Request for Sub-collection Under the Approved Generic ICR:
Formative Research and Tool Development
OMB No. 0920-0840, Expiration 02/29/2016

Section B: Supporting Statement B

Title:

DSTDP Assessment of STD clinic users

March 6, 2013

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection request does not employ statistical sampling methods. The following is a description of data collection procedures.

B.1 Respondent Universe and Sampling Methods

This study will be conducted with a total of 4,400 English speaking men and women who have sought healthcare in STD clinics in large U.S. cities with a high burden of STDs. Our sample will be a non-probability based purposeful sample.

The study will consist of 4,400 10-minute paper-based surveys to field test the survey instrument. The results of the field study will be used to refine and revise the survey instrument for use in monitoring STD clinic users after full implementation of the Patient Protection and Affordable Care Act (ACA) of 2010 (ACA), and will also serve to test the feasibility of administering surveys to clinic users in STD clinic waiting rooms. We will survey each participant only once and will be able to develop all materials through a one-time data collection.

B.2 Procedures for the Collection of Information

B.2.1 Recruitment

A total of 4,400 persons will be recruited at U.S. STD clinics to complete a paper-based survey. Persons who register for care at each of 22 STD clinics will be approached consecutively and invited to participate in the survey until 200 persons (100 men and 100 women) per clinic have completed the survey. To reduce the effects of nonsampling error, nonresponse and post-stratification weighting adjustments will be applied to the sample when feasible.

B.2.2 Screening and Scheduling Procedures

Survey vendors contracted by the National Association of County and City Health Officials (NACCHO) will approach consecutive patients in the waiting area of the STD clinic after they have registered for care, and invite them to participate in the survey. The vendor will read an informed consent script to a potential participant and obtain verbal informed consent (**Attachment 2**). Only participants who provide verbal informed consent will be given the survey to complete. An information sheet that contains the same content as the informed consent script will also be given to each participant (**Attachment 2**). The vendor will track those who were approached and those who provided verbal informed consent using non-identifiable designations (i.e., S001, S002, S003, etc.).

B.2.3 Data Collection Methods

Participants will complete a paper-based survey. Each participant can complete the survey only once. The vendor will maintain a worksheet of persons approached (designated as S001, S002, S003, etc.), those who provided verbal consent, and those who completed the survey, all stratified by sex.

The survey vendor will collect completed surveys from participants and place them in a locked cabinet in a secure location for storage until completion of the data collection period at that site.

Surveys with no PII from all 22 collection sites will be delivered to CDC by FedEX. Individual surveys will be assigned an identification number upon data entry by CDC into an Access database for analysis. All data collection materials are at an 8th grade reading level or below due to sample eligibility criteria and CDC requirements.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

The following procedures will be used to maximize cooperation and achieve the desired participation rates:

- Clients will be approached and invited to participate in the survey in the STD clinic waiting area, while waiting for their clinical visit. Time spent completing the survey will not delay their clinical encounter or otherwise interfere with their visit at the clinic.
- The survey vendor will provide toll-free telephone numbers to all sampled individuals and invite them to call with any questions or concerns they might have about any aspect of the study. NACCHO will provide a toll-free telephone number for the NACCHO project director and a toll-free telephone number for the CDC IRB in case participants have any questions about the study or their rights as study participants.
- The survey vendor data collection staff will work with NACCHO project staff to address any concerns that may arise.

B.4 Test of Procedures or Methods to Be Undertaken

This submission is a request for authorization to conduct tests of procedures and methodologies typical in methods and instrument development.

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

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