**Request for Sub-collection Under the Approved Generic ICR:**
**Formative Research and Tool Development**
OMB No. 0920-0840, Expiration 01/31/2019

# Assessment of STD Service Needs and Provisions

## Section B: Supporting Statement

**June 14, 2018**

**STD clinic users survey**

## TABLE OF CONTENTS

**Section** **Page**

## 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 5,000 English speaking men and women who seek healthcare in U.S. STD clinics. Our sample will be a non-probability based purposeful sample. The 25 STD clinics will be chosen by using CDC STD surveillance data, ranking the top 25 metropolitan statistical areas (MSA) in the U.S. based on average reported rates for chlamydia, gonorrhea and syphilis. Within those 25 MSA's STD clinics will be asked to participate in the survey. The survey will also entail a 10 minute survey of 1 clinic staff person at 25 clinics.

The research will consist of 5,000 5-minute paper-based surveys and 25 10 minute staff surveys to field test the survey instruments. The results of the field study will be used to refine and revise the survey instrument for use in monitoring STD clinic users and clinic staff after full implementation of the Patient Protection and Affordable Care Act (ACA) of 2010 (ACA), and will provide baseline data for these future comparisons. 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 paper-based survey will be used. At each of 25 STD sites, persons who register for care at the STD clinic will be approached consecutively and invited to participate in the survey until 200 eligible persons (100 men and 100 women) have completed the survey for each site. Additionally, one staff person at each clinic will be asked to complete one ten minute survey. A recruitment letter describing the survey will be sent the director of each identified clinic.

#### B.2.2 Screening and Scheduling Procedures

Persons who agree to complete the survey will be given an informed consent form, and after reviewing it will be asked to state "YES, I agree to participate" or "NO, I do not wish to participate." Only participants who agree to participate will be given the survey.

All persons who agree to participate will complete the survey, and the eligibility will be determined by reviewing the question on the survey that asks reasons for visiting the clinic.

#### B.2.3 Data Collection Methods

Survey vendors contracted by NACCHO will approach participants in the waiting area of the STD clinic after they have registered for care, invite them to participate in the

survey, and give them a consent form (see **Attachment 4**) that provides general information about the study, topics to be covered in the survey, and potential risks of participation in the survey. After reading the informed consent, each participant must state “YES, I agree to participate” or “NO, I do not wish to participate.” Only participants who state “YES” will be given the survey to complete. Each participant can complete the survey only once.

The survey vendor will also approach a clinic staff member to complete a survey. The staff member will be invited to participate and will be given a consent form (see Attachment 3) that provides general information about the study, topics to be covered in the survey and the potential risks of participation in the survey. After reading the informed consent, each staff participant must check either a box labeled “YES, I agree to participate” or “NO, I do not wish to participate.” Only participants who select “YES” will be given the survey to complete. Each participant can complete the survey only once.

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.

The survey vendor will review completed surveys to determine if each participant met inclusion criteria, and whether exclusion criteria apply. The vendor will keep a running tally of the number of completed surveys that met enrollment criteria, stratified by sex.

Surveys with no PII from all 25 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:

- A recruitment letter from the Director of the Division of STD Prevention will be sent to clinic administrators asking them to participate in the survey.
- Clients attending the clinic for care will be approached as they are waiting to see a clinician in the STD clinic, so time spent completing the survey will not delay their care or otherwise interfere with their visit to 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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