

Transgender HIV Behavioral Survey

0920-08XX

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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 term of 2 years for a new project that will pilot a questionnaire and protocol for an HIV-related behavioral survey among transgender persons of color. The purpose of the survey is to collect ongoing HIV-related behavioral data for monitoring the epidemic among transgender persons.

CDC's HIV Prevention Strategic Plan establishes four goals to reduce the annual number of new HIV infections in the United States. One of these goals is to strengthen the national capacity to monitor the HIV epidemic. Historically, the HIV epidemic in the United States was monitored primarily by tracking cases of HIV infection and AIDS, although some supplemental surveillance systems and surveys have been used to provide additional information about behaviors related to HIV infection. Because many years may pass between the time when a person is infected with HIV and the time that HIV infection is diagnosed, case surveillance for HIV infection and AIDS does not reflect recent trends in the behaviors that fuel the epidemic. Therefore, an ongoing, systematic collection on behaviors related to HIV acquisition is an important component of an integrated surveillance system. An integrated surveillance system will be more effective in directing and evaluating prevention efforts that are currently required to reduce the annual number of new infections.

To achieve the goal of strengthening the national capacity to monitor the HIV epidemic, an aim of the strategic plan is to improve the surveillance of HIV-related risk behaviors among populations vulnerable to acquiring HIV infection. The plan specifically calls for more information about the HIV risks behaviors and prevention experiences of transgender persons, a population vulnerable to HIV infection but for which little is known.

In response to the strategic plan's goal of strengthening the national capacity to monitor the epidemic, 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 HIV 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 be offensive to transgender persons as these questions are designed with the assumption that the respondent has certain genitalia. Lastly, transgender persons are members of a stigmatized group. As a result, transgender persons often hide their transgender identity, making it difficult to recruit a broad sample from this group. Therefore, to monitor the HIV epidemic among transgender persons the following are needed: a method for identifying transgender persons, a questionnaire to accurately capture their risk behaviors, and a sampling methodology for recruiting transgender persons.

The proposed information collection is being conducted to address these gaps in knowledge by conducting a pilot study of an HIV-related behavioral survey among transgender persons. Having a good HIV-related behavioral survey is key to designing a behavioral surveillance system. Unlike other populations vulnerable to HIV infection, few HIV-related surveys have been conducted among transgender persons. As a consequence, little is known about how to identify eligible transgender persons, ask about their risk behaviors, or recruit transgender persons. For the pilot study, CDC has developed an eligibility screener, behavioral questionnaire, and sampling strategy for recruiting transgender persons. The Transgender HIV Behavioral Survey (THBS) is the pilot study of this screener, questionnaire and sampling method. The pilot study will determine the feasibility of using the survey as a part of a behavioral surveillance system.

The pilot data may also be useful for identifying much needed prevention services among African American and Latino male-to-female transgender persons, who are disproportionately affected by the HIV epidemic. A recent meta-analysis of findings from published surveys among transgender persons reported higher prevalence of HIV infection among African American male-to-female transgender persons than among their White counterparts (Herbst et al., 2007). Consistent with this prevalence data are findings that also indicate higher rates of new infections among African American and multi-racial male-to-female transgender persons than other racial groups (Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Simon, Reback, & Bemis, 2000). HIV prevalence in these populations is alarmingly high, ranging from 16% to 68% (Kellogg, et al., 2001; Elifson et al., 1993; Clements-Nolle, Marx, Guzman, & Katz, 2001; Murrill et al., 2005) with new infections ranging from 3.4 to 7.8 new infections per 100 persons (Kellogg, et al., 2001; Simon, et al., 2000).

Latino male-to-female transgender persons are at increased risk for acquiring HIV infection as well. Although HIV prevalence in Latino or Hispanic transgender populations is similar or lower than that of their White peers (Herbst et al., 2007), general surveillance suggests that incidence is rising among Latino and Hispanic populations in the United States. Although Hispanics make up only about 13% of the population of the United States and Puerto Rico, they account for 16% of the AIDS cases diagnosed since the beginning of the epidemic (Ramirez & de la Cruz, 2003; CDC, 2007). Hispanic and Latinos have the second highest rate of AIDS diagnoses; African Americans have the

highest rate (CDC, 2007). In 2002, HIV/AIDS was the fourth leading cause of death among Hispanic women aged 25-44 (CDC, 2004).

Without THBS data, there is no alternate source of HIV-related behavioral data for transgender persons – particularly racial and ethnic minority transgender persons. HIV-related behavioral data available through case surveillance only collects a limited amount of information and does not readily identify transgender cases. HIV-related behavioral data from small, ad hoc behavioral surveys are not likely to have large sample sizes or geographic diversity. In addition, they may not yield adequate samples of African-American or Latino persons to identify much needed HIV prevention services in these populations. Not having THBS data would adversely affect the ability to monitor the HIV/AIDS epidemic in transgender populations both locally and nationally. Once the screener, questionnaire, and methods are devised for a behavioral surveillance system in this population, State and local health departments will have a method of monitoring the HIV-related behaviors of transgender persons. When THBS becomes a surveillance system, a new information collection request will be written to cover that system.

This study will be conducted under Title III – General Powers and Duties of Public Health Service, Section 301 (241.)a.(Attachment 1).

Privacy Impact Assessment

Overview of data collection system

The THBS pilot will use Respondent Driven Sampling (RDS) to recruit participants into the survey. THBS will collect data through a combination of a face-to-face and computer assisted self interview. 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 various eligibility criteria and limited demographics (Attachment 3). If eligible for the survey, and the respondent consents to complete the questionnaire, the respondent will be trained to use the computer-based interview instrument installed in a laptop dedicated to this study. The respondent can complete the computer-assisted interview in the absence of the interviewer. The electronic data collected in these interviews is maintained indefinitely at CDC.

Items of information to be collected

Data collected in the eligibility screener and behavioral questionnaire will include self-reported demographics, the number of transgender persons the respondent knows (or network size), sexual and substance use behaviors, hormone and silicone injection behaviors, HIV testing patterns and exposure to and use of HIV prevention services (Attachment 3). At the end of the interview, the respondent will return the laptop to the interviewer, who will then ask a few questions to assess questionnaire items.

Full date of birth is collected for the purpose of identifying potential duplicate records or participants who have done the survey more than once. Records that have the same date of birth, race, and education level will be returned to the health department to determine whether a record is a duplicate or a participant who has previously taken the survey. The data received by CC will not include any information that would lead to the identification of a participant. The link between Survey ID and the identifiers of the participant are available only to the local health departments and not submitted to CDC.

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 or refer respondents to websites. This system does not host a website.

2. Purpose of Use of the Information Collection

The purpose of this pilot study is to develop a transgender-specific survey instrument and sampling method(s), in order to strengthen the national capacity to monitor the HIV epidemic and improve the direction and evaluation of prevention efforts among male-to-female transgender persons. The THBS data will also serve to meet the CDC HIV Prevention Strategic Plan objective of improving surveillance of HIV-related risk behaviors among transgender or gender variant persons.

THBS will be used to describe the prevalence of risk behaviors, HIV testing, self-reported HIV infection, and the use of both HIV testing and prevention services. This information will be used to meet a national need to identify and address gaps and deficiencies in HIV prevention science, especially for at-risk populations with fewer interventions of documented effectiveness, such as male-to-female transgender persons. The explicit ability to identify gaps in HIV prevention services among transgender persons is a unique aspect of THBS. THBS data may indicate the need for State and Local health departments to obtain, allocate, or shift prevention resources. In addition, these data may suggest the need for prevention strategies that are tailored to male-to-female transgender persons. For example, individual and group prevention programs may be more effective if the activities and discussions are sensitive to transgender persons. Lastly, THBS data may be used to assess progress in performance goals of CDC's National Center for HIV, STD, and TB Prevention (NCHSTP) to: Increase the proportion of people who consistently engage in behaviors that reduce risk of HIV transmission or acquisition; track the prevalence of disease; monitor behaviors that increase the risk of HIV infection (among those who are not infected); and provide locally relevant data for community planning.

Privacy Impact Assessment

Being a pilot, THBS will not yield data that can be generalized to broader populations. The pilot data will be used to evaluate the extent to which behavioral data could be generalized if it were collected through a surveillance system using the piloted methods. Thus, at best, data from the THBS pilot may be used to describe behaviors related to HIV infection and current usage of prevention efforts, including HIV testing among the sampled transgender persons.

The information from the pilot survey will be used to improve the eligibility screener, behavioral questionnaire, and sampling methodology for future data collection. The objectives of the pilot will be to assess the usefulness of the recruitment methods for a surveillance system among transgender persons and the appropriate content of the eligibility screener and behavioral questionnaire.

Full date of birth is collected for the purpose of identifying potential duplicate records or participants who have done 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. 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.

Other than date of birth, no identifying information is collected. With the safe guards described above to protect the security and confidentiality of the data, the impact on privacy is expected to be minimal and limited. In addition, these safeguards are in place to prevent breaches of confidentiality.

3. Use of Improved Information Technology and Burden Reduction

The information will be collected by means of computerized interview programs stored on laptops to minimize burden to respondents and interviewers. The eligibility screener and behavioral questionnaire (Attachment 3) will be provided by CDC in an electronic format for use on a laptop computer. The electronic format will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). The eligibility screener will be conducted by trained THBS staff using a computer-assisted personal interview (CAPI) on the laptop. If the person is eligible and consents to completing the questionnaire, the interviewer will instruct the participant on how to self-administer the behavioral questionnaire on the laptop computer. The behavioral questionnaire will be conducted in an audio, computer-assisted self-interview (ACASI).

Data linking recruiters and recruits using RDS will be entered directly into a computer program, called "Coupon Manager." By entering data directly into the computer, the efficiency of data collection is improved as compared to using paper and then entering

the data. The Coupon Manager program also reduces the time and effort to validate coupons and tracks payments of incentives. During a participant's visits to the field site, data can be called up efficiently through use of search terms, such as by coupon number. 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.

An evaluation of survey data using handheld computers has shown the following: a reduction in the duration of the interview by up to 20%; a decrease in the average number of interviewer errors per interview such as skip patterns, out of range answers and missing data from an average of 2.5 per interview to 0.3 per interview; and the elimination of 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 only 1 month. 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. Although THBS will use laptop computers and ACASI technology, the findings from this evaluation are expected to be true for THBS because the overall cost of laptop computers used for THBS is expected to be less than the overall cost of the handheld computers in the evaluation. Also, the difference in cost between the laptops and handheld computers is expected to be about the same that it would cost to add audio files to the computer program in the initial evaluation. Adding the audio component may add a marginal cost to the data collection, but the audio component is important because of the low literacy rate in these populations.

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.

Computer-assisted self interviewing reduces burden for the respondent because it collects the data using a computer. The computer customizes the question wording for each respondent. In addition, previous studies have shown that respondents are more likely to

reveal engaging in sensitive behaviors in a computer-assisted self interview without an interviewer than in a face-to-face format (Gribble, Miller, et al., 1999).

CDC is investigating several software products which will enhance the security of data stored on the laptop computers. It is anticipated that this software will be installed on the laptop computers prior to the start of data collection in fall 2008. The THBS data files must be transferred, or uploaded, from the laptop computers to the project area's secure storage drive on a frequent basis. All THBS data files must be transmitted to CDC using the Secure Data Network (SDN).

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently-funded programs and did not identify potential areas of duplication. No known department or agency maintains behavioral data among transgender persons. There are no known sources for HIV-related behavioral data from transgender persons available within the department or agency. Hence, THBS is a unique a survey.

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. 06/30/2010
- 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 because they do not have a means of determining transgender persons or of collecting the risk behaviors of transgender persons. CDC discontinued the SHAS project in anticipation of MMP and to avoid duplication of data collection efforts. MMP collects data on a population-based sample of HIV-infected patients in care, not specific populations at increased risk for HIV. NIC collects similar data among HIV-infected persons who are not in care. NHBS will collect data from populations at-risk for HIV infection, regardless of infection, including men who have sex with men, injection drug users, and high-risk heterosexuals. However, NHBS will not collect data from transgender persons, because a questionnaire and method for systematically collecting data has not been tested in this population. THBS is a pilot to develop a questionnaire and survey method for systematically collecting data from this vulnerable population.

CDC established relationships with other federal stakeholders and consultants during the conception and development of national, integrated HIV surveillance system, for which

THBS is being piloted. 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. 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. The Computer Retrieval of Information Scientific Projects (CRISP) database was also searched for federally funded projects involving HIV-related research or prevention among transgender populations. Many of these persons attended a consultation meeting for THBS in September 2006.

Meetings with these federal stakeholders and consultants who are aware of data collection on transgender persons ensured that duplicate or similar data collection efforts do not exist. Other surveys may have obtained data related to topics covered in THBS, but most were limited in the questions they ask, the populations they represent, the geographic areas covered, or all of these factors.

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

THBS data collection activities will occur from 2008-2010. The pilot survey is a one-time study and respondents will provide the information only once. Participants interviewed for THBS are only eligible to participate once. Each person will be asked if they have been interviewed previously for the survey; those who indicate that they have been interviewed already will not be interviewed again.

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 July 24, 2007, page numbers 40298-40299). A copy of this publication is attached (Attachment 2). We did not receive public comments.

Several consultations were conducted with various scientists and public health practitioners outside the agency. All names, affiliations, and contact information is included in Attachment 4.

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. Their titles and institutional affiliations are in Attachment 4.

The purpose of this meeting was to obtain their input on 1) strategies for detecting transgender persons 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 representative of the transgender groups from which THBS data will be obtained. The discussion also focused on the utility of the information 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 into the survey. Among her observations was the need for incentives towards increasing referrals and towards reaching a high response rate. In October 2006, CDC began to hold regular conversations with Dr. Michael Burke 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 eligibility screener and questionnaire items.

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

9. Explanation of Any Payment or Gift to Respondents

Incentives will be used in THBS as the project seeks to conduct surveys with hard-to-reach and highly selective populations and ask them highly sensitive questions about issues such as their gender identity, sexual behavior and substance use (Kulka, 1995). Because the interview will take approximately 45 minutes to complete, eligible persons

will be offered an incentive to participate, thereby increasing response rates. With increased response rates, the reliability of the data will be improved as the samples will be more representative of the underlying populations of interest.

Participants will be given approximately \$25 in cash for their participation. If local regulations prohibit cash incentives, equivalent incentives 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 an incentive for completing the survey and for recruiting their peers. To increase peer recruitment, additional incentives will be provided to those who recruit an eligible participant who completes the survey (the “recruiter reward”). Recruiter rewards will be approximately \$10 for up to three peer referrals, which is standard for RDS studies (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2004). As with the survey incentives, if local regulations prohibit cash incentives, equivalent incentives may be offered in the form of gift certificates or cash cards.

The need for and amount of incentives is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions among populations at increased risk for HIV infection in the cities where THBS will be conducted offer similar incentives. Thus, THBS would be competing with local researchers who do offer incentives; without incentives, it is likely that participation in THBS would be low (McKnight, 2006; Stueve, 2001; Valleroy, 2000). Incentives were used in other similar surveys: SHAS (OMB 0920-0262, exp. 06/30/2004); MMP (OMB-0920-0740, exp. 06/30/2010); 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 THBS and has a similar length of time for completing the survey. These incentives were used to help increase participation rates; participants were offered approximately \$25 as an incentive.

10. Assurance of Confidentiality Provided to Respondents

ICRO has reviewed the survey and 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 done 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. 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 5). 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

This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply.

- A. THBS data will be transmitted to CDC using the 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 (www.cdc.gov/hiv/surveillance.htm).

The following safeguards are applied to the data on laptop computers used for interviews. 1) the laptop computers are solely used for THBS data collection activities. 2) THBS data are encrypted when stored on a laptop computer. 3) Laptop computers are protected by using a coded password only known by authorized THBS project staff. 4) The laptop computers are kept with the staff at all times when in the field; 5) the computer are collected and secured by the field supervisor after the last interview each day. 6) When not in use in the field, the laptop computer is to be locked in a drawer or office.

- B. THBS is covered by an Assurance of Confidentiality under Section 308(d) of the Public Health Act granted for HIV/AIDS surveillance data (Attachment 5). 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 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." Contracts to state and local health departments will reference the Assurance of Confidentiality as a condition of award. Any THBS data maintained at CDC that is released to persons other than study staff would 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 in the data collection form on the laptop computer. An example of the consent document is included as Attachment 6. 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. 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. This project was submitted and approved by the CDC IRB (See Attachment 7).

The consent form also informs the respondent that participation in the survey is voluntary. Almost all the questions in the eligibility screener and behavioral survey allow the respondent the option of refusing to provide a response without a refusal form. Respondents will be advised that summary and not individual information will be shared in CDC reports and used for the purposes of improving national surveillance for HIV among transgender individuals.

11. Justification for Sensitive Questions

Because, HIV can be transmitted from person to person through sexual contact and the sharing of HIV-contaminated needles and syringes, specific behaviors, experiences or conditions unique to transgender individuals are essential for devising a sensitive yet, effective surveillance system. Collection of these data will be used to understand barriers to engaging in protective behaviors and to using HIV prevention services. 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.

12. Estimates of Annualized Burden Hours and Costs

The goal is to interview a convenience sample of 400 persons; 100 in each of four project areas. However, it may take more than 12 months to implement the survey in all 4 areas and reach the goal of 400. Therefore, the annual goal is 200 interviews. To achieve the annual goal, an additional 40 persons must be screened for eligibility. We timed how long it would take an interviewer and respondent to go through the computer program for the screener and survey. The screener takes 5 minutes to complete. Each survey will take approximately 45 minutes.

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
Referred individuals	Screener	240	1	5/60	20
Eligible participants	Survey	200	1	45/60	150
TOTAL					170

Table 12.B: Estimated Annualized Burden Costs

Type of	Form	No. of	No. of	Average	Total	Average	Total
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Respondent	Name	Respondents	Responses per Respondent	burden per Response (in hours)	burden (in hours)	Hourly Wage Rate	Annual Respondent Cost
Referred individuals	Screeners	240	1	5/60	20	\$17.75	\$355.00
Eligible participants	Survey	200	1	45/60	150	\$17.75	\$2,662.50
TOTAL					170		\$3,017.50

In order to estimate the cost to the respondents, we used the seasonally adjusted average hourly wage earnings of total production and non-supervisory workers on private nonfarm payrolls proposed for January 2008 by the US Department of Labor. For each year, the proposed data collection is estimated to cost \$3,017.50 for all respondents listed in Table 12.B

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-14, .05 FTE)	\$5,391
	CDC Principal investigator (GS-13, .25 FTE)	\$22,808
	CDC Behavioral Scientist (GS-14, .05 FTE)	\$5,391
	CDC Public Health Analyst (GS-12, .25 FTE)	\$19,180
	Travel	\$2,000
	Subtotal, direct costs to the government	\$ 54,770
Contractor and other expenses		
	Data manager/analyst on-site at CDC (.25 FTE)	
	Contract with RTI, Inc. to implement survey	\$305,500
	TOTAL COST TO THE GOVERNMENT	\$360,270

Travel is related to providing technical assistance and site visits as well as to attend interviewer training. THBS is funded through a 3-year contract with Research Triangle Institute, Inc. in the amount of \$611,000. This contract includes salaries, travel, equipment, and supplies; and incentives, as well as the funds for subcontracts to four state and local health departments (project areas) to conduct THBS locally. The RTI, Inc. contract also includes funds for developing the eligibility screener, behavioral questionnaire, and survey protocol. It also includes the data management, validation, and analysis needed to conduct the evaluation of the eligibility screener, behavioral questionnaire, and sampling method, which will be summarized in a final report of the pilot data.

Funding for THBS was obtained from the Minority AIDS Initiative (MAI) in fiscal year 2006.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.A: Project Time Schedule

Activities	Time Schedule
Begin field work	1 month post OMB approval
Complete field work	15 months post OMB approval
Data management and validation	13 - 16 months post OMB approval
Evaluation of questionnaire/sampling method	9 – 17 months post OMB approval
Dissemination of results	18-24 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 laptop 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.