

Attachment 9
CDC Project Determination



REQUEST for Project Determination & Approval - NCHHSTP ADS/ADLS OFFICE

This form should be used to submit proposals to the NCHHSTP ADS/ADLS Office for determination that have not begun and do not require routing to the CDC Human Research Protection Office at this time. Projects eligible for this classification are (1) non-research activities; (2) research that does not involve identifiable human subjects; (3) human subject research in which CDC is not "engaged".

Project Title:
STD Surveillance Network (SSuN)

Project Location/Country(ies): US

Project Officer(s): Eloisa LLata, Mark Steng

Division: DSTDP Telephone: 404-639-6183

Proposed Project Dates: Start: 8/1/2014

End: 9/29/2018 Laboratory Branch Submission:

Please check appropriate category and subcategory:

- I. Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- A. Epidemic or endemic disease control activity; collected data directly relate to disease control (e.g. Epi-AIDs; provide Epi-AID number & documentation of request for assistance, if division policy). Epi-AID #
- B. Routine disease surveillance activity; data used for disease control program or policy purposes.
- C. Program evaluation activity; data are 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.** 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 and/or support; development of patient registries; needs assessments; and demonstration projects intended 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 which are 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) of the following are required:
1. No contact with human subjects is involved for the proposed activity...**and**...
2. Data or specimens are/were collected for another purpose...**and**...
3. No extra data/specimens are/were collected for **this** purpose...**and**...
4. Identifying information was: (one of these must be checked)
- a. not obtained
- b. removed prior to this submission, or prior to CDC receipt, so that data cannot be linked or re-linked with identifiable human subjects
- c. protected through an agreement. (*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 below: 'A' indicates the project is funded, 'B' or 'C' indicate there is **no** current funding
- A. This project is funded under a grant/cooperative agreement/contract award mechanism. **ALL** of the following 3 elements are required:
1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
2. CDC employees or agents will not obtain individually identifiable private information.
3. Supported institution must have a Federalwide Assurance (FWA) and project must be reviewed by a registered IRB linked to the supported institution's FWA.
- Supported Institution/Entity Name: _____
- Supported Institution/Entity FWA # _____ FWA Expiration Date (mm/dd/yyyy): _____
- Expiration Date of IRB approval: _____ *Attach copy of the IRB approval letter.
- B. CDC staff provide technical support that does not involve possession or analysis of identifiable 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).

Approval initials & printed name: HW. Hillard Weinstock 5/29/14
Branch Chief Date

Indee Joshi 6/17/14
ADS/ADLS or Division Director Date

Division Notes/Comments:

Project Title: Sexually Transmitted Disease Surveillance Network (SSuN)

NCHHSTP ADS/ADLS Review Date received in NCHHSTP ADS /ADLS office: July 1, 2014

Concur, project does not require human subject research review beyond NCHHSTP at this time

Project constitutes human subject research that must be routed to CDC HRPO

Comments/Rationale for Determination:

- All participating partners and sites need to receive approval for this project before its initiation, per their review process and 45 CFR regulations.
- Adherence to all relevant regulations, laws, policies, and procedures for protecting rights, welfare, and data of participants and integrity of the project is required.

Signed: Salaam Senaan, DrPH

July 2, 2014

Name
Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP
OR
Associate Director for Laboratory Science, NCHHSTP
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Date

NOTE: This page is an outline for a proposal to ensure all required information is included for review and approval. You may submit a proposal following the outline provided below, or a full protocol that includes information pertaining to all applicable elements.

PROJECT TITLE: Enhanced STD Surveillance Network (eSSuN)

1. Principal Investigator(s): Eloisa LLata, Mark Stenger

CDC, NCHHSTP, division of STD prevention

2. CDC Project Officer(s) including roles and responsibilities:

- Coordination of development of methods and protocols for eSSuN activities.
- Facilitation of routine eSSuN communications.
- Coordination of routine conference calls and annual collaboration meetings to review and plan program activities.
- Provision of technical assistance facilitating secure electronic transmission of data.
- Provision of technical assistance with SAS licensure and SAS coding.
- Monitoring of grantee progress toward achieving eSSuN objectives, including grantee implementation of data quality assurance processes.
- Management of eSSuN data warehouse or other central data store to support data provisioning for collaborative analyses.
- Provision of guidance and technical assistance (where requested or identified by CDC) essential to implementation of activities in compliance with these protocol.
- Ensuring that analyses and dissemination of findings from eSSuN surveillance activities are conducted collaboratively by both CDC and appropriate participating sites.
- Facilitating discussions with awardees to identify emerging trends/issues in STDs/HIV and sexual health, Enhanced STD surveillance technologies and methods and other issues that merit further investigation by the Enhanced STD surveillance network.
- Coordinating the development, dissemination and approval of proposals for eSSuN analytic projects
- Assisting co-authors and lead authors in the development of manuscripts.
- Facilitating CDC clearance for manuscripts and presentations based on eSSuN findings.
- Working with awardees to assure that eSSuN activities, at both the awardee and CDC level, adhere to NHHSTP data security and confidentiality guidelines.

3. Other participants in research:

Baltimore City Health Department (Award#1H25PS004259)
 California Department of Public Health (Award#1H25PS004244)
 Florida Department of Health (Award#1H25PS004261)
 Massachusetts Department of Public Health (Award#1H25PS004253)
 Minnesota Department of Health (Award#1H25PS004255)
 Multnomah County Health Department (Award#1H25PS004256)
 New York City Department of Health & Mental Hygiene (Award#1H25PS004247)
 Philadelphia Department of Public Health Award#1H25PS004248)
 San Francisco Department of Public Health (Award#1H25PS004258)
 Washington State Department of Health (Award#1H25PS004271)

4. Sponsoring institution(s): CDC

5. Project Goals: The goal of the project is to enhance and improve STD surveillance data by informing a