

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

**OMB No. 0920-1402 OMB Expiration 05.31.2026**

**Attachment 7. Project Determination**

**Project Officer:**

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## Project Determination

### Surveillance of HIV-Related Service Barriers Among Individuals with Early or Late HIV Diagnoses (SHIELD)

|                                      |   |
|--------------------------------------|---|
| <b>Project ID:</b>                   | 0900f3eb8202df58                            |
| <b>Accession #:</b>                  | NCHHSTP-SST-11/10/22-2df58                  |
| <b>Project Contact:</b>              | Marc Pitasi                                 |
| <b>Organization:</b>                 | NCHHSTP                                     |
| <b>Status:</b>                       | Pending Clearance                           |
| <b>Intended Use:</b>                 | Project Determination                       |
| <b>Estimated Start Date:</b>         | 08/01/22                                    |
| <b>Estimated Completion Date:</b>    | 07/31/26                                    |
| <b>CDC/ATSDR HRPO/IRB Protocol#:</b> |   |
| <b>OMB Control#:</b>                 | Docket No. CDC-2022-0087; CDC ID# 0920-22HK |

#### Description

##### Priority

Standard

##### Determination Start Date

11/10/22

##### Description

The Enhanced Surveillance of Persons with Early (Stage 0) and Late (Stage 3) HIV Diagnosis, also known as Surveillance of HIV-Related Service Barriers Among Individuals with Early or Late HIV Diagnoses (SHIELD)", is a non-research demonstration surveillance project that builds upon current case surveillance. It is expected that the new data collection involved will require PRA review by OMB. The project aims to supplement existing surveillance of people with diagnosed HIV

conducted by the Medical Monitoring Project (MMP) by enhancing surveillance among key subgroups of people with diagnosed HIV — those who received their HIV diagnosis at early or late stages of infection. This new demonstration surveillance activity will recruit adults with diagnosed HIV in participating project areas for a quantitative behavioral interview. A small subset of participants will also be recruited to participate in a qualitative in-depth interview. The information collected will be used to monitor and inform HIV prevention and testing services in participating project areas. Additionally, this project will pilot a new centralized interviewing system that, if successful, may be adopted by MMP or other DHP surveillance activities. The project has the potential to continue through additional funding cycles or expand to additional project areas, contingent on the availability of funding. Each project area will use their local Enhanced HIV/AIDS Reporting System (eHARS) data to generate and update lists of all persons who received a stage 0 or stage 3 diagnosis in the past 12 months. Once identified, all persons in the list will be contacted to invite them to participate in this surveillance activity. During first contact, the project area staff will confirm eligibility for the project. Eligible and interested persons will be invited for either a phone or web-based interview in English or Spanish. Eligible respondents must: 1) be at least 18 years old, 2) speak English or Spanish, 3) have received an HIV diagnosis at stage 0 or stage 3 in the past 12 months, and 4) be able to participate in either a phone or web-based interview.

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission**

No

**IMS Activation Name**

Not selected

**Select the primary priority of the project**

Not selected

**Select the secondary priority(s) of the project**

Not selected

**Select the task force associated with the response**

Not selected

**CIO Emergency Response Name**

Not selected

**Epi-Aid Name**

Not selected

**Lab-Aid Name**

Not selected

**Assessment of Chemical Exposure Name**

Not selected

**Goals/Purpose**

The goal of the project is to assess individual and systems level factors that are likely to contribute to barriers and gaps in testing and prevention that contributed to having persons receiving either an early (stage 0) or late (stage 3) diagnosis. The data obtained through this enhanced surveillance activity will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions and efforts. The findings will enhance evidence-based local and national decisions to address HIV testing and prevention gaps, prevent new HIV infections, and facilitate early diagnosis and linkage to care.

**Objective**

The objectives of this project are: 1) to understand current barriers and facilitators to HIV testing and prevention services, including pre-exposure prophylaxis (PrEP), among persons receiving either an early (stage 0) or late (stage 3) diagnosis in the past 12 months; and 2) to pilot test a centralized interviewing system to improve the standardization of data collection.

**Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?**

No

**Project does not incorporate elements of health equity science**

Not selected

**Measuring Disparities**

Yes

**Studying Social Determinants of Health (SDOH)**

Yes

**SDOH Economic Stability**

Yes

**SDOH Education**

Not selected

**SDOH Health Care Access**

Yes

**SDOH Neighborhood and Environment**

Not selected

**SDOH Social and Community Context**

Yes

**SDOH Indices**

Not selected

**Other SDOH topics**

Not selected

**Assessing Impact**

Not selected

**Methods to Improve Health Equity Research and Practice**

Not selected

**Other**

Not selected

**Activities or Tasks**

New Collection of Information, Data, or Biospecimens

**Target Population to be Included/Represented**

Pregnant Women; Prisoners; American Indian or Alaska Native; Asian; Black or African American; Hispanic or Latino; Native Hawaiian or Other Pacific Islander; White; Female; Male; Transgender; Adult 18-24 years; Older adults > 64 years; Immigrants or Refugees; Patient-

**Tags/Keywords**

HIV; recent diagnosis; stigma; PrEP

**CDC's Role**

Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided; CDC employees or agents will obtain data by intervening or interacting with participants; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens; CDC employees will participate as co-authors in presentation(s) or publication(s); CDC employees will provide substantial technical assistance or oversight; CDC is providing funding

**Method Categories**

Individual Interview (Quantitative); Individual Interviews (Qualitative)

**Methods**

Each of the funded project areas (City of Houston, Florida, Michigan, and Louisiana) will use their local Enhanced HIV/AIDS Reporting System (eHARS) data to generate and update lists of all persons who received a stage 0 or stage 3 diagnosis in the past 12 months. Once identified, all eligible persons in the list will be contacted to invite them to participate in this surveillance activity. This census design allows for national and state or local estimates of certain characteristics and

behaviors that will be generalizable to HIV-diagnosed adults in the U.S. SHIELD project area staff will conduct direct recruitment of persons in the list by using contact information from eHARS and if this information is out-of-date, searching for contact information in other databases used routinely for public health work. Such databases include health department surveillance and intervention databases for other diseases such as tuberculosis or sexually transmitted diseases, electronic medical record systems to which health departments have access, as well as the Social Security Death Index. Project area staff will log the time, date, method, and outcome of recruitment attempts locally, and will provide CDC with aggregate recruitment progress indicators. Any contact information collected for the purposes of recruiting (i.e., name and telephone number) will only be accessed by local and state health departments. Project area staff will be allowed to recruit persons from other project areas or non-participating areas to which the potential participants have moved as this is expected to increase response rates if there are no local legal or policy barriers that prevent this activity. Interviewing residents of non-participating jurisdictions is conditional on local law and policy and will take place in a manner specified by a written, project-specific agreement with the HIV surveillance unit at the project area in the jurisdiction of current residence. Upon first contact, the project area staff will confirm eligibility for the project. Eligible and interested persons will be invited to participate in either a phone or web-based interview in English or Spanish. The Project area staff will register all participants. The Contractor will generate a unique identification code (Participant ID) at the time of participant registration. Each Participant ID will include a health department-specific prefix, and the Participant ID shall not include PII (i.e., no date of birth, social security number, etc.) neither the Contractor nor CDC will receive any PII. The Contractor will ensure Participant IDs are unique and not duplicated. This Participant ID will be used as a link between all processes (registration, scheduling, completion status, distribution of token of appreciation, etc.). Project area staff will be responsible for securely maintaining the link between the generated Participant ID and the health department's record of each participant's contact information. The mode of interview administration will be chosen by the participant. Based on their selection, the project area staff will either provide a link for the web-based survey, transfer the participant directly to the Contractor's interviewer, or schedule an interview at a time convenient for the participant to complete the interviewer-administered phone surveys. The survey will take an average of 50-minutes to be completed.

### **Collection of Info, Data, or Bio specimens**

CDC has developed a survey instrument which the contractor will administer to up to 4,500 persons recently diagnosed at stage 0 (early) or stage 3 (late). The survey instrument will be programmed by the Contractor on a web-based platform to be used with the computer-assisted telephone interviewing (CATI) method and the computer-assisted web interviewing (CAWI) technique. The Contractor will program and test the survey in English and Spanish. The Contractor will provide trained interviewers to conduct the computer-assisted telephone interviewing of persons recently diagnosed at stage 0 (early) or stage 3 (late). Sensitive information collected by the Contractor will not be linked to any other personally identifiable information (PII) and cannot be used to reveal the identity of any one person. No information that could directly identify an individual will be collected as part of the interview by the Contractor. CDC will also develop a qualitative in-depth interview guide, which the contractor will administer to up to 60 persons recently diagnosed at stage 0 (early) or stage 3 (late). The Contractor will provide trained interviewers to conduct 90-minutes in-depth interviews using the CDC-developed interview guide. Project area staff will recruit participants for the in-depth interviews using the same methods and strategies used to recruit for the quantitative survey described above. HIV and AIDS case surveillance data are collected according to the Assurance of Confidentiality under Sections 306 and 308(d) of the Public Health Service Act (42 U.S.C. Sections 242k and 242m(d)). Information collected in the surveillance system that would permit identification of any individual or establishment is collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual or the establishment in accordance with Section 306 and 308(d) of the Public Health Service Act. Because data collected for the Stage 0/3 Project constitutes enhanced

surveillance activity, these data are reported to and maintained by CDC in the same manner as are current HIV and AIDS surveillance data and accordingly are covered by the existing Assurance of Confidentiality for the National HIV Surveillance System and Surveillance-Related Data (HIV AoC).

#### **Expected Use of Findings/Results and their impact**

The findings from the enhanced surveillance of people with early and late diagnoses will identify actionable missed opportunities for early diagnosis and prevention, thus informing allocation of resources, development and prioritization of interventions, and evidence-based local and national decisions to address HIV testing and prevention gaps, prevent new HIV infections and facilitate early diagnosis and linkage to care. Results will be useful at the local level to improve services, prevent new HIV diagnoses, and facilitate early diagnosis and prompt treatment. Each project area will work with CDC to release local estimates. Local data results will be reported to the community and patients through multiple conduits, such as local publications, epidemiologic profiles, and presentations to local AIDS service organizations and community planning groups and at conferences and workshops. Other results are more meaningful after the data from all project areas have been aggregated. CDC has primary responsibility for aggregated estimates from the project areas and will disseminate this information nationally. These data will be distributed to providers, researchers, policymakers, and other interested persons through presentations at local, national, and international conferences, publications in peer-reviewed journals, and presentations at forums such as continuing medical education courses and seminars. Furthermore, CDC will publish a surveillance report based on the data collected.

#### **Could Individuals potentially be identified based on Information Collected?**

Yes

#### **Will PII be captured (including coded data)?**

Yes

#### **Does CDC have access to the Identifiers (including coded data)?**

Yes

#### **Is this project covered by an Assurance of Confidentiality?**

Yes

#### **Assurances of Confidentiality associated with this project:**

NCHHSTP - AIDS and HIV Surveillance

#### **Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?**

No

#### **Is there a formal written agreement prohibiting the release of identifiers?**

No



## Funding

| Funding Type              | Funding Title  | Funding #          | Original Fiscal Year | # of Years of Award | Budget Amount |
|---------------------------|--|--------------------|----------------------|---------------------|---------------|
| CDC Cooperative Agreement | Enhanced surveillance of persons with early and late HIV diagnosis to understand system and individual factors associated with new infection and delayed testing | CDC-RFA-PS22-2211  |                      | 4                   |               |
| CDC Contract              | Enhanced Surveillance of Persons with Early and Late HIV Diagnosis   | HHSD2002013M53944B |                      | 3                   |               |

## HSC Review

## Regulation and Policy

**Do you anticipate this project will be submitted to the IRB office**

No

## Institutions

| Institution                                      | FWA #       | FWA Exp. Date | IRB Title                             | IRB Exp. Date | Funding #          |
|--|-------------|---------------|---------------------------------------|---------------|--------------------|
| Florida Department of Health                     |             |               |                                       |               | CDC-RFA-PS22-2211  |
| Houston Health Department                        | FWA00027730 | 01/15/24      |                                       |               | CDC-RFA-PS22-2211  |
| ICF Inc. and Subsidiary Organizations            | FWA00002349 | 10/13/25      | icf IRB #1                            | 08/09/24      | HHSD2002013M53944B |
| Louisiana Department of Health                   | FWA00026681 | 03/19/23      | Louisiana Department of Health IRB #2 | 03/29/24      | CDC-RFA-PS22-2211  |
| Michigan Department of Health and Human Services | FWA00007331 | 09/12/24      |                                       |               | CDC-RFA-PS22-2211  |

## Staff

| Staff Member   | SIQT Exp. Date | Citi Biomedical Exp. Date | Citi Social and Behavioral Exp. Date | Citi Good Clinical Exp. Date | Staff Role          | Email                         | Phone #      | Organization/ Institution             |
|----------------|----------------|---------------------------|--------------------------------------|------------------------------|---------------------|-------------------------------|--------------|---------------------------------------|
| Billy Robinson | n/a            | n/a                       | n/a                                  | n/a                          | Co-Investigator     | billy.robins on@la.gov        |              | Louisiana Department of Health        |
| Brian Emerson  | 07/13/2025     |                           |                                      |                              | Project Officer     | nsy2@cdc.gov                  | 404-718-3492 | SPECIAL STUDIES TEAM                  |
| Daniel Grischy | n/a            | n/a                       | n/a                                  | n/a                          | Co-Investigator     | daniel.grisc hy@flhealth .gov |              | Florida Department of Health          |
| Dave Roe       | n/a            | n/a                       | n/a                                  | n/a                          | Project Coordinator | dave.roe@i cf.com             |              | ICF Inc. and Subsidiary Organizations |

| Staff                  |                |                           |                                      |                              |                                 |                              |              |  |
|------------------------|----------------|---------------------------|--------------------------------------|------------------------------|---------------------------------|------------------------------|--------------|--|
| Staff Member           | SIQT Exp. Date | Citi Biomedical Exp. Date | Citi Social and Behavioral Exp. Date | Citi Good Clinical Exp. Date | Staff Role                      | Email                        | Phone #      | Organization/ Institution                        |
| Marc Pitasi            | 02/27/2023     | 12/03/2021                | 12/07/2021                           |                              | Project Officer                 | vva1@cdc.gov                 | 404-639-6361 | SPECIAL STUDIES TEAM                             |
| Mariana Gutierrez      | 05/06/2023     |                           | 05/01/2025                           |                              | Project Officer                 | qge3@cdc.gov                 | 404-718-3274 | SPECIAL STUDIES TEAM                             |
| Mary-Grace Brandt      | n/a            | n/a                       | n/a                                  | n/a                          | Co-Investigator                 | brandtm4@michigan.gov        |              | Michigan Department of Health and Human Services |
| Melissa Cribbin Sharma | 11/08/2025     |                           | 12/31/2021                           |                              | Contract Officer Representative | mwc4@cdc.gov                 | 404-639-2016 | BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH      |
| Pollyanna Chavez       | 12/29/2024     | 12/28/2021                | 12/28/2021                           |                              | Program Official                | geo5@cdc.gov                 | 404-639-1742 | SPECIAL STUDIES TEAM                             |
| Salma Khuwaja          | n/a            | n/a                       | n/a                                  | n/a                          | Co-Investigator                 | salma.khuwaja@houston.tx.gov |              | Houston Health Department                        |
| Toria Reaves           | 08/05/2024     |                           |                                      |                              | Project Officer                 | ryy9@cdc.gov                 | 404-498-6423 | SPECIAL STUDIES TEAM                             |

| DMP                                 |  |
|-------------------------------------|--|
| Proposed Data Collection Start Date | 06/01/23   |
| Proposed Data Collection End Date   | 06/30/26   |
| Proposed Public Access Level        | Restricted   |
| Data Use Type                       | Other- External requestors may request summary data from CDC |

|  |   |
|--|---|
|  |   |
| <b>Data Use Type Data Use Type URL</b>                           | TBD   |
| <b>Data Use Contact</b>  |   |
| <b>Public Access justification</b>                               | Surveillance data collected under an Assurance of Confidentiality   |
| <b>How Access Will Be Provided for Data</b>                      | <p>Only the Contractor and CDC staff working on this project will have access to the data during the data collection period. Project areas will have access to names and other identifying information through NHSS. All individually identifying information is kept at the health department and not sent to CDC or the contractor. The CDC staff will retain all the coded, deidentified data collected by the Contracting staff in a secure data drive for which only designated staff will have access. The Contractor will share line level data from the quantitative survey and the transcripts from qualitative in-depth interviews with the CDC only. The Contractor will provide each funded project area their corresponding local line level data from the quantitative survey data. CDC will share with the project areas a summative report of the qualitative analysis. CDC will develop formal procedures for providing deidentified data to external requestors (i.e., collaborators outside of CDC, ICF, or participating project areas). External requestors will be required to submit a concept proposal to CDC describing details of the proposed analysis. CDC will have a public-facing website for the project that will include the concept proposal form and instructions for data requests. If the CDC study team approves the concept proposal, the CDC study team will perform the analysis and provide aggregate results to the external requestor. All scientific products arising from a national data request must include at least one CDC co-author. External requestors will not have direct access to the national dataset. In the event that external researchers request local data from a participating project area, project areas must develop formal procedures for data requests and sharing and include them in their local DMP. Project areas will alert CDC prior to sharing any data. Project areas must always abide by the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs</p> |
| <b>Plans for archival and long-term preservation of the data</b> | <p>All data produced as a result of this project will be transferred to CDC. The Contractor shall not retain any copies of data generated under the task order. During or after the life of the task order, no data may be released except after CDC approval. All requests which the Contractor receives from third parties for access to the data must be referred to the COR. On or about one week prior to the end of the task order, the Contractor shall provide a one-page letter certifying that all data and associated information under this task order have been destroyed. The letter shall be on letterhead</p>   |

and signed by a senior manager at the contracting company and sent to the COR “through” the CDC Information Systems Security Officer.

## Spatiality (Geographic Location)

| Country       | State/Province | County/Region |
|---------------|----------------|---------------|
| United States | Texas          | Harris County |
| United States | Michigan       |               |
| United States | Louisiana      |               |
| United States | Florida        |               |

## Determinations

| Determination                               | Justification   | Completed | Entered By & Role                              |
|---|---|-----------|--|
| HSC:<br><b>Does NOT Require HRPO Review</b> | Not Research - Public Health Surveillance<br><br><i>45 CFR 46.102(l)(2)</i> | 11/17/22  | Dodson_Janella R. (jhd7) CIO HSC               |
| PRA:<br><b>PRA Applies</b>                  |   | 11/17/22  | Bonds_Constance (akj8) CTR OMB/PRA Coordinator |