

**Surveillance of HIV-related service barriers among Individuals
with Early or Late HIV Diagnoses (SHIELD)**

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**Supporting Statement
Part B**

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1. Respondent Universe and Sampling Methods

The respondent universe for this prospective data collection includes adults (>18 years old) who have been recently diagnosed (diagnosed within the previous 12 months), meet the surveillance HIV case definition for HIV infection at stage 0 or at stage 3 (AIDS) and reside in one of the 4 participating project areas (City of Houston, Texas, State of Florida, State of Louisiana, or the State of Michigan).

For this data collection, we plan to interview and/or survey the entire study universe. We will employ a census approach and identify and recruit all eligible adults in participating project areas. This will result in a convenience sample of adults with recent stage 0 and stage 3 diagnoses because participation rates are anticipated to be less than 100%. There will not be a population of inference because probability sampling will not be conducted. However, based on recent surveillance data reported by the 4 participating health departments and the National HIV Surveillance System (NHSS), we estimate that as many as 20% of all eligible stage 0 and stage 3 diagnoses in the United States may occur in these 4 jurisdictions. If high participation rates (e.g., >75%) are achieved, the resulting convenience sample could provide information about a substantial proportion of US adults with recent stage 0 and stage 3 diagnoses.

Respondent Universe Size

The proposed respondent universe will vary in each jurisdiction based on the number of reported early (Stage 0) and late (Stage 3) HIV diagnoses identified during the data collection period.

The table below provides the number of stage 0 and stage 3 diagnoses in 2019 reported by the Project Areas.

Of all new diagnoses identified in 2019 in these four health departments, 595 received a diagnosis at stage 0, and 1,496 received a diagnosis at stage 3. It is anticipated that these annual sample sizes will remain comparable during the years of data collection. We estimate up to 2,500 persons will be recruited annually into the study.

Project Area	Stage 0 (early HIV diagnoses)	Stage 3 (late HIV diagnoses)	Total: Stage 0 + Stage 3
	2019	2019	2019
Houston	121	219	340
Florida	264	945	1,209
Louisiana	94	186	280
Michigan	116	146	262
TOTAL	595	1,496	2,091

Surveillance HIV case definition for HIV infection at stage 0 or at stage 3 (AIDS)

Stage 0 [3; reference in **Attachment 3**]: The criteria for stage 0 consist of a sequence of discordant test results indicative of early HIV infection in which a negative or indeterminate result was within 180 days of a positive result. The criteria for stage 0 supersede and are independent of the criteria used for other stages.

Stage 0 can be established either:

- 1) Based on testing history (previous negative/indeterminate test results): a negative or indeterminate HIV test (antibody, combination antigen/antibody, or nucleic acid test) result within 180 days before the first confirmed positive HIV test result of any type. The first positive test result could be any time before the positive supplemental test result that confirms it

OR

2) Based on a testing algorithm: a sequence of tests performed as part of a laboratory testing algorithm that demonstrate the presence of HIV-specific viral markers such as p24 antigen or nucleic acid (RNA or DNA) 0-180 days before or after an antibody test that had a negative or indeterminate result. Examples of algorithms that would fulfill this requirement include:

- A positive initial HIV immunoassay result (e.g., antigen/antibody or antibody only) followed by a negative or indeterminate supplemental antibody test result (e.g., HIV-1/HIV-2 antibody differentiation assay or Western blot) and a positive NAT result. All three tests are usually performed as part of the same testing algorithm, but time might elapse between tests if additional specimens must be obtained for definitive supplemental testing.
- A negative initial HIV immunoassay result followed by a positive NAT result that might have been done to evaluate the presence of acute HIV infection

Stage 3 [13]: A confirmed case can be classified as stage 3 if either:

1) A stage-3 defining opportunistic illness has been diagnosed according to Appendix: Stage-3-Defining Opportunistic Illnesses. [3]

OR

2) The person is 6 years or older and their CD4+ T-lymphocyte count is <200 cells/ μ L or their CD4+ T-lymphocyte percentage of total lymphocytes is <14%.

2. Procedures for the Collection of Information

SHIELD will employ a mixed methods approach designed to understand individual and systems-level barriers, gaps, and failures in HIV prevention and testing services and systems that allow people to become infected or receive a late diagnosis.

Eligibility Criteria

Eligible participants must meet the following criteria:

- HIV diagnosis reported to participating project area in eHARS
- Alive at the time of recruitment
- Able to complete survey or interview in English or Spanish
- Able to complete survey or interview using phone or internet
- Aged ≥ 18 years at the time of recruitment
- Currently resides in the participating project area or in a jurisdiction that permits recruitment for this project
- Resided within the United States during the 12 months before the first HIV diagnosis
- Received first HIV diagnosis at stage 0 or stage 3 of infection
- Received first HIV diagnosis within 12 months of identification

Participating health departments will use their local eHARS database as the source of information from which to identify eligible adults. Health departments will run a SAS program provided by the CDC to identify adults reported to eHARS who meet the eligibility criteria. Each eligible person identified will be added to a case list, and each eligible person on the case list will be contacted and recruited. Health departments will run the SAS program routinely at a designated frequency to keep the case list updated. Eligible persons on the case list who are successfully recruited and who complete the survey will be removed from the case list or denoted as "closed" cases.

After a diagnosis that meets eligibility criteria is identified and added to the case list, participating health departments will attempt to locate, contact, and recruit survey respondents. CDC will provide a model recruitment script (**Attachment 4A and 4B**) to provide guidance to recruitment staff.

The CDC contractor, ICF Macro, will conduct all data collection activities for this project. All consenting, eligible participants who the participating health departments successfully recruit will complete the quantitative survey and/or the qualitative interview.

Quantitative Survey. The contractor will program the CDC-furnished survey for both modalities (CATI and web-based). Prior to data collection, the CDC contractor will develop detailed interviewer training plans in collaboration with CDC.

For quantitative survey participants, the survey will be completed via the participant's chosen modality. Participants will choose to complete either the CATI or web-based survey; both modalities will use the same survey instrument. The same survey instrument will be used regardless of the participant's stage at diagnosis.

CATI. If an eligible participant chooses to complete the CATI, health department staff will register the participant in the contractor's scheduling system and schedule the date and time of the interview. The recruiter will enter the participant's month and year of HIV diagnosis and stage at diagnosis. This information will be pre-populated in the survey; the month and year of diagnosis will serve as the basis of the recall period. Once scheduled, the participant will call the phone number provided by the recruiter at the scheduled time to gain direct access to the interviewer. The participant will use a unique ID provided by the recruiter to verify their identity for the interviewer. No personally identifying information (PII) beyond the month, year, and stage at diagnosis will be included in the scheduling or data collection systems. The interviewer will confirm the participant's eligibility (currently aged ≥ 18 years, month and year of initial HIV diagnosis within the past 12 months) and administer verbal consent (**Attachment 5A and 5B**). Participants may end the interview at any time.

Health department recruiters will be responsible for sending the participant reminders before the interview. The recruiter will also monitor completion of scheduled interviews. If a participant does not attend their scheduled interview, the recruiter will attempt to recontact and reschedule the participant for another CATI or recruit the participant for the web-based survey.

Following the CATI, interviewers will have an opportunity to provide national and local service referrals provided by the health department based on the participant's responses to select survey items. Health department staff will also make themselves available for the participant to contact them for additional referrals or information about the project.

CAWI - Web-based survey. Participants who choose to complete the self-administered web-based survey will receive a personalized web link to the survey from the recruiter via

an appropriate method agreed upon by the participant (e.g., email, text message). The participant will access and complete the survey at their convenience; however, web-based surveys will not remain open indefinitely after recruitment. Health departments will develop local procedures for determining how often and for how long to send reminders about the survey. Recruiters will attempt to recontact participants who do not complete the web-based survey within the designated timeframe to encourage them to complete the survey or schedule a CATI.

Upon initiating the web-based survey, the participant will enter their unique ID provided by the recruiter to verify their identity. They will confirm their current age and the month and year of their initial HIV diagnosis to confirm eligibility. Eligible participants will agree to a written consent statement before proceeding to the survey. Participant names or any other PII will not be collected during the consent process. Participants may complete the survey in one sitting or save their progress and return to complete the survey in multiple sittings. After completing the survey, participants will receive written national and local referrals based on their responses to select survey items. These referrals could include websites, hotlines, local case managers, or local services or resources near the participant's area of residence. Referrals will be provided for HIV care as well as for potential unmet needs for ancillary services identified during the survey.

Qualitative In-Depth Interview (IDI). Up to 100 participants a year will be selected to complete the qualitative IDI (50 in English and 50 in Spanish). All qualitative IDI participants will also be offered the opportunity to complete the quantitative survey. Individuals who participate in both the qualitative and quantitative components of SHIELD will be compensated \$100.

If an eligible participant chooses to complete the qualitative IDI, health department staff will register the participant in the contractor's scheduling system and schedule the date and time of the IDI. The recruiter will enter the participant's month and year of HIV diagnosis and stage at diagnosis. This information will be pre-populated in the survey; the month and year of diagnosis will serve as the basis of the recall period. Once scheduled, the participant will call the phone number provided by the recruiter at the scheduled time to gain direct access to the

interviewer. The participant will use a unique ID provided by the recruiter to verify their identity for the interviewer. No personally identifying information (PII) beyond the month, year, and stage at diagnosis will be included in the scheduling or data collection systems. The interviewer will confirm the participant's eligibility (currently aged ≥ 18 years, month and year of initial HIV diagnosis within the past 18 months) and administer verbal consent (**Attachment 5C and 5D**). Participants may end the IDI at any time.

Health department recruiters will be responsible for sending the participant reminders prior to the IDI. The recruiter will also monitor the completion of scheduled IDIs. If a participant does not attend their scheduled IDI, the recruiter will attempt to recontact and reschedule the participant for another time to complete the IDI or recruit the participant for the quantitative survey.

Following the IDI, interviewers will have an opportunity to provide national and local service referrals provided by the health department based on the participant's responses to select survey items. Health department staff will also make themselves available for the participants to contact them for additional referrals or information about the project.

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

The response rates for a 2019 survey of similar length (Medical Monitoring Project, MMP, OMB #0920-0740) conducted in 3 of the 4 project areas (Houston, Florida, Michigan) were 45.3%, 39.4%, and 45.0%, respectively [14]. The estimated response rate for the proposed data collection would be, at a minimum, the same and hopefully better. For instance, in this data collection persons identified to participate will be recently diagnosed, their contact information will be more up-to-date than the information available for the MMP sample. This might facilitate their identification and recruitment and might result in a higher response rate than for the MMP survey.

Project Area recruiters will be trained as case managers which will allow them to offer referrals to needed services and might

facilitate initial conversations with persons that have been recently diagnosed.

Participating health departments are encouraged to develop creative and innovative strategies, in collaboration with community partners, to maximize participation rates. For additional information on methods to maximize response rates, please see Supporting Statement A, Section 9.

Recruitment will be monitored through on-going data reports generated weekly from the data submitted to CDC. The project area 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 facility staff to identify solutions to the problem.

Taking all in account, we estimate a response rate between 60-80%.

Assessing Non-Response Bias

Minimal data on the respondent universe from eHARS will be extracted using a computer program run by project staff in each project area or at CDC. Minimal data on respondents and non-respondents will be compared to identify predictors of non-response.

4. Tests of Procedures or Methods to be Undertake

Quantitative Data Collection. The quantitative data collection instrument was developed by CDC in consultation with internal and external subject matter experts (**Attachment 8**). The quantitative data collection instrument collects information about participants' experiences with HIV testing, PrEP, PEP, healthcare access and utilization, stigma and discrimination, and potential barriers to healthcare and prevention services (**Attachment 6A and 6B**). Most survey items measure experiences during the 12 months prior to HIV diagnosis to allow understanding of access, gaps, and barriers that enabled HIV infection and led to either early or late diagnosis.

The development of the data collection instruments involved an extensive literature review looking for missed opportunities and

barriers related to testing and diagnosis. Some of the themes identified included: not being aware of where to go for HIV testing, not being aware of, or not being able to access, PrEP, and failure from healthcare staff to deliver culturally appropriate or competent care. Consistent with established literature, structural and social barriers, such as not having enough time or money, as well as fear of receiving bad news were also common concerns. Marginalized and low-income populations were also more likely to experience these missed opportunities and barriers to care [15,16].

Several of the data collection instrument items were adapted from pre-existing surveys, such as the Medical Monitoring Project (OMB No. 0920-0740), the National HIV Behavioral Surveillance (OMB No. 0920-0770), the General Social Survey (<https://gss.norc.umd.edu/>), the National Survey of Family Growth (OMB No. 0920-0314), the American Men's Internet Survey (<https://emoryamis.org/>), and the Behavioral Risk Factor Surveillance System (OMB No. 0920-1061).

Agency consultants included staff from other branches within the Division of HIV Prevention who provided their expertise on several items, including discrimination, topics related to racism, sexual orientation, HIV risk behaviors, and drug use.

During the entire instrument development process, community members and external subject matter experts were also consulted.

External consultants included community members, such as community leaders who work directly with people with HIV in non-profit and human rights organizations, as well as a licensed family and marital therapist whose work combines mental and sexual health, as well as AIDS-related death and trauma (**Attachment 8**).

To inform the refinement of the quantitative survey, we consulted with two associate professors, one from Duke University and the other from University at Buffalo. Both have extensive backgrounds in qualitative and mixed methods research, specifically in HIV prevention.

In addition, we received input and feedback on survey items from the MMP community and provider advisory boards in 2022. The advisory board members reviewed items from the survey to ensure the items were reflective of patient experiences.

We also partnered with researchers at Emory University to conduct 9 cognitive interviews in English to refine specific items from

the survey. Some of the items included barriers to testing for HIV, reasons for not taking PrEP, access to healthcare, experiences with discrimination/harassment, and certain types of risk behaviors such as binge drinking alcohol and condom use frequency. We also conducted 9 cognitive interviews in Spanish to assess the cultural appropriateness and cognition of specific items of the translated survey.

In 2022, upon award of the cooperative agreement, the survey instrument was shared with staff from the four project areas, who reviewed it in consultation with their community partners and provided feedback and local questions.

Once the quantitative survey data collection instrument is programmed, the Contractor will conduct exhaustive testing of all features and functions and validate all aspects of the programmed survey in CATI and CAWI. The Contractor will conduct testing of the programmed survey in both English and Spanish. The Contractor will utilize specific testing scenarios that cover every possible skip and logic pattern in each data collection instrument and ensure all items in the requirements document are 100% implemented. The Contractor will ensure that the user-interface displays all items appropriately in each language on each computer type to be used. The Contractor will conduct 100% validation of the programmed survey data collection instruments and provide documentation of testing conducted, errors detected, and resolutions.

At the start of quantitative survey data collection, the Contractor will conduct a pilot testing phase. In this pilot testing phase, the Contractor will conduct and audio record pilot phone-based survey interviews and submit the audio recordings for CDC staff to review. The pilot interviews will be actual phone-based survey interviews with actual registered participants that will collect valid data; however, during these pilot interviews the Contractor shall observe the interviewers' engagement with the participant, their ability to build rapport, and to ask questions in a non-biased way. This pilot phase will allow the Contractor the opportunity to monitor data collection quality. The Contractor shall ensure that each trained survey interviewer conducts two phone-based pilot survey interviews with actual respondents using the programmed survey data collection instruments. The Contractor will also ensure that pilot interviews are conducted in both Spanish and English. The Contractor will prepare a phone-based survey interview pilot

testing lessons learned report, including tips for interviewers, areas for improvement, and suggested solutions.

Qualitative Data Collection.

An exploratory qualitative component for SHIELD is needed to provide novel insights into HIV prevention and testing barriers. The literature review and information gathered to develop the quantitative survey were used to inform the thematic areas of the IDI guide (**Attachment 6C and 6D**). The priority topic areas that were chosen from the quantitative survey are: health care experiences and beliefs, HIV knowledge, PrEP use, and HIV testing. The qualitative IDI will provide participants the opportunity to share detailed information on their experiences, in their own words. The guide was developed with input from HIV Behavioral Science subject matter experts across the Behavioral and Clinical Surveillance Branch in the Division of HIV Prevention. These experts reviewed the guide and provided feedback from their experiences in qualitative research among individuals living with HIV, such as the Qualitative Medical Monitoring Project. In addition, input from the Contractor and participating project areas were incorporated to finalize the IDI guide.

The Contractor will use the IDI guide to conduct a maximum of 100 qualitative IDIs in English and Spanish. Qualitative interviews will be conducted virtually and audio recorded. Once complete, the interviews will be transcribed verbatim. Qualitative interviews conducted in Spanish will be translated and back-translated to ensure that the meaning is maintained. Any identifying information will be redacted from the transcripts such as names of workplaces, hospital systems, etc. Interview recordings will be destroyed after data collection ends.

Prior to the start of qualitative data collection, the Contractor will develop a qualitative interviewer training plan. The Contractor will conduct at least one qualitative interviewer training event that will be video recorded and attended by CDC Project Staff.

At the start of qualitative data collection, the Contractor will conduct a pilot testing phase of the IDI guide. This pilot phase will allow the Contractor the opportunity to monitor data collection quality. In this pilot testing phase, the Contractor will conduct, and audio record the first two IDIs for each qualitative interviewer to allow the Contractor to observe the qualitative interviewers' ability to conduct reflexive listening, build rapport, and probe in a non-biased way. The Contractor will conduct the pilot IDIs with actual respondents, and the data will be included in the qualitative analysis. The Contractor will pilot IDIs in both English and Spanish. The Contractor shall prepare transcripts within three days of each pilot IDI and shall submit the transcripts and audio recordings to the CDC Project Staff electronically through a secure data transfer along with a pilot IDI debriefing report on each qualitative interviewer. Each transcript and/or audio will be reviewed by the Contractor and with the respective qualitative interviewers before the next IDI is conducted. For the transcripts translated from Spanish to English from the pilot IDIs, the Contractor will ensure that the meaning was preserved during translation (e.g., via back-translations). The pilot debriefing report shall capture concrete feedback and lessons learned, including areas to probe, opportunities to minimize bias, and utilization of an open-ended approach. The Contractor shall meet with CDC Project Staff after submitting the pilot debriefing reports. If substantial issues with the administration of the qualitative IDIs are noticed (e.g., leading questions or cutting the participant off), the Contractor shall provide refresher training to qualitative interviewers.

After the pilot qualitative IDIs are completed, the Contractor will develop debriefing reports on a weekly basis and submit them to the CDC Project Staff. In the weekly debriefing report, the Contractor will capture lessons learned, including areas to probe, opportunities to minimize bias, and techniques to utilize an open-ended approach. The weekly IDI debriefing report will also capture new and recurrent information learned through the verbatim transcripts and analysis.

OMB will be informed of any changes to data collection procedures or instruments as quickly as possible.

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

Consultants on Statistical Aspects

The following individuals consulted on statistical aspects:

Kevin Delaney, PhD
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The Contractor who will Collect the Data

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Individuals Analyzing Data: CDC Project Staff

CDC is not directly engaged with human subjects during data collection. However, CDC Project Staff below will provide technical assistance in data collection methods, monitor the progress of recruitment by health department staff, and analyze the data.

All CDC project staff can be reached at the following address and phone number:

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