

Generic Clearance

Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States

Supporting Statement B

OMB No. 0920-1091

April 22, 2018

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

This proposed data collection will consist of a series of qualitative studies to understand issues related to HIV prevention, care, and treatment in specific communities within the United States. This current Generic Information Collection Request (ICR) extends a similar existing and previously approved Generic ICR (OMB No. 0920-1091) for three more years.

Each of the proposed studies under this extended Generic ICR will involve a focused scope and small or moderate sized samples. The qualitative studies will include multiple well-established methodologies, which may include but not be limited to qualitative in-depth open-ended individual interviews, semi-structured open-ended individual interviews, focus groups, direct observations (for example, of neighborhoods), and document reviews (for example, of testing venue procedures for linking recently diagnosed persons to medical care). In some assessments, additional contextual information may be collected using structured questions, such as information about the respondents' characteristics, community, workplaces, or organizations and places where they interact.

In studies covered under this extended Generic ICR, obtaining probability-based samples to reach the desired

subpopulations of interest will be cost prohibitive and not needed for achieving study goals. Purposeful, targeted sampling and other non-probability sampling designs will be used to develop a pool of potential respondents for a particular region of interest in the US. The target populations for studies included in this extended Generic ICR include, but are not limited to: persons living with HIV who are in treatment; persons living with HIV who are out of treatment and who may or may not be seeking treatment at healthcare facilities; persons at high risk for HIV acquisition (HIV negative) and HIV transmission (HIV positive); persons from groups at high risk for HIV including gay, bisexual and other MSM, transgender persons, women, and injection and non-injection drug users; persons from racial and ethnic minorities; and healthcare providers or other professionals who provide HIV prevention, care and treatment services. Other populations may include individuals who provide non-HIV services or otherwise interact with persons living with HIV or persons at risk for HIV acquisition. Studies will only provide local contextual information about the barriers and facilitators to HIV prevention, care, and treatment experienced by specific communities at risk for acquiring HIV infection, by HIV-positive persons across the HIV care continuum, and by organizations or individuals providing HIV prevention, care, treatment, and related support services.

Contractors will use a range of sources to obtain their samples of respondents. Because the samples are not randomly selected, they may not fully represent the entire study population. The samples of respondents obtained for each study are highly targeted; therefore, respondents will represent some segments, but not all, of the target populations. The qualitative study's respondents may be different when compared with the entire population of interest. However, detailed information on respondent characteristics will be gathered via brief structured response questions. For example, the brief structured response questions will gather basic socio-demographic items and other respondent characteristics, such as characteristics of respondents' communities, workplaces, affiliated organizations, or locations, from which we can describe the sample. The collected socio-demographic and contextual information will be used to describe the characteristics of the study sample and to discuss limitations of generalizability to other populations.

Study outcomes will be communicated to local stakeholders and organizations in positions to consider and implement site-specific improvements in HIV prevention, care, and treatment for each of the study sites examined. For stakeholders, organizations, or agencies outside the local affected communities, all communications will include clear discussion of the limitations of the region-specific, qualitative methods and

the non-generalizability of the study outcomes. In presenting our findings, given the study methods, it will be clearly stated that any of the practical antidotes developed are not being recommended as policy recommendations or appropriate for widespread adoptions. The methods are intended to allow researchers to gather information for a specific geographic area or subpopulation, and are not being done in a way that is generalizable to other areas or the national population.

B.2 Procedures for the Collection of Information

Recruiters will consist of contractor staff members of the project team. Partner organizations such as health clinics and community organizations that serve the target populations in the respective geographic locations may be contacted for their assistance in recruitment of potential candidates. Respondents will be selected and invited to participate by contractor staff members. Respondents may also be recruited using recruitment materials such as but not limited to flyers, emails, ads on websites or referrals from partner organizations until the target total of respondents indicated in each study is met.

Individuals who are interested in participating will be screened by members of the contractors' recruitment team. If they are eligible to participate in the face-to-face interview, they will be given a detailed explanation of the study, their

role in the study, study requirements, time commitment, and any additional questions they may have will be answered. Eligible respondents will be invited to participate in an interview, focus group, or some other established method of collecting qualitative data, along with additional structured response data. Prior to beginning the data collection, respondents will be asked to sign an informed consent form that will include an explanation of the study, risks and benefits of participation, duration of participation, contact person for the research including the chair of the IRB, the voluntary nature of participation, and the right to withdraw without penalty. Respondents may ask additional questions they may have. If they choose to participate and sign the consent form they will be given a copy of the form for their records.

The data collection will take place at a time and place that is convenient to the respondent. Locations will be private. They will be audio-recorded with the consent of the respondent, and transcribed. Location will also be selected based on low ambient sound when possible so as not to interfere with the recording quality. Contractors will also collect data with pencil and paper in situations where audio recordings are not feasible. Two recording devices will be used to ensure no data is lost secondary to an inferior recording. All materials will be kept in locked cabinets in secure locations. All personal identifiable

information will be maintained on paper. The exception will be any possible personal identifiable information (PII) provided by the respondent inadvertently in the recorded interview.

Transcripts of the data collection will exclude respondent names or contact information. Recordings will be kept in locked secure areas. Respondent names and contact information required to schedule interview appointments, will be kept in separate locked cabinets away from the paper materials or recordings. Respondent names and contact information will be destroyed by the contractor at the end of the study and will never be given to CDC.

We anticipate that specific studies under this Generic ICR mechanism will use mixed methods for data collection. Although the majority of data will be collected by using qualitative open-ended questions, use of brief structured response questions will be appropriate for collecting descriptive information on topics such as the respondents' age, race/ethnicity, sex and gender identity, sexual orientation, HIV risk behaviors, attitudes, socio-economic status (e.g., education, income, employment, housing, health insurance status), or characteristics of the respondents' community or workplaces. Use of closed-ended questions to obtain descriptive information will help minimize time burden on the respondent. Regardless of the mixture of open-ended and closed-ended questions used in each study, all data collection methods will be pre-tested and conducted by trained

personnel. For in-depth interviews and focus groups, questions may be open-ended so respondents can reply freely of their own accord. For these types of interviews, the trained data collector will guide the discussion with probing questions as needed. The content of open-ended questions will vary by each task order. Qualitative interview guides, focus group guides, and structured response questions will be submitted with each specific study's Generic Information Collection (GenIC) covered under this overall Generic ICR mechanism.

Following each collection, the contractor's project staff will immediately check the quality of the recordings and written notes. If any issues are found, the data collector will immediately fill out the notes from memory to supplement the audio recording (e.g., for parts of the audio recording that could not be heard due to background noise). In the event of an emotional or anxious response from the respondent, respondents will be provided with a city-specific list of mental health care referral services that they may consult as needed. Respondents will also be informed that they may stop the data collection at any time without penalty.

Analysis will include descriptive demographic characteristics of respondents and other relevant data obtained from structured response questions. The bulk of the analysis will

be done as traditional qualitative analysis, describing how respondents with different characteristics (e.g. demographics, city, etc.) inform the research question posed within the relevant qualitative study.

Our sample design is based on the assumption of purposeful sampling recruitment strategies for the target populations. Based on previous studies using similar methodological approaches^{1,2,3} we conservatively estimate that at least 50% of those screened will be eligible for participation, and among those eligible to participate, 75% will agree to participation.

Exhibit B2.1. Total Number of Respondent Respondents for the Qualitative Studies Over a Three Year Period

| Numbers and Cooperation Rates | Three Year Total |
|---------------------------------------|-------------------------|
| Number of respondents to be contacted | 4800 |
| Expected cooperation rate | 75% |
| Number of completed data collections | 1800 |

B.3 Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used to maximize cooperation and to achieve the desired high response rate:

- Potential respondents will be identified through targeted recruitment efforts or purposive selection of key informants selected from the relevant study population.
- A token of appreciation in cash or gift card, will be provided to respondents.
- Telephone or face-to-face screening of interested individuals will be used to determine eligibility and to further identify and recruit potential respondents. Screening questions will be used to determine eligibility.
- All recruitment materials indicate the voluntary nature of the study.

B.4 Tests of Procedures or Methods to be Undertaken

The project team includes experts with the targeted populations and qualitative methods, including screening and data collection development and implementation. To estimate response burden for each respondent, contractors will conduct mock data collections among trained interviewers who will role-play potential participants and respond to all questions. In this way, the burden estimate will most closely resemble a maximum average burden, since all survey questions were presented in the data collection. The estimated maximum average burden for the study screener is estimated to be 5 minutes per respondent. Contractors will test each data collection survey separately. Any one survey

will consist of items that take no more than an average of 60 minutes to complete. All screeners and in-depth interview guide items for each study will be included in the corresponding GenIC. A sample study screener is provided in **Attachment 3a**. A sample in-depth interview guide is provided in **Attachment 3d and 3f**.

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

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