analyst (GS-13, .25 FTE)	\$24,250
	Spanish translation	\$5,000
	Travel	\$12,000
	Subtotal, direct costs to the government	\$138,250
Indirect cost to the Federal Government		
	Contracted data manager/analyst on-site at CDC (.25 FTE)	\$20,000
	Contracted project coordinator on-site at CDC (.25 FTE)	\$20,000
	Contracted questionnaire programmer on-site at CDC (.25 FTE)	\$20,000
	Cooperative Agreements to State and Local Health Departments	\$1,000,000
	Subtotal, direct costs to the government	\$1,060,000
	TOTAL COST TO THE GOVERNMENT	\$1, 198,250

The total annualized cost to the federal government is \$1,198,250. Personnel related to the proposed future activities include: a GS-13 level project officer, a GS-13 level public health analyst, a contracted project coordinator, and a contracted data manager. Travel for future activities is related to providing technical assistance and site visits. Two meetings are planned: a train-the-trainer meeting; an investigator meeting. The train-the-trainer meeting will train supervisory-level field staff on how to conduct their local trainings. In addition, cooperative agreements will be used to provide funds to about five state/local health departments for local field staff, tokens of appreciation, HIV testing, computer hardware/software, travel, and local data management.

The information collection described in this request will be funded through cooperative agreements with state and local health departments. This represents a change from the previously approved data collection, which was funded through a 3-year contract with Research Triangle Institute, Inc. This change is consistent with the transition from a pilot to an ongoing data collection as CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments.

15. Explanation for Program Changes or Adjustments

Proposed future activities will incorporate changes to the questionnaire and recruitment methods based on the past information collection. These changes include:

- 1) Increasing the sample size from 100 to 200 respondents interviewed in each participating area to allow increase the ability to describe when using the data to describe the HIV risk behavior among transgender persons in participating locations.
- 2) Increasing the number of participating areas where the survey is conducted from 4 to 5 areas. This change will provide one more jurisdiction with the ability to monitor the epidemic among male-to-female transgender persons;
- 3) Removing the racial restriction on eligibility and allowing transgender persons to recruit any transgender person within their network. Removing this restriction is expected to allow a better understanding of the impact HIV has on the transgender community in participating jurisdictions and to describe any disparities between racial groups;
- 4) Providing a Spanish version for monolingual Spanish speakers to increase the likelihood that Latino and Hispanic persons could participate (**Attachment 3e**) ;
- 5) Switching the format of the interview from an audio-computer assisted self interview (ACASI) conducted on a laptop to a computer-assisted personal interview conducted on a handheld computer. Since the goal of this request is to collect data that can be used to describe risk behaviors in participating jurisdictions to direct HIV prevention efforts; therefore, it is important that the resulting data be comparable to HIV-risk behavior data collected from other at-risk populations through the NHBS system (OMB 0920-0770 exp 03/31/2011) as these other at-risk populations will also be considered when prevention funding decisions are made.
- 6) Re-numbering the eligibility screener and behavioral assessment questionnaire instruments and provided section headers. Instead of the numbering being sequential from the beginning of each instrument, the numbering begins at the beginning of each section header. This change was made to avoid having to renumber the entire instrument which could yield errors in documented skip patterns. The renumbering of the survey also makes it easier for the questionnaire's software programmer and Spanish translator to follow the survey and skip logic;
- 7) Moving the main network question from the eligibility screener to the behavioral assessment questionnaire as these questions typically provide the general eligibility requirements for the survey;
- 8) Deleting 6 of the network questions that assessed the race of the social network as these questions were used in the pilot survey, which had racial and ethnic eligibility limitations; these questions are cognitively difficult for respondents to answer.
- 9) Deleting 2 of the 4 questions used to determine transgender identity in the eligibility screener. Almost all the participants in the previously approved data collection identified as transgender using two of the four questions. These two questions remain in the eligibility screener and are consistent with the recommendations from the Center for Excellence of Transgender Health for collecting data from transgender persons (see <http://transhealth.ucsf.edu/pdf/data-recommendation.pdf> for these recommendations) Changes in the text of the eligibility screener are documented in (**Attachment 9**);
- 10) Modifying the behavioral assessment questionnaire based on feedback from the respondents and local field staff during the previously approved data collection to ensure that behavioral assessment is collecting information in the best format. These changes to the text are documented in (**Attachment 10**) and include:

- a. Deleting 129 questions (some of the deleted questions were modified and added as new questions);
 - b. Adding 77 questions to the instrument. Reasons for adding these questions are documented in (**Attachment 9**).
 - i. Some of these new questions resulted from moving the hormone and silicone use questions from the drug use section to a new section titled transgender-specific procedures. As transgender persons tended to view hormone and silicone use separate from illicit drug use. During the previously approved data collection , some respondents were offended by their placement with the illicit drug use questions; and
 - c. Changing the text of 63 items in the behavioral assessment questionnaire. This change was necessary to administer a face-to-face interview (the previously approved data collection involved a self-administered questionnaire).
- 11) Adding an instrument to be used to debrief peer recruiters by asking questions to assess coupon distribution and coupon refusal. This information will help assess non-response bias.

16. Plans for Tabulation and Publication and Project Time Schedule

Reinstatement of the previously approved Transgender Behavioral Survey (OMB No. 0920-0794, expired December 31, 2010) is requested for a period of 3 years. Data collection is expected to take up to 12 months.

Table 16.A: Project Time Schedule

Activities	Time Schedule
Conduct formative work	1-6 months post OMB approval
Training staff	4-5 months post OMB approval
Complete field work	12-15 months post OMB approval
Data management and validation	13 - 16 months post OMB approval
Dissemination of results	16-20 months post OMB approval

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

The OMB Control number and expiration date will be displayed on the computer in the questionnaire program.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

There are no exceptions to the certification statement identified in Item 13, Paperwork Reduction Act Submission Worksheet, Part I: Information Collection Request.

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