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: Strengthening U.S. Response to Resistant Gonorrhea (SURRG)

NCHHSTP Project Number:

Division: DSTDP

Project Location/Country(ies):
CA, CO, GA, HI, IN, NYC, NC, WA,WI

CDC Project Officer or CDC Co-Leads:
Karen Schlanger; Shacara Johnson

Telephone: (404) 718-5660

Project Dates:
Start 01/01/2017
End 07/31/2021

Laboratory Branch Submission:
If applicable, select the checkbox: ☐

Project Categories

Select the corresponding checkbox to choose the category and subcategory.

- **I. <u>Activity is not human subject research</u>.** 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: Strengthening U.S. Response to Resistant Gonorrhea (SURRG)

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:

Karen L. Schlanger, Ph.D., MPH
Division of STD Prevention, Epidemiology and Statistics Branch

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

Shacara Johnson, MPH
Division of STD Prevention, Epidemiology and Statistics Branch

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

DSTDP: Robert D. Kirkcaldy, MD, MPH, Kyle Bernstein, PhD: Epidemiology and Statistics Branch; John Papp, PhD., Cau Pham, PhD, Ellen Kersh, PhD: Laboratory Reference and Research Branch; LaZetta Grier and Rodney Pressley, PhD: Surveillance and Data Management Branch

Grantees: San Francisco Department of Public Health/California Department of Public Health; Denver Public Health/Colorado Department of Public Health and Environment; Fulton County Department of Health and Wellness/Georgia Department of Public Health; City & County of Honolulu/Hawaii State Department of Health; Marion County Public Health Department/Indiana State Department of Health; Guilford County Department of Health and Human Services/North Carolina Division of Public Health; New York City Department of Health & Mental Hygiene; Public Health – Seattle and King County/Washington State Department of Health; Milwaukee Health Department/Wisconsin Division of Public Health

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

5. Project goals:

- Enhance timeliness and sensitivity of local surveillance for resistant gonorrhea
- Strengthen local resistant gonorrhea response capacity (programmatic, laboratory and epidemiological)
- Enhance local capacity to rapidly conduct gonorrhea case investigations and partner services, to ensure appropriate treatment of patients with resistant gonorrhea infections, and halt the spread of identified resistant strains
- Evaluate yield and impact of gonorrhea case investigations for halting spread of identified resistant strains
- Develop deeper understanding of sexual networks and gonorrhea transmission (using observational clinical, epidemiological, network, and genomic data) to identify opportunities for innovative approaches to gonorrhea prevention and control

6. Project objectives:

- Substantially increase local specimen collection for Neisseria gonorrhoeae culture and AST
- Build and expand local capacity to routinely conduct rapid antibiotic susceptibility testing (AST) capacity (via Etest with ~5 day turnaround)
- Strengthen local data system functionality and interoperability to strengthen surveillance and programmatic response capacity
- Build capacity for local STD programs to conduct enhanced cluster field investigations of and partner services for persons diagnosed with gonorrhea of public health significance (such as resistant/reduced susceptibility) and those in his/her sexual network
- Ensure appropriate treatment of patients diagnosed with gonorrhea with resistance/reduced susceptibility; ensure partners are tested and treated
- Utilize genomic data of N. gonorrhoeae isolates to support and inform local cluster investigations
- Conduct local and multi-site analyses using clinical, epidemiological, network, and genomic data to identify opportunities for inform cluster field investigations and develop and evaluate prevention/control interventions

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

Gonorrhea is a nationally notifiable disease, and state and local health departments have authority to conduct surveillance of gonorrhea and collect patient-level data about persons with gonorrhea and their contacts. Gonorrhea is the 2nd most commonly reported notifiable disease in the United States; in 2015, over 300,000 cases were reported to CDC. Rapid detection and effective treatment is a cornerstone of public health gonorrhea control and prevention. However, treatment of gonorrhea has been complicated by the organism's keen ability to develop antimicrobial resistance. Widespread emergence of resistance to currently recommended therapies could cripple treatment and control efforts, increase rates of gonorrhea and complications of inadequately treated gonorrhea, and contribute to estimated additional direct medical costs of at least $235 million. CDC designated N. gonorrhoeae one of three "urgent" antimicrobial threats facing the US. Addressing the threat posed by N. gonorrhoeae is featured prominently in the White House National Strategy and National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB). The Action Plan calls for maintenance of the prevalence of ceftriaxone-resistant N. gonorrhoeae below 2% through 2020, a target supported by a goal of slowing the emergence of resistant bacteria and preventing spread of resistance.The Strengthening U.S. Response to Resistant Gonorrhea (SURRG) project is a critical vehicle for achieving this target

AST currently requires culturing of live bacteria. Detection of resistance in the US is severely hampered by the widespread shift to molecular assays for diagnosis of gonorrhea and limited use of culture. CDC conducts surveillance of N. gonorrhoeae susceptibility trends through the Gonococcal Isolate Surveillance Project (GISP). While GISP provides robust data on long-term trends, GISP does not provide AST data in a timely manner to support rapid response and has limited sampling (only up to 25 men monthly in STD clinics). Many local STD programs lack resources to adequately respond to outbreaks of resistant infections. SURRG seeks to fill these critical gaps in our public health infrastructure by enhancing local capacity to rapidly identify and respond to resistant gonorrhea and identify best practices that can be implemented more widely to prevent the emergence of untreatable gonorrhea.

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

*Clinic-based populations
- Patients with culture-positive gonorrhea presenting at project health centers (public health STD clinics and other partnering health centers reporting large numbers of gonorrhea cases) in nine regionally dispersed jurisdictions of the United States (clinic-based populations)
- for program evaluation purposes, minimal demographic will be collected on persons diagnosed in STD clinics with gonorrhea by nucleic acid amplification tests (NAATs) but who had negative cultures

*Field investigations
- Patients (from clinic-based population) identified as having resistant gonorrhea and their named recent sexual partners and social contacts
- (As local capacity builds) Patients (from clinic-based population) identified with drug-susceptible gonorrhea and their named sexual partners and social contacts

9. Project methods:

- Per clinic protocol (determined locally), eligible patients will have swab(s) collected for gonorrhea culture and NAAT at all anatomic sites of exposure
- The local public health lab will perform cultures and conduct AST via Etest on all positive cultures (isolates). All purified bacterial isolates will be sent onto a regional laboratory for confirmatory AST via agar dilution, and whole genome sequencing for molecular characterization will be conducted on a subset (no human DNA will be included in the sample).
- Public health disease intervention specialists (DIS) will conduct cluster case investigations and partner services activities (using a standardized but locally modifiable SURRG case investigation protocol) for all patients identified as having resistant gonorrhea. As local capacity builds, investigations and partner services for non-resistant infections can be conducted. DIS will collected data from patients about recent sexual exposures and elicit names and contact information for their recent sexual contacts and up to 2 social contacts who might benefit from STD screening. DIS will attempt to contact named sexual partners and social contacts, and refer them to the local STD clinic for STD testing (including gonorrhea culture) and treatment (as appropriate). To enhance the speed of investigations and before the partners' test results are available, DIS will also attempt to collect identifying information on partners from the index patients' partners (i.e. 2nd generation sexual partners to the index case); DIS will attempt to contact them and refer them to the STD clinic for testing and treatment (as appropriate). Any sexual partner or social contact who tests positive for gonorrhea will become a new index case; DIS will attempt to conduct SURRG case investigations and partner services with that patient, two social contacts, and 1st and 2nd generation sexual partners. The investigation will continue until no new cases are identified.
- Demographic, clinical, and laboratory data will be abstracted from the health records participating clinics by the local epidemiological coordinator. Unique patient identifiers will be assigned locally that will not contain personally identifiable information. These de-identified data will be linked by the locally assigned identifier and transmitted to CDC following the Secure Access Management Service protocols.

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

-Men or women attending a participating STD clinic or partnering health care site will be selected for gonorrhea culture according to local clinical practice, standards of care, and CDC screening recommendations (such as patients who meet CDC/USPSTF gonorrhea screening criteria, are to be presumptively treated for gonorrhea [e.g. symptomatic, sexual contact of a case], or who are diagnosed with gonorrhea by NAAT and are returning to the clinic for treatment).
- Selection of anatomic sites for specimen collection will be guided by patient self-report of which anatomic sites were exposed.

11. Incentives to be provided to participants:

None.

12. Plans for data collection and analysis:

Standardized data elements for the project have been defined and can be found in Appendices A-C. Clinical data will be collected in the electronic medical records at participating sites; laboratory data on culture, AST and NAAT results will be collected in the local public health laboratory's information management system. Case investigation and partner services data will either be collected in the grantees' STD management information system or a secure Access database created specifically for this project (depending on site capacity). CDC will provide guidance to grantees on required data structure for submission, as well as proper syntax for data cleaning and validation checks. All data will be de-identified prior to submission to CDC. Data will be submitted to CDC every two months following CDC's Secure Access Management Service (SAMS) protocol. Data from the ARLN laboratory network will be transmitted to CDC via a secure AIMS data portal and an existing CDC secure genomic pipeline. Data will be analyzed cross-sectionally for prevalence estimates and longitudinally for trends. Partnership data will be analyzed using network approaches.

13. Confidentiality protections:

No individually identifiable information is collected by CDC. CDC will treat data/information in a secure manner and will not disclose, unless otherwise compelled by law. A unique number will be locally assigned to each isolate and corresponding patient. This identifier will not be a medical record number nor will it include PII. Grantees will adhere to NCHHSTP Data Security and Confidentiality guidelines. All individually identifiable information PII (e.g., name, address) on individual patients is retained by the local clinic, STD program, and laboratory, and is not recorded with data sent to CDC or the regional laboratories.
At CDC, only the SURRG data manager and project epidemiologists have direct access to these data; data may be shared with Laboratory Reference and Research Branch and Surveillance and Data Management Branch partners. The electronic SURRG database will stored on the CDC mainframe computer and only the Division of STD Prevention (DSTDP) data managers have access rights to the data.

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

Participants may be nervous about answering questions about sexual activity and/or identifying sexual partners. However, such questions are part of routine STD care. Participants may feel minor discomfort during the urethral, rectal, or oral pharyngeal swab collection; the discomfort should resolve once the swab is removed. Participants may benefit from having AST susceptibility testing performed and partner services conducted, and information from this project may help prevention and control of gonorrhea in the future. Personally identifiable information will be collected locally in accordance with local confidentiality policies. No personally identifiable information will be submitted to CDC. No incentives are provided. The risks are minimal.

15. Projected time frame for the project:

January 2017: Training and local piloting of expanded cultures and performance of AST via Etest
June 2017: Train DIS staff on SURRG case investigation and partner services practices and data to collect
July 2017: Sites to begin conducting SURRG case investigation and partner services for patients with resistant gonorrhea
December 2017 (pending OMB approval): Grantees will begin submitting line-listed data (clinical, laboratory, and investigation data) to CDC
January 2018: Sites to begin conducting SURRG case investigations and partner services on small subset of patients with susceptible gonorrhea
January 2018: Review submitted data; work with grantees to address identified issues
February 2018: Begin data cleaning and analysis (continue through 2021)
March 2019: Draft initial manuscript(s) and submission for publication
July 2021: End data collection
June 2022: Draft and submit additional manuscripts for publication

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

Project findings will be published as at least three manuscripts in peer-reviewed journals. Investigators will submit abstracts based on study findings to scientific conferences. Evidence on effective practices or interventions will be shared with participating and non-participating jurisdictions through publications, conference presentations, webinars, or other communication approaches.

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

Data dictionary:
A. Required data elements from STD clinics and non-STD clinics
B. Required data elements from local PHL lab
C. Required data elements from case investigations and partner services

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

Barbee, L.A. (2014). Preparing for an era of untreatable gonorrhea, Current Opinion Infectious Disease, 27(3): 282-287.

Bolan, G.A., Sparling, F.P., Wasserheit, J.N. (2012). The emerging threat of untreatable gonococcal infection, The New England Journal Of Medicine, 366(6), 485-7.

Bowen, V.B., Johnson, S.D., Weston, E.J., Bernstein, K.T., Kirkcaldy, R.D. (2017). Gonorrhea, Current Epidemiology Reports, 4:1-10.

Unemo, M., and Shafer, W.M. (2014). Antimicrobial Resistance in Neisseria gonorrhoeae in the 21st Century: Past, Evolution, and Future, Clinical Microbiology Reviews, 27(1): 587-613.

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)

X Kyle T. Bernstein -S Digitally signed by Kyle T. Bernstein -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000698282, cn=Kyle T. Bernstein -S Date: 2017.05.11 15:05:56 -04'00'	X Frederick Bloom -S Digitally signed by Frederick Bloom -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000343387, cn=Frederick Bloom -S Date: 2017.06.01 14:53:43 -04'00'
Branch Chief or Branch Science Officer	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	X
Office Associate Director or Designee	NCHHSTP ADS or Designee

NCHHSTP ADS/Deputy ADS or ADLS Review and Approval

Project Title: Strengthening U.S. Response to Resistant Gonorrhea (SURRG)

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: Strengthening U.S. Response to Resistant Gonorrhea (SURRG)

X Alcia A. Williams -S6

Digitally signed by Alcia A. Williams -S6
Date: 2017.06.20 11:17:00 -04'00'

NCHHSTP ADS, Acting ADS, or Deputy ADS

Or

X

NCHHSTP ADLS or Designee