

National HIV Surveillance System (NHSS)

Attachment 9.
Project Determination



REQUEST FOR NCHHSTP PROJECT DETERMINATION & APPROVAL

NCHHSTP ADS/ADLS Office on behalf of CDC (New, Continuation, or Amendment)

This form should be used to request NCHHSTP/OD/ADS or ADLS office review and approval on behalf of CDC of a new, continued, or amended project for those projects for which NCHHSTP staff/employees, branches, divisions, and center/OD/ADS or ADLS office are responsible.

Any NCHHSTP activity that meets the definition of a project (see the following section) and represents one of the four project categories must be approved by the respective NCHHSTP branch and division and by the NCHHSTP/OD/ADS or ADLS office. Approval by the NCHHSTP ADS or ADLS office (nchstphs@cdc.gov) of these projects indicates approval by CDC. This review and approval process complies with obligations for adherence of projects to federal regulations, state laws, ethics guidelines, CDC policies, and publication requirements.

For research that involves identifiable human subjects in which CDC/NCHHSTP is engaged, use CDC Human Research Protection Office forms and submit them to CDC Human Research Protection Office through the NCHHSTP ADS human subjects email box after approval at the branch and division levels.

RELEVANT INFORMATION

What is a project?

A project is defined as a time-limited activity that is funded for a specific period of time, an activity with specified funds for a limited time, or as a limited time responsibility by specific CDC employees or staff, including projects that might be ongoing or continuous for an extended period. A project has defined objectives, tasks (e.g., essential public health services), dedicated resources, and is funded for a specified time. NCHHSTP reviews and approves projects for the four project categories listed on this form. Every project officer, project team and staff, NCHHSTP branch, and NCHHSTP division or office is responsible for submitting this form for each project and for obtaining NCHHSTP OD/ADS or ADLS approval on behalf of CDC before project initiation, continuation, or amendment. Such programs as surveillance are approved and funded as specific projects for certain periods.

What is research?

The federal regulations and CDC/OD/ADS office define **research** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, regardless if these activities are conducted or supported under a program that is not considered research for other purposes. For example, demonstration and service programs sometimes include research activities.

What is a human subject?

A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual or
2. identifiable private information.

What is an intervention?

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

What is private information?

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is occurring and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information identifies individuals (i.e., the identity of the person is or might be readily ascertained by the investigator or associated with the information) for the information to constitute research involving human subjects.

What does being “engaged” mean?

An institution becomes “**engaged**” in human subjects research when its employees or agents intervene or interact with living individuals for research purposes, or obtains individually identifiable private information for research purposes. An institution is automatically considered to be engaged in human subjects research whenever it receives funding or resources (e.g., a direct award) to support such research. In such cases, the awardee institution has the ultimate responsibility for protecting human subjects under the award.

What is surveillance?

CDC defines **surveillance** as “the ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know. The final link of the surveillance chain is the application of these data to prevention and control. A surveillance system includes a functional capacity for data collection, analysis, and dissemination linked to public health programs.”

What is program evaluation?

Program evaluation is the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, or inform or guide decisions about future program development. Program evaluation should not be confused with *treatment efficacy*, which measures how well a treatment achieves its goals and that can be considered research.

Sources (links)

- <http://intranet.cdc.gov/od/oads/osi/hrpo/>
- <http://www.hhs.gov/ohrp/index.html>

PROJECT REQUEST

Project Stage

Choose one by selecting a checkbox:

New: Fill out entire form, even if a protocol is attached (approval is for work by CDC/NCHHSTP employees).

Continuation: For projects expected to continue beyond NCHHSTP approved date; include brief description of changes and attach clean and marked copies of approved determination (approval is for continued work by CDC/NCHHSTP employees).

Amendment: Include brief description of changes and attach relevant documentation and a copy of approved project (approval is for continued work by CDC/NCHHSTP employees).

Project Information:

Project Title: Integrated HIV Surveillance and Prevention Programs for Health Departments (Component A)

NCHHSTP Project Number: PS18-1802

Division: DHAP

Project Location/Country(ies):

Telephone: (404) 639-2006

60 jurisdictions throughout the U.S.

Project Dates:

CDC Project Officer or CDC Co-Leads:

Start 01/01/2018

End 12/31/2022

Laboratory Branch Submission:

If applicable, select the checkbox:

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

- **I. Activity is not human subject research.** The primary intent of the project is public health practice or a disease control activity.
 - A. Epidemic or endemic disease control activity; collected data directly relate to disease control. If this project is an Epi-AID; provide the Epi-AID number and documentation of the request for assistance, per division policy. Epi-AID no.
 - B. Routine disease surveillance activity; data will be used for disease control program or policy purposes.
 - C. Program evaluation activity; data will be used primarily for that purpose.
 - D. Post-marketing surveillance of effectiveness or adverse effects of a new regimen, drug, vaccine, or device.
 - E. Laboratory proficiency testing.

- **II. Activity is not human subjects research.** The primary intent is public health program activities.
 - **A.** Public health program activity (e.g., service delivery; health education programs; social marketing campaigns; program monitoring; electronic database construction or support; development of patient registries; needs assessments; and demonstration projects to assess organizational needs, management, and human resource requirements for implementation).

B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment).

III. Activity is research but does NOT involve identifiable human subjects.

A. Activity is research involving collection or analysis of data about health facilities or other organizations or units (i.e., not individual persons.)

B. Activity is research involving data or specimens from deceased persons.

C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1–4) below are required:

1. No one has contact with human subjects in this project; **and**
2. Data or specimens are or were collected for another purpose; **and**
3. No extra data or specimens are or were collected for this project; **and**
4. Identifying information was (one of the following boxes must be checked)
 - a. not obtained;
 - b. removed before this submission, or before CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects; or
 - c. protected through an agreement (i.e., CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. A copy of the agreement must be attached.)

IV. Activity is research involving human subjects, but CDC involvement does not constitute “engagement in human subject research.” Select only one option by checking the box: A indicates the project has current funding; B or C indicates no current funding is applicable.

- A. This project is funded under a grant, cooperative agreement, or contract award mechanism. **ALL** of the following 3 elements are required:
1. CDC staff will not intervene or interact with living individuals for research purposes.
 2. CDC staff will not obtain individually identifiable private information.
 3. Supported institution(s) must have a Federalwide Assurance (FWA), and the project must be reviewed and approved by a registered IRB or an institutional office linked to the supported institution’s FWA.*
Supported institution of primary investigator or co-Investigators/entity name:*

Supported institution/entity FWA Number:*

FWA expiration date:*

Expiration date of IRB approval:*

***Attach copy of IRB approval letter(s) supporting project review and approval.**

- B. CDC staff provide technical support that does not involve possession or analysis of data or interaction with participants from whom data are being collected (no current CDC funding).
- C. CDC staff are involved only in manuscript writing for a project that has closed. For the project, CDC staff did not interact with participants and were not involved with data collection (no current CDC funding).

Project Description

Participating project staff must complete all 18 elements of this section.

This is a required description from CDC employees or staff for review and approval of a project plan or proposal (or for changes) for projects conducted by CDC or in which CDC is involved. All 18 elements are required to standardize the review and approval process across NCHHSTP, document that all 18 elements have been addressed, expedite review and approval by the NCHHSTP ADS or ADLS office, and minimize CDC/OD/ADS office audit requests for additional information. A protocol may be attached to this form, but it does not eliminate the requirement to complete all 18 elements.

PROJECT TITLE: Integrated HIV Surveillance and Prevention Programs for Health Departments (Component A)

Instructions: Use the following boxes to complete the 18 items. Each box will expand as you type, and you are not limited in the length of your answers. Formatting features and symbols also may be used.

1. CDC Principal Investigator(s) or Project Directors and branch/division/office affiliations:

Dr. Stan A. Phillip, Chief (Acting), Prevention Program Branch, DHAP
Erica Dunbar, Senior Adviser (Acting), Prevention Program Branch, DHAP
Dr. Angela Hernandez, Chief, HIV Incidence and Case Surveillance Branch, DHAP
Dr. Azfar Siddiqi, Associate Chief of Science, HICSB, DHAP

2. CDC Project Officer(s) and each person's role and responsibilities and affiliations:

Dr. Renata D. Ellington, Assoc. Deputy Director, Prevention Programs, DHAP/OD
-NOFO Project Officer of Record

3. Other CDC project members, branches, divisions, and other participating institutions, partners, and staff:

All Project Officers, Epidemiologists, and Public Health Advisors in the Division of HIV/AIDS Prevention monitoring the project: James Powell, Richard Selik, Levator Brown, Darrin Brown, Rita Volpitta, Alexa Oster, Kevin Ramos, Zanetta Gant, Laura Kearns, Nivedha Panneer, Benjamin Laffoon, George Hill, Bill Longdon, Melissa Thomas-Proctor, Laurie Linley, Damarys Cordova, Carla Alexander-Pender, Angela Hernandez, Yolanda Gonzalez Alvarez, Christian Spears, Shuenae Smith, Debra Karch, Yvonne Greene, Veronica McCants, Mi Chen, Benjamin Puesta, Patricia Joyce, Stacy Muckleroy, Sheryl Lyss, Tracy Clopton, Andrew Mitsch, Nicole Crepaz, Dwayne Banks, Anne Marie France, Angie Allen, Richard Kline, Ndidi Nwangwu-Ike, Kisha Hampton, Sonia Singh, William Adih, Harneyca Hooper, Stephanie Celestain, Daphne Kennebrew, Patricia Sweeney, Azfar-e-Alam Siddiqi, Anne Peruski, Gabrielle O'Meara, Magan Pearson, Donato Clarke, Cheryl Banez Ocfemia, Alexandra Balaji, Tracy ford, Ronald Buchanan, Kristen Gray, Kristen Hess, Anna Satcher-Johnson, Roderick Joiner, Tracy Luster-Welch, Karin Bosh, Meg Watson, Janet Scott.

4. Institution(s) or other entity(ies) funding the project:

This project is funded by CDC. No other entities fund this project.

5. Project goals:

The purpose of this Notice of Funding Opportunity (NOFO) is to implement an integrated comprehensive HIV surveillance and prevention program to prevent new HIV infections and achieve viral suppression among persons living with HIV. In particular, the NOFO promotes and supports improving health outcomes for persons living with HIV through achieving and sustaining viral suppression, and reducing health-related disparities by using quality, timely, and complete surveillance and program data to guide HIV prevention efforts, in accordance with the national prevention goals, HIV Care Continuum, and CDC's High-Impact HIV Prevention (HIP) approach.

The integration of the surveillance and prevention programs allows each jurisdiction to operate in unison and maximize the impact of federal HIV prevention funding. An integrated NOFO strengthens implementation of HIP by further allowing health departments to align resources to better match the geographic burden of HIV infections within their jurisdictions and improve data collection and use for public health action.

6. Project objectives:

The NOFO priorities are to increase individual knowledge of HIV status, prevent infections among HIV-negative persons, reduce transmission from persons living with HIV, and strengthen interventional surveillance to enhance response capacity and intensive data-to-care activities to support sustained viral suppression. Priority activities include (but are not limited to) HIV testing; linkage to, re-engagement in, and retention in care and support achieving viral suppression; pre-exposure prophylaxis (PrEP) related activities; community-level HIV prevention activities; HIV transmission cluster investigations and outbreak response efforts.

7. Public health (program or research) needs to be addressed:

Achieve and sustain viral suppression
Prevent new infections
Increase awareness of infection and link and retain HIV-positive individuals in HIV medical care
Detect and interrupt active HIV transmission

8. Population(s) or groups to be included:

All persons, with emphasis on populations at greatest risk for acquiring and transmitting HIV infection living in the United States, Puerto Rico and the US Virgin Islands.

9. Project methods:

Strategies and activities include: systematically collect, analyze, interpret, and disseminate HIV data to characterize trends in HIV infection, detect active HIV transmission, implement public health interventions, and evaluate public health response; identify persons with HIV infection and uninfected persons at risk for HIV infection; develop, maintain, and implement plans to respond to HIV transmission clusters and outbreaks; provide comprehensive HIV-related prevention services for persons living with diagnosed HIV infection (PLWH); provide comprehensive HIV-related prevention services for HIV-negative persons at risk for HIV infection; conduct perinatal HIV prevention and surveillance activities; conduct community-level HIV prevention activities; develop partnerships to conduct integrated HIV prevention and care planning; implement structural strategies to support and facilitate HIV surveillance and prevention; conduct data-driven planning, monitoring, and evaluation to continuously improve HIV programs; and build capacity for conducting effective HIV program activities, epidemiological science, and geocoding.

10. Selection, inclusion, or sampling of participants (persons or entities):

The funded health department jurisdictions will provide HIV surveillance and prevention services in accordance with state, local, and federal laws and regulations. The funded jurisdictions are responsible for overall public health in their respective jurisdictions. Therefore, this project will not involve sampling of participants.

11. Incentives to be provided to participants:

No incentives will be provided to participants.

12. Plans for data collection and analysis:

Data collection for the HIV prevention program has been approved by the Office of Management and Budget (OMB) under OMB Number 0920-0573, National HIV Surveillance System, Expiration Date: June 30, 2019, and OMB Number 0920-0696, National HIV Prevention Monitoring and Evaluation, Expiration Date: February 28, 2019. Changes to data collection requirements during the project period will be subject to review and approval by OMB.

Additionally, the funded jurisdictions will work in close collaboration with CDC to finalize their detailed Evaluation and Performance Measurement Plans (EPMP), including a Data Management Plan (DMP), in accordance with CDC program guidance.

13. Confidentiality protections:

The awardees are required to fully comply with NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs (2011): <https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf>

14. Other ethics concerns (e.g., incentives, risks, privacy, or security):

Please see the attached NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs (2011).

15. Projected time frame for the project:

January 1, 2018 - December 31, 2022

16. Plans for publication and dissemination of the project findings:

CDC activities, in collaboration with the awardees include routine release of summarized surveillance data via, but not limited to, reports, slide sets, manuscripts etc., the sharing of information, best practices, lessons learned, and evaluation results between awardees (e.g., through conferences, guidance, material development, webinars, data sharing publications, other social media, participation in meetings, committees, conference calls, and working groups related to the cooperative agreement and its projects).

17. Appendices — including informed consent documents, scripts, data collection instruments, focus group guides, fact sheets, or brochures:

There are no appendices included.

18. References (to indicate need and rationale for project):

Please reference the PS18-1802 website for additional information.

1. NOFO <https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/cdc-hiv-ps18-1802-nofo.pdf>
2. PS18-1802 Evaluation and Performance Measurement Plan (EPMP) Guide
https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-AttachmentC-EPMP_Final.pdf
3. PS18-1802 Local Evaluation Plan Guide
<https://www.cdc.gov/hiv/pdf/funding/announcements/ps18-1802/CDC-HIV-PS18-1802-AttachmentC-ME-Local-Plan.pdf>

PROJECT APPROVAL

Choose one of the following options (Division or Center/OD Project)

DIVISION PROJECT

NCHHSTP BRANCH AND DIVISION ADS REVIEW AND APPROVAL (Sign electronically by clicking next to the X and following the prompts)

Angela L.
Hernandez -S

Digitally signed by Angela L.
Hernandez -S
Date: 2018.01.19 11:29:55
-05'00'

X Stanley Phillip
-S

Digitally signed by Stanley
Phillip -S
Date: 2018.01.19 12:52:59
-05'00'

Branch Chief or Branch Science Officer

X Laura J. Fehrs
-S

Digitally signed by Laura J.
Fehrs -S
Date: 2018.01.22 10:25:11
-05'00'

Division ADS, Acting ADS, or Deputy ADS

CENTER/OD PROJECT

NCHHSTP OD OFFICE REVIEWS AND APPROVALS (Sign electronically by clicking next to the X and following the prompts)

X

Office Associate Director or Designee

X

NCHHSTP ADS or Designee

NCHHSTP ADS/DEPUTY ADS OR ADLS REVIEW AND APPROVAL

Project Title: Integrated HIV Surveillance and Prevention Programs for Health Departments (Component A)

Date received in NCHHSTP ADS or ADLS office:

Date received by NCHHSTP Deputy ADS or ADLS:

Select the checkbox for each applicable comment for Nos. 1–5 or select the checkbox for No. 6 if all of the comments apply. Additional applicable comments may be added to No. 7. If additional information is required before approval can be granted, select No. 8.

1. This project is approved by NCHHSTP/CDC and CDC (per CDC policies and federal regulations) for CDC staff participation.
2. Participating partners and sites must obtain project review and approval, according to their institutional policies and procedures and according to local, national, and international regulations and laws, including 45 CFR 46 regulations and state laws. CDC project officers must maintain a current copy of local sites' approvals in project records.
3. CDC investigators and project officers need to adhere to the highest ethics standards of conduct and to respect and protect the privacy, confidentiality, autonomy, data, welfare, and rights of participants and integrity of the project. All applicable country, state, and federal laws and regulations must be followed.
4. Informed consent or script is needed as required by laws and regulations. Information conveyed in an informed consent or script process needs to address all applicable required elements of informed consent. Consent of employees in related projects about their institutions needs to include a statement that their voluntary participation or withdrawal would not affect their employment status or opportunities.
5. OMB Paperwork Reduction Act determination by the NCHHSTP OMB/PRA Coordinator might be needed for this project.
6. All previous comments apply.
7. **Other applicable comments:** Type your comment in the box. The space will expand as you type.

8. **More information is required before approval is granted:** Explain what additional information is requested by typing in the box. The space will expand as you type.

Date Information was requested:

Date Information was received:

Approval must be granted by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Associate Director for Science (ADS), Acting ADS, or Deputy ADS, or for laboratory-associated projects, by the Associate Director for Laboratory Science (ADLS) or Acting ADLS.

Project Title: Integrated HIV Surveillance and Prevention Programs for Health Departments (Component A)

X Alcia A.
Williams -S6
Digitally signed by Alcia A.
Williams -S6
Date: 2018.01.22 10:51:06
-05'00'

NCHHSTP ADS, Acting ADS, or Deputy ADS

Or

X

NCHHSTP ADLS or Designee