

Local Effectiveness Assessment Project (LEAP), Part II
Generic Information Collection Request under OMB #0920-1091
(Expires 12/31/2018)

Section A: Supporting Statement

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Attachment 4a Emory IRB Amendment Approval

- **Goals of the study:** The purpose of this qualitative research study is to describe key features of the local HIV prevention landscape and to identify barriers and facilitators of both HIV primary prevention and HIV care and treatment service utilization among men who have sex with men (MSM).

- **Intended use:** Data collected through this study will be used locally to improve HIV services and programs for MSM; the results of this study are not intended to be generalized to the larger population.
- **Methods to be used to collect data:** Data will be collected from 120 individuals through semi-structured, qualitative key-participant interviews.
- **The subpopulation to be studied:** We will target 120 adult participants who are 1) local government employees involved in HIV prevention with MSM, 2) employees or volunteers in community-based organizations that provide HIV prevention or treatment services and 3) community activists, volunteers, or venue employees of organizations serving the MSM community. Participants will be from Houston, Miami, New Orleans, and Washington DC.
- **How data will be analyzed:** Qualitative coding of 120 in-depth interview transcripts using computer-assisted qualitative data analysis software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention’s (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for a qualitative extramural research study entitled, “Local Effectiveness Assessment Project, Part II” under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 12/31/2018). CDC will sponsor this data collection activity. Data collection will be carried out by the CDC’s contractor, Research Support Services, in conjunction with its subcontracting partners, Emory University and IMPAQ International.

This project will conduct detailed case studies of the factors that influence successes in and unmet needs for HIV prevention, care, and treatment among MSM residing in four large urban areas in the United States. These case studies will provide descriptions of factors that affect local HIV service delivery efforts for MSM in each jurisdiction. The study will prioritize assessment of what is and what is not working well in controlling HIV locally among MSM and understanding what can be done to improve the local response to HIV among this population. Our case studies will yield four separate reports that present a comprehensive picture of jurisdictional efforts, successes, and needs concerning HIV services for MSM residing in Houston, Miami, New Orleans, and Washington, DC.

HIV incidence and prevalence in the United States are higher among men who have sex with men (MSM) than other at-risk groups. Approximately half of all diagnosed HIV infections in the United States are among gay, bisexual and other MSM,¹ despite the fact that MSM only comprise about 2% of the U.S. population.² Moreover, while HIV incidence has remained stable or declined among many other at-risk groups, incidence among MSM has increased in recent years and has sharply increased among young MSM, particularly among young MSM of color.³ There is an on-going need to improve HIV primary prevention services for MSM populations. In addition, ensuring that all MSM living with HIV are engaged in care, receiving treatment and achieving viral suppression is essential to a combination prevention approach that will ultimately reduce new HIV infections in these populations. Although a large proportion of MSM living with HIV infection are linked to care within 3 months of an HIV diagnosis (82%), only 55% are retained in care.⁴ However, among MSM who do remain engaged in

care, 80% are virally suppressed,⁵ which suggests that there is a large gap in the care continuum with respect to engagement in HIV medical care. Bridging these HIV prevention, care, and treatment gaps for MSM will be critical to meeting the goals of the 2020 National HIV/AIDS Strategy (NHAS).⁶

To reduce HIV burden among MSM populations, it is essential to identify the specific factors and conditions that facilitate or hinder provision of HIV prevention, care, and treatment services to MSM. These factors and conditions may vary widely between different local jurisdictions. Therefore, as a step toward service delivery improvement in a specific jurisdiction, it is important to identify and understand the unique set of factors that are associated with HIV prevention, care, and treatment needs of MSM residing in that area.

2. Purpose and Use of the Information Collection

The purpose of this information collection is to conduct detailed case studies of the factors that influence successes in and unmet needs for HIV prevention, care, and treatment among MSM residing in Houston, Miami, New Orleans and Washington, DC. The information collected through this study will additionally be used to describe the challenges related to the delivery of HIV prevention and treatment services to MSM residing in each location. The results of these case studies will provide descriptions of factors that affect local HIV service delivery efforts for MSM in each jurisdiction. These findings will help us to determine what is and is not working well within each jurisdiction and to improve local HIV services and programs for MSM.

The qualitative data collected through this study will be used to generate four separate reports that present a comprehensive picture of jurisdictional efforts, successes, and needs concerning HIV services for MSM residing in Houston, Miami, New Orleans, and Washington, DC. The primary target audience for these case study reports is local health department officials and other stakeholders involved with HIV prevention efforts among MSM in each jurisdiction. Understanding the city-specific set of local conditions that influence MSM services will allow local public health program staff and other stakeholders to design well-tailored responses to improve HIV prevention, care and treatment efforts. Due to the qualitative nature of the data collected, results will not be generalizable beyond the specific populations and geographic contexts in which they were obtained. CDC and/or its partners may also analyze these data and publish results in peer-reviewed journals.

One-hundred and twenty participants, including 1) health department staff, 2) representatives of community-based organizations (CBOs) and other local HIV services providers, and 3) MSM community activists or advocates, will be recruited for in-depth, key participant interviews across all four cities (30 respondents per city). We will use a purposive sampling approach to recruit participants to the study from a predefined list. Recruiters will contact potential participants either via phone or email to determine if they are eligible and interested in participating (**Attachment 1**). Participants who choose to enroll in the study will be scheduled for an in-depth interview at a time and location that is convenient to them. At the time of the interview, staff will review the study procedures and participants will complete the informed consent (**Attachment 2**).

We will use qualitative, in-depth interviews to collect information for this study (**Attachments 3a-b**). Interviews will include a short, structured response section to collect participants' demographic information and to assess their experience in HIV prevention or MSM outreach within the community. The key-participant interviews will primarily include open-ended questions designed to elicit information on HIV prevention, care and treatment among MSM in the jurisdiction and to address special topics relevant to the local context of each jurisdiction. Key variables to be explored through the

key-participant interviews are described in Exhibit 2.1 below. All data collection instruments have been approved by the Emory IRB (**Attachment 4 and 4a**).

Exhibit 2.1: Overview of Key Variables

Health Department/CBO Interviews (Att 3a)	Community Member Interviews (Att 3b)
<ul style="list-style-type: none"> • Perception of the local HIV prevention and care efforts, activities and context of the jurisdiction, • Local HIV prevention and care efforts, activities and context of the KP role/organization, • Policies and procedures their organization (or organizations they work with) has in place to support MSM in the jurisdiction, • Partnerships and outreach they or their organization have in place to support MSM in the jurisdiction, and • Barriers and facilitators/innovations for controlling HIV among MSM within the jurisdiction. 	<ul style="list-style-type: none"> • Perception of the local HIV situation among MSM in the jurisdiction • Needs and gaps in HIV prevention care and treatment for MSM in the jurisdiction • Programs and policies available that address HIV prevention care and treatment of MSM in the jurisdiction • Communication forms and effectiveness with MSM and how aware MSM are of the services available in the jurisdiction • Partnerships between agencies, organizations and the local MSM population • Barriers and facilitators to HIV prevention care and treatment in the jurisdiction • Perceived innovations within the jurisdiction

3. Use of Improved Information Technology and Burden Reduction

The contracting team will conduct individual interviews at a time and location that is convenient to the selected key participants. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing the necessary rapport between interviewer and respondent for a successful qualitative interview on a sensitive topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer’s ability to read both. Thus, the contracting team will conduct the individual, in-depth interviews (IDIs) in person. After asking for and receiving permission from the respondent, the contracting team will audio-record the interviews and transcribe recordings after the interview. This limits the burden on the respondent (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

This study will gather information about HIV prevention, care and treatment programs and services for MSM that is specific to each local jurisdiction in which it is collected. Although CDC conducted a small pilot study using a similar methodology and designed to ask similar questions, the findings of that pilot are limited to Philadelphia and not applicable to the current study locations. While we expect that some of the factors associated with HIV service effectiveness will be similar across all the sites, we also expect that many of the findings will be unique to each jurisdiction. Therefore, the Agency believes this information is not captured elsewhere. The Agency believes no other data collection effort has been conducted or has been planned to collect similar information for this population in these jurisdictions. Prior to the issuance of the contract, CDC investigated the possibility of using existing data to examine our research questions, but none of these existing data included rapid assessment methods administered to at risk populations regarding personal experiences with the HIV prevention, care and treatment continuum. The Agency also conducted a review of similar studies and determined that this study is

collecting unique information. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This information collection will provide the primary qualitative data needed for federal policy makers to understand local jurisdictional trends and to assess barriers and facilitators to HIV prevention, care, and treatment among MSM. If this case study were not conducted, it would not be possible to form an in-depth contextual understanding of local jurisdictional trends and needs for HIV prevention in this population. Collecting this type of jurisdiction-specific information is important, as it will allow us to provide feedback to health department staff and other stakeholders that is relevant to the local context and can be used to tailor HIV prevention, care and treatment efforts to have the greatest impact among MSM locally. The length of data collection is 3-4 months and data will only be collected once.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection effort does not involve any special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60 day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 02/24/2015, Volume 80, Number 36, Page Number 9727-9728. No public comments were received.

In addition, Emory University, Research Support Services, and IMPAQ International were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

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9. Explanation of Any Payment or Gift to Respondents

Interview participants will each receive a \$40 token of appreciation in the form of cash. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses.^{7,8}

Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research. In a recent study of recruitment and retention of Black men who have sex with men (BMSM) by a Community Based Organization (CBO), recruiters found it difficult to obtain information from the BMSM because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to an HIV prevention program.⁹ Some of those who were screened provided incorrect contact information, making it difficult or impossible to locate them later. In this study, offering a token of appreciation improved participation among BMSM.⁹ A meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons’ enrollment and retention in research studies found that remuneration enhanced retention among this group.¹⁰

Remuneration has been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014) and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019), which included similar populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCHHSTP PRA Coordinator has reviewed this project and determined the Privacy Act does not apply since personally identifiable information (PII) will not be transmitted to the CDC.

We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals’ data will be kept private and protected to the extent permitted by law.

As the nature of this information collection is to better understand local jurisdictional trends and needs for HIV prevention among men who have sex with men (MSM), we are sensitive to the need to protect personal health information (PHI). To ensure that respondents’ PHI is protected, we will take several measures to separate personally identifiable information (PII) from study-related data. All researchers

with access to PII will be required to read and sign a “Rules of Behavior.” Contact information collected for the purposes of recruitment (i.e., name, telephone number, and email address) will be collected via paper form only, will be used only for the purpose of scheduling interviews. All respondents will be assigned a unique identification code, which will be the only link between the PII contained on the contact information sheet and the interview responses. Both contact information and interview responses will be stored securely in locked cabinets, separately from one another. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. The participant interview will be kept in a password-protected file and only authorized staff will be able to access the information. If any personally identifying information is accidentally disclosed by the respondent during the interview, that information will be fully redacted from the interview transcripts and data sets used for analysis. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. Only staff authorized by the contractors will have limited need-to-know access to personal identifiers, and this information will be destroyed as quickly as possible after it no longer is required for study purposes. The contractors will be prepared to describe these procedures in full detail and to answer any related questions raised by interviewees. CDC will never have access to any personally identified information.

In conjunction with the data policy, members of Contractor project staff are required to:

- Comply with a privacy pledge and security manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the project director, and the organizational security officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the project director and the organizational security officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by project staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of personal identifying information) will be stored on encrypted flash drives. The contractor will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. Unless otherwise required by CDC, these documents will be destroyed when no longer needed for the project.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study has been reviewed and approved by the Emory IRB (**Attachment 5**).

Sensitive Questions

This study is an initiative aimed to learn local jurisdictional trends and needs for HIV prevention among MSM. As such, our information collection entails measurement of sensitive HIV-related information. All contracting staff will be trained to provide respondents with city-specific hotlines for HIV and

mental health care organizations as needed. No sensitive information will be collected during the semi-structured interviews with key participants about the people they work with. We will inform all key participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

All potential respondents will be selected from a pre-determined list and recruited to the study either via telephone or email. During our initial outreach, we will provide a brief overview of the study, determine respondents' interest in participating, confirm their contact information, and verify that all respondents are at least 18 years in age (**Attachment 1**). Because participants will be selected from a pre-determined list, no additional screening will be required. Interested participants will be required to complete the informed consent (**Attachment 2**) and then will take part in an in-depth interview (**Attachments 3a-b**).

Exhibits 12.1 and 12.2 provide further details about how the estimates of burden hours and costs were calculated. We anticipate that individual, in-depth interviews will take approximately 60 minutes (1 hour) to complete (**Attachments 3a-b**). The total number of burden hours is 120.

12A. Estimated Annualized Burden Hours

Exhibit 12.2: 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
General Public-Adults	Key Participant Interview, Community Members (Att. 3a)	40	1	1	40
General Public-Adults	Key Participant Interview, Health Dept/CBO (Att. 3b)	80	1	1	80
Total					120

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.3. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2014 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to respondents is approximately \$2,725.20. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate (\$22.71).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Key Participant Interview, Community Members (Att. 3a)	40	\$22.71	\$908.40

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public-Adults	Key Participant Interview, Health Dept/CBO (Att. 3b)	80	\$22.71	\$1,816.80
Total				\$2,725.20

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The annualized cost to the government is 537,166.

Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Project Officer (GS-14 0.20 FTE)	\$23,362
	CDC Scientist(GS-13, 0.20 FTE)	\$19,770
	CDC Scientist(GS-13, 0.10 FTE)	\$9,885
	CDC Project Coordinator (GS-12, 0.30 FTE)	\$23,471
	Subtotal, Direct Costs	\$76,488
Contract Costs	Annual Contract Costs (RSS, #200-2013-57341)	\$ 460,678
	TOTAL COST TO THE GOVERNMENT	\$ 537,166

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of respondents collected in the first part of the interview (e.g., city, age, race/ethnicity, job category). Data collection will occur between October 2016 and January 2017, analyses will be carried out in February – April 2017, and the final data set and report will be submitted in May 2017. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools,	September 2015 – April 2016

sampling and data plans, study protocol	
OMB Submission	May 2016
Recruitment	After OMB Approval
Data Collection	1-4 months after OMB Approval
Data analysis finalized and report drafted	5-7 months after OMB Approval
Final data set and final report submitted to CDC	8 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names, other PII, and locations will be removed) qualitative database for this study along with the corresponding data documentation, which will be made publicly available within 30 months of the end of data collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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