# Monitoring Outcomes of the Enhanced Comprehensive HIV Prevention Planning (ECHPP) Project

0920-NEW

**Supporting Statement B** 

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# **Supporting Statement**

#### **B.** Justification

# 1. Respondent Universe and Sampling Method

The selection of six metropolitan statistical areas (MSAs) in which survey data collection will occur was based on 1) areas with the highest numbers of people living with AIDS at the end of 2007 and 2) health department reporting capacity for HIV surveillance data (e.g., CD4 count and viral load for HIV-diagnosed individuals). Out of the top 12 MSAs in the U.S. with highest AIDS prevalence, six MSAs were selected: District of Columbia, Houston, Los Angeles, Miami, New York City, and San Francisco.

There are two (2) data collection periods (winter 2012 to summer 2012; 2013 to 2014). Statistical methods will not be used to select respondents for the surveys in this project. The size of the respondent universe (injection drug users and heterosexuals at risk of HIV infection) for the community survey is unknown. Thus, it is not possible to create sampling frames of these populations.

The respondent universe for the clinic survey is HIV-diagnosed adults receiving medical care at select HIV clinics during the two data collection periods. Although the exact number of individuals living with HIV is not known, the number of individuals believed to be living with an HIV infection in the six data collection areas is provided in Table B-1-1.

**Table B-1-1:** Number of People Living with HIV Infection in Data Collection Areas (at end of 2007)

Metropolitan Statistical Area	Number		
District of Columbia	25,138		
Houston	19,660		
Los Angeles	35,744		
Miami	24,148		
New York City	104,949		
San Francisco	16,321		

SOURCE: Centers for Disease Control and Prevention. <u>HIV</u>
<u>Surveillance Report</u>, 2008; vol. 20. Published June 2010. Accessed June 1, 2011.

Individuals eligible to participate in the surveys are injection

drug users, heterosexuals at increased risk of HIV infection, and HIV-positive individuals who access HIV-related medical care from facilities that provide HIV services. The data collection activity is specifically designed to characterize individuals in these risk groups who: 1) attend specific venues (for the community survey) or select clinics/health facilities (for the clinic survey), 2) agree to participate in an interview about their health, and 3) meet the eligibility criteria. The project is not intended to yield representative data about any group except those who meet the above description (i.e., high-risk persons who meet eligibility criteria and who attend specific venues).

Across all six MSAs, 750 injection drug users (age ≥ 18 yrs) and 750 high-risk heterosexuals (age 18 to 60 yrs) will be screened per data collection year for eligibility in the community survey (3000 total). Across all six MSAs, 600 injection drug users (age ≥ 18 yrs) and 600 high-risk heterosexuals (age 18 to 60 yrs) will be administered the community survey per data collection year (2400 total). These participants will be asked about sexual behaviors, alcohol and substance use, HIV testing experiences, participation in HIV prevention services and programs, and exposure to HIV prevention messages. We estimate that approximately 90% of individuals screened will be eligible and approximately 90% of eligible individuals will consent to participate.

Across all six MSAs, 1400 HIV-positive individuals who visit HIV clinics (age  $\geq$  18 yrs) will be screened for eligibility in the clinic survey per data collection year (2800 total). Across all six MSAs, 1200 HIV-positive individuals who visit HIV clinics (age  $\geq$  18 yrs) will be administered the clinic survey per data collection year (2400 total). They will be asked about the same information included in the community survey as well as about HIV treatment, HIV treatment adherence, sources of care, clinical outcomes, and employment and productivity. We estimate that approximately 95% of individuals screened will be eligible and approximately 90% will consent to participate.

Eligibility criteria for each survey are described below.

Respondent eligibility criteria: The following data will be collected in both the community and clinic eligibility screeners: age; race/ethnicity; previous participation in community, clinic, Medical Monitoring Project (MMP), or National HIV Behavioral

Surveillance System (NHBS) surveys; county of residence; and gender.

The eliqibility screener for the community survey (Attachment 3a) is based on criteria used with NHBS (OMB Control #0920-0770, EXP. DATE 6/1/2014), and will include questions about injection drug use (lifetime), vaginal and anal sex with person of opposite gender (previous 12 months), highest level of education, employment status, household income (previous 12 months), and number of people living on this household income. Respondents will be classified as injection drug users if they indicate they have injected drugs in the last 12 months (regardless of responses to other eligibility questions). Respondents will be classified as high-risk heterosexual individuals if they indicate they have never injected drugs, they have had sex with a partner of the opposite sex in the previous 12 months, and their answers to the education and income questions qualify them as low socioeconomic status according to the current HHS poverty guidelines (CDC, 2011). These guidelines are updated periodically in the Federal Register by the U.S. Department of Health and Human Services (http://aspe.hhs.gov/poverty/11poverty.shtml). To qualify as low socioeconomic status, an individual's highest education level must be high school or less, or his/her income must be based on the 2011 HHS Poverty Guidelines (DiNenno et al., in press).

Table B-1-2: 2011 HHS Poverty Guidelines Income Limits

Persons in Family	48 Contiguous States and D.C.			
1	\$10,890			
2	14,710			
3	18,530			
4	22,350			
5	26,170			
6	29,990			
7	33,810			
8	37,630			
For each additional person, add	3,820			

**SOURCE:** Federal Register, Vol. 76, No. 13, January 20, 2011, pp. 3637-3638

In addition to the items described above, the eligibility screener for the clinic survey (Attachment 3c) will also include a question regarding self-reported HIV status (i.e., result for most recent HIV test). The clinic screener items are based on criteria used with MMP (OMB Control #0920-0740, EXP. 5/31/2012).

Selection of respondents: The recruitment and data collection methods for the ECHPP surveys were determined in consultation with representatives from the MMP and NHBS projects (given the surveys are designed for the same target populations). Individuals in these target populations are typically difficult to identify in the general population and, as a result, they are difficult to enumerate for sampling purposes. Obtaining representative samples is complicated by the fact that these groups tend to be marginalized, hidden, or otherwise stigmatized due to illegal or illicit behaviors of group members. Thus, a population-based sample is not feasible.

Several guiding principles will be used to determine the most appropriate sampling for these groups. First, recruitment venues for the community survey will be identified in collaboration with local health department staff to increase the likelihood that injection drug users and high-risk heterosexuals will be accessible and interested in participating. Second, HIV care clinics from which HIV-positive individuals will be recruited for the clinic survey will be identified in collaboration with health department staff. Additionally, project staff will attempt to visit these venues and clinics on multiple days of the week, at varying times, to increase their opportunities for interacting with a wide variety of individuals that frequent those venues/clinics.

For the community survey data collection, project staff will limit the number of surveys they administer on any one venue visit to 10. Staff will plan to identify 30-50 venues in each MSA so the likelihood of having to visit the same venue multiple times is low.

Potential participants will be screened and surveyed in the same location, where possible. A protocol for identifying and assessing potential venues for recruitment and survey administration will be established and coordinated in each MSA by SciMetrika staff. SciMetrika will assess and select venues and clinics in consultation with local health department staff,

community advisors, and the local clinic staff under the guidance of CDC staff.

Venues (for the community survey): Identifying local health department staff and community consultants who are involved with the local HIV Prevention Community Planning Group will be critical to successful venue identification and selection. These local subject matter experts will have valuable knowledge about various locations in their city where the target populations can be found. Additionally, for the community survey, SciMetrika will also consult with local NHBS staff to identify and prioritize potential venues for data collection from injection drug users and high-risk heterosexuals. Venues eligible for consideration include bars, dance clubs, retail businesses, cafes and restaurants, health clubs, social and religious organizations, adult bookstores, high-traffic street locations, parks, and beaches.

Interviewers will use a convenience, venue-based sampling method where surveys are administered to any eligible person who is willing to participate while the interviewer is visiting the venue. Venues will first be identified based on the likelihood of encountering injection drug users or high-risk heterosexuals, logistics and feasibility of recruiting participants and conducting the data collection activities, and staff safety. The approval of venue owners or managers will be necessary to proceed with data collection in many entertainment and commercial venues. Commercial/private venue owners and managers will be contacted to find out if SciMetrika staff can approach venue patrons to ask them if they are interested in participating in the community survey. A script will be used by field staff when contacting venue owners/managers and explaining the project (Attachment 7b). Project staff will schedule data collection at those venues on the days and times that allow for greatest recruitment and they will screen, recruit, and interview respondents during those times. The project staff members are expected to identify new venues that open during the data collection period and likewise to keep track of those that have closed or no longer serve the populations of interest.

The interviewer will collaborate with local health department staff and community advisors to determine the best strategy for approaching individuals about the project. Strategies may vary across venues. Interviewers will bring copies of an information sheet (Attachment 4) that describes the project to the venue in case individuals who are approached decline to take the survey at that time but indicate possible interest in the future. The

information sheet will contain a project description and a phone number/e-mail address where the interviewer can be reached. An interviewer script (Attachment 9a) will be used by all interviewers when approaching potential participants and describing the project. Oral consent will be obtained from potential respondents. The consent process will involve the interviewer reading a consent form script to the potential respondent (Attachment 5a) and documenting whether consent was provided by the individual (yes or no) on the survey.

Individuals will normally be approached for recruitment in public, but eligibility screening will occur in a private or semi-private area at the venue. The interviewer will prioritize the safety and privacy of the respondent when determining where to administer the survey.

Clinical facilities (for the clinic survey): HIV care facilities will be identified using methods similar to those used for MMP (OMB Control #0920-0740, EXP. 5/31/2012). A facility is defined as any clinic, health care institution, private or group physician practice that shares common medical records or a medical record system. Thus, a facility is defined in terms of medical record storage, not in terms of a physical location (address) or the names of individual practitioners. Clinic facilities that participate in the current MMP cycle (whereby data collection is taking place at the same time) will be excluded where possible. Initially, clinic directors will be contacted to find out if they are interested in participating in the clinic survey data collection. A script will be used by field staff when initially contacting clinic directors (via e-mail) and explaining the project (Attachment 7a). For clinics who agree to participate, a meeting will be scheduled with a clinic staff person identified by the clinic director to orient them to the project.

The availability of a private area for interviewing will be a required criterion for participating clinics. Alternate locations for conducting the clinic survey will not be needed. No added burden in placed on the clinical facilities for the space used to administer the survey.

Candidate clinic facilities are those that provide HIV care. An HIV care facility is operationally defined as a facility conducting CD4 or HIV viral load testing or providing prescriptions for antiretroviral medications in the context of treating and managing a patient's HIV disease. Thus, facilities providing HIV care could include outpatient facilities such as

hospital-affiliated clinics, free-standing clinics or private physician offices.

The following facility types will not be selected for this project:

- Facilities that do not provide medical care (e.g., sites that only conduct HIV counseling and testing)
- Facilities where medical providers obtain CD4 counts and HIV viral loads only for referral purposes
- Facilities where medical providers only provide antiretroviral refill prescriptions and do not play an active role in managing their patients' HIV infection
- Facilities that provide exclusively inpatient care, including hospices
- Emergency departments
- Facilities located outside the funded jurisdiction
- Federal, state and local correctional and work-release facilities
- Tribal facilities
- Health facilities located on military installations
- Facilities that only provide HIV care only to patients under the age of 18

Veterans Administration (VA) facilities in every MSA will be considered in the facilities selection process.

The method used to approach and recruit HIV-positive individuals in clinics will vary by facility based on clinic provider consultations. Some patients may be approached by clinic staff during one of three time points during their medical visit: at check-in, at triage, and during the office visit with the medical provider (Attachment 7d). Information sheets (Attachment 4) will be distributed by clinic staff within the clinics and they will also be available in the waiting rooms with the permission of clinic staff. This sheet will contain project information and a phone number/e-mail address for the interviewer. Clinic staff will be asked to provide estimated patient loads on a weekly basis to SciMetrika staff so that SciMetrika staff can determine the best days/times to recruit potential participants (Attachment 7c).

When SciMetrika interviewers first approach potential participants, they will use an interviewer script (Attachment 9b) to describe the project. Oral consent will be obtained from potential respondents. The consent process will involve the interviewer reading a consent form script to the potential

respondent (Attachment 5b) and documenting whether consent was provided by the individual (yes or no) on the survey. SciMetrika will consult with clinic staff to determine the best strategy for approaching individuals and each clinic recruitment strategy will be tailored based on staff recommendations.

SciMetrika staff will also establish a schedule whereby they are available on specific days of the week to be onsite at the facility to administer surveys. The schedule will be published in the information sheet and clinic staff will also be informed of the schedule. Where possible, interviews will be conducted in the clinic after the patient finishes with his/her appointment. Interested individuals who would like to participate but would prefer to do so on a different day will be encouraged to return to the facility clinic during the regularly-scheduled SciMetrika times/days.

All venues and clinical facilities (both surveys): It is expected that clients will be surveyed upon arrival for services (clinic survey) and when attending specific venues (community survey). However, contact information may be collected if a potential participant selects to participate in the survey at another time. When it is necessary to collect this information, the information will only be used by SciMetrika staff for scheduling purposes. The contact information will be kept separately from all interview materials and survey data. Potential participants will be encouraged to use pseudonyms or first names only when scheduling a day/time to take the survey. All contact information for a participant will be destroyed after his/her survey has been completed.

Sample size: 750 injection drug users (age  $\geq$  18 yrs) and 750 high-risk heterosexuals (age 18 to 60 yrs) will be screened per data collection year for eligibility in the community survey combined for all six MSAs. Across all six MSAs, 600 injection drug users (age  $\geq$  18 yrs) and 600 high-risk heterosexuals (age 18 to 60 yrs) are estimated to consent to participate and will be administered the community survey per data collection year.

Across all six MSAs, 1400 HIV-positive individuals who visit HIV clinics (age  $\geq$  18 yrs) will be screened for eligibility per data collection year in the clinic survey. Across all six MSAs, 1200 HIV-positive individuals who visit HIV clinics (age  $\geq$  18 yrs) are estimated to consent to participate and will be administered the clinic survey per data collection year.

This information collection involves monitoring of services

provided through the ECHPP project and only descriptive findings at aggregate level will be reported. No a priori hypotheses were identified and power calculations which are typically used in sample size determinations for testing specific hypotheses will not be performed. Although no a priori hypotheses were identified, evaluation questions related to this information collection request are listed below.

- Was there a reduction in HIV risk behaviors among HIVpositive individuals and high-risk, HIV-negative/HIVunknown individuals?
- Was there an increase in service access and participation in HIV prevention activities among HIVpositive individuals and high-risk, HIV-negative/HIVunknown individuals?
- Was there an increase in overall positive health outcomes for HIV-positive individuals?

SciMetrika staff will work closely with local subject matter experts and health department staff in each city to develop appropriate and feasible recruitment strategies that will increase the likelihood of participation (and ultimately increase the sample size).

# Expected response rates

Response rates for venue-based, convenience sampling are largely dependent on how many people accept being approached for recruitment and meet the eligibility criteria; among those who do accept and are found eligible, participation rates are expected to be high (Diaz, 2001; Muhib, 2001; Valleroy, 2000).

The expected response rate and sample size for the three target populations in ECHPP are provided in the table below:

Table B-1-3: Expected Response Rates and Sample Sizes\*

	HIV-positive individuals in care		Injection drug users		High-risk heterosexuals	
	Screener	Survey	Screener	Survey	Screener	Survey
TOTAL	2800	2400	1500	1200	1500	1200
Hispan.	448	384	300	240	420	336
Black	1316	1128	750	600	540	432

White	840	720	370	300	360	288
Other	196	168	80	60	180	144

<sup>\*</sup> These estimates are based on race/ethnicity, gender, and age frequency distributions observed among NHBS and MMP samples in past data collection cycles.

#### 2. Procedures for the Collection of Information

All eligibility screening and surveys will be conducted by trained SciMetrika staff. Participation in the project is voluntary. Respondents may refuse to participate at all or in part. Respondents may refuse to answer questions or stop participation at any time without penalty. The approved Project Determination Form (Attachment 8) 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, SciMetrika project staff will obtain local IRB approvals in the six MSAs prior to data collection, per local IRB and human subjects requirements in the six MSAs.

When SciMetrika interviewers first approach potential participants, they will use an interviewer script (Attachment 9a and Attachment 9b) to describe the project and potential participants will be given an information sheet (Attachment 4). The method used to approach and recruit HIV-positive individuals in clinics will vary by facility based on clinic provider consultations. Some patients may be approached initially by clinic staff during one of three time points during their medical visit: at check-in, at triage, and during the office visit with the medical provider (Attachment 7d). Information sheets (Attachment 4) will be distributed by clinic staff within the clinics and they will also be available in the waiting rooms with the permission of clinic staff. The interview schedule (i.e., days of the week when SciMetrika interviewers will be onsite) will be printed in the information sheet. Patients may also contact the interviewers listed in the information sheet for more information.

When SciMetrika interviewers are onsite at the clinical facilities, any patient who has indicated interest in participation will be invited to be screened for eligibility (Attachment 3a and Attachment 3b). Eligible individuals who are interested in participating will be read the consent script (Attachment 5a and Attachment 5b). Interviewers will specify on a handheld computer (IPad or Palm Pilot) whether the person provided verbal consent. Persons who consent to participate will

be administered a structured questionnaire. The community survey (Attachment 3b) collects data on demographics, sexual behavior, alcohol and drug use history, HIV testing experiences, exposure to HIV prevention messages, and participation in HIV prevention activities. The clinic survey (Attachment 3d) collects data on demographics, HIV care and testing experiences, sources of care, met and unmet needs, HIV treatment and adherence, sexual behavior, alcohol and drug use history, exposure to HIV prevention messages, participation in HIV prevention activities, gynecological and reproductive history, health conditions, and preventative therapy.

Surveys will be web-based and will be accessed from a secure server through an IPad or Palm Pilot. Surveys will be administered face-to-face by interviewers. These handheld computers will be password- protected and data will be encrypted using standard, 128-bit encryption software. No personal identifiers will be collected or entered into the electronic surveys and no data collected will be linked directly or indirectly to survey participants. The community survey will take approximately 25 minutes to complete, the clinic survey will take approximately 40 minutes to complete.

The community survey will be administered in a private or semiprivate area at the venue. The interviewer will prioritize the safety and privacy of the respondent when determining where to administer the survey. The availability of a private area for interviewing will be a required criterion for participating clinics. Alternate locations for conducting the clinic survey will not be needed.

### Quality control

Data quality is ensured by the use of computer-assisted interviewing, interviewer training and monitoring (by both CDC and SciMetrika project managers), site visits, and data editing.

Computer-assisted interviewing improves data quality in several ways:

- a) Interviewer errors are reduced because interviewers do not have to follow complex routing instructions; the computer does the routing for them.
- b) Respondent errors are also reduced. Consistency checks are programmed into the surveys so that inconsistent answers or out-of-range values can be corrected or explained while the behavioral assessment is in progress.
- c) Use of computer-assisted interviewing also reduces coding and coding errors, which makes it possible to prepare the

data for analysis faster and with fewer errors.

A multi-day interviewer training will be offered by SciMetrika before the start of data collection- some training components will be delivered via webinar and some components will be inperson. This training covers general interviewing skills, sampling and recruitment protocols, and a question-by-question review of the survey to ensure interviewers understand the purpose of each question and how it should be read and be coded in the handheld computer. Interviewers will have opportunities to practice administering the survey during the training. The training also addresses interviewer integrity, underscoring the importance of collecting quality data and the consequences of inappropriate behaviors, including falsification of data. Project staff will also be trained on how to conduct recruitment procedures, such as approaching substance users and high-risk heterosexuals at recruitment venues and approaching HIV-positive individuals accessing care at clinical facilities.

During data collection, interviewers will be routinely monitored by SciMetrika field supervisors and management staff. Feedback will be provided in cases of incorrect implementation of protocols as well as to help interviewers improve interviewing techniques as needed. Monitoring of venue-based convenience sampling also includes recruitment procedures. Supervisors will provide feedback on ways to help improve response rates.

CDC will conduct at least one site visit to each of the six MSAs during each data collection period. The purpose of the site visits are to monitor adherence to the ECHPP protocols; observe recruitment, screening, and survey administration; and provide feedback on project procedures as needed.

SciMetrika staff will routinely check the quality of survey data submitted to the secure server and edit data as needed following quality assurance protocols. Routine processing allows for identification of errors in the data sets (such as incorrect identification codes, such as venue or site identifiers, or incorrect coding of other critical data elements) or incorrect local data management procedures. CDC will hold weekly calls with SciMetrika during each data collection period to get updates on data collection, recruitment numbers, problems encountered, etc.

The community and clinic surveys will not collect specific, personal identifiers (e.g., name, address, social security number). There is no link to any name, either locally or at CDC, on surveys and no data will be collected on paper forms. When

necessary to collect contact information, for example, if an individual would like to schedule the survey for a different time or day, contact information will only be recorded on paper and will be not be submitted to CDC. This information will be destroyed after that individual has completed the survey.

# Data storage and confidentiality

Data collected through these surveys will be stored and accessed by a survey identification number (at SciMetrika). The sensitive information collected will not be linked to any personally identifiable information and cannot be used to reveal the identity of any person. There is no link to any name, either locally or at CDC, on surveys and data will not be collected on paper forms.

In the event that an Internet connection is not available, the survey administrator will complete the survey manually using a paper copy of the survey instrument. The paper copies that will be administered if an Internet connection is not available are provided in **Attachment 3b** (community survey) and **Attachment 3d** (clinic survey). The completed paper survey will be secured temporarily in a locked satchel that will be transported back to the SciMetrika field office by the next work day close of business. If Internet service is not re-established, no further paper surveys will be administered that day. Data from the paper survey will be entered manually into the Web survey application within 24 hours.

# 3. Methods to Maximize Response Rates and Minimize Non Response

The proposed data collection does not employ statistical sampling methods. However, specific methods will be employed to improve response rates.

# <u>Maximizing Response Rates</u>

Response rates for venue-based sampling are dependent on how many people accept the approach. Among those who do accept and are found eligible, participation rates are expected to be high (Diaz, 2001; Muhib, 2001; Valleroy, 2000). Among those who accept the approach, approximately 10% are expected to be ineligible and 10% of persons who meet the eligibility criteria are expected to refuse to participate (community survey); (5% of those approached for clinic survey are expected to be ineligible and 10% of eligible individuals are expected to refuse to participate). Some

data loss due to interruption in internet service or interviewer error may occur but this is expected to affect less than 1% of surveys collected.

Given these estimates, to reach the target number of respondents, project staff will need to screen 1500 injection drug users, 1500 high-risk heterosexuals, and 2800 HIV-positive individuals visiting HIV care facilities. If 10% of potential community participants are ineligible and 5% of those individuals refuse to participate, 2565 community survey participants would be expected. If an additional 1% of surveys are lost due to computer/human error, 2539 community surveys would be collected. If 5% of potential clinic participants are ineligible and 10% of those individuals refuse to participate, 2394 clinic survey participants would be expected. If an additional 1% of surveys are lost due to computer/human error, 2370 clinic surveys would be collected.

Response rates for ECHPP may be adversely affected by the anonymous nature of the survey (no follow-up contacts by project staff are possible) and the sensitive nature of the questions. During each data collection period, CDC will monitor response rates via weekly conference calls and progress reports and provide guidance as needed. Progress reports will include number of screened individuals, number of completed surveys, and demographic information about respondents to ensure the appropriate groups are being targeted (e.g., Hispanics/Latinos and African Americans).

Research has shown that monetary tokens of appreciation are effective at increasing response rates among residents in minority zip codes (Halberti, 2010; Whiteman, 2003). A metaanalysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority enrollment and retention in research studies found that incentives enhanced retention among this group (Yancy, 2006). Tokens of appreciation are also useful for groups that are hard to reach, including those for whom conventional means of motivation may not work (e.g., disenfranchised populations). In addition, these populations (particularly injection drug users) have been frequently the focus of health-related data collections, in which provision of financial incentives is the norm (Thiede, 2001; MacKellar, 1996, 2005). Thus, providing tokens of appreciation to ECHPP respondents is critical to achieving acceptable response rates. Tokens of appreciation are also provided to persons from these same target populations in other CDC projects, such as MMP (OMB 0920-0740, EXP. 5/31/2012) and NHBS (OMB Control #0920-0770,

EXP. DATE 6/1/2014). Tokens will be no less than \$25 and no more than \$30 (per respondent) to be decided upon in each survey site based on established local research norms, and discussion with local NHBS and MMP staff and community stakeholders.

To maximize response rates, the initial approach is also critical. Training for interviewers will focus on effective communication (enthusiasm, rapport building in a short period of time) and ability to communicate the value of the overall project (persuasion); demonstrated motivation, persistence, and high energy are critical for successful recruiting. The training will focus on methods for averting refusals and methods to seek participation of sampled persons who are initially reluctant, including role-playing of different scenarios in which the respondent may be difficult to recruit. The basic recruitment philosophy is "respectful persistence;" interviewers are trained to know when to stop.

Venue-based sampling offers the benefit of access to large numbers of the target population in a single location; however, a disadvantage is that the rate of refusal of the approach and of participation (among those who accept the approach) can be high because people attend venues for reasons other than participating in a data collection. In limited cases, respondents who are interested in participating but are not willing or able to complete the behavioral assessment at the time they are approached will be offered an appointment to participate on another day. Offering of these "other-day appointments" will be limited, as it is expected that "no show" rates for the appointments will be high.

# <u>Assessing Non-Response Bias</u>

The use of an eligibility screener will allow the comparison of demographic and eligibility-related behavioral data between eligible and ineligible individuals. The venue-based, convenience sampling method is not conducive to collecting information from those who refuse to be approached.

SciMetrika interviewers will also submit a progress plan to CDC that identifies problems associated with approaching potential participants, decreased participation rates, problems with electronic data collection, and changes in relationships with clinic staff or venues, including methods to resolve such problems. This plan will be submitted on a regular basis and will include days/times of highest activity at specific venues/clinics and participant characteristics (for each geographic area). This

information will be used to monitor data collection overall, including interviewer approaches used with three different target populations. The SciMetrika field staff and CDC will use the data in these reports to identify problems with recruitment. When a problem with response or recruitment arises during data collection, field staff will be instructed to consult with local stakeholders and members of the local target populations to help identify solutions to the problem.

#### 4. Tests of Procedures or Methods to be Undertaken

The community and clinic surveys were modeled after questionnaires used in other CDC surveillance projects (MMP- OMB 0920-0740, EXP. 5/31/2012; OMB Control #0920-0770, EXP. DATE 6/1/2014). The NHBS and MMP surveys have been tested thoroughly and administered to thousands of individuals (injection drug users, HIV-positive individuals visiting HIV care facilities, and high-risk heterosexuals) over a number of years. CDC staff from NHBS and MMP provided guidance to ECHPP CDC staff and SciMetrika staff in the development of all data collection protocols and instruments. Prior to implementation in the field, SciMetrika and CDC staff will test the electronic surveys extensively to ensure skip patterns are correct and that the data collection instruments are working properly. However, because the surveys are very similar to the NHBS and MMP surveys, no substantial problems are expected during testing.

# 5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The individuals below have provided input on the sampling and statistical strategies to be used for ECHPP. It is expected that these individuals will remain consultants on ECHPP for the entire program evaluation period (until 2015) and provide their expertise on data collection, management, and analysis.

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