Attachment 5

Non-Research Determination Approval

Sexually Transmitted Disease (STD) Morbidity Surveillance System

REQUEST for Project Determination and Approval -- NCHHSTP ADS OFFICE

This form should be used to submit to NCHHSTP ADS proposals for projects and activities involving CDC investigations prior to initiation that do not require routing to the CDC Human Research Protection Office. Projects are eligible for this classification are (1) research that do not involve "human subjects" where the primary intent is not to generate generalizable knowledge, (2) research projects that do not involve identifiable human subjects, or (3) research projects in which CDC is not "engaged". (See page 3 of this form for helpful definitions and weblinks.) These projects do not require submission to the CDC Human Research Protection Office (HRPO) for human subjects research review. Do **NOT** use this form for "exempt" research that must be routed to HRPO.

Project Title_____ *Sexually Transmitted Disease (STD) Morbidity Surveillance*
Project Locations/Sites: ___All 50 states, the District of Columbia, selected cities, & U.S. dependencies & possessions and independent nations in free association with the U.S.
Project Officer(s)_Sam Groseclose, Hillard Weinstock_ Division:_DSTDP__ Telephone: __404-639-6494_____
Proposed Project Dates: Start: _01_/__01_/_2009 End: __12/__31_/_2011 (and ongoing thereafter)
Please check appropriate category and subcategory:

_x__ **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 needs.
- __x_**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 (including service delivery, health education, social marketing campaigns, program monitoring and process measures, and risk reduction interventions).
- ___**B.** Activity is purely administrative (e.g., purchase orders or contracts for services or equipment) and not related to research

___ **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 either: (one of these must be checked)
    - __a. not obtained
    - __b. removed prior to this submission so that data cannot be linked or re-linked with identifiable human subjects.
    - __c. protected through an agreement. The investigators and the holder of the key (code linking the data to identifiable human subjects) enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased. Please attach a copy of the agreement.

___ **IV. Activity is research involving identifiable human subjects but CDC involvement does not constitute "engagement in the research".** :
- ___A. This project is conducted under a grant or cooperative agreement award mechanism. **ALL** of the following 3 elements are required:
  - ___1. CDC employees or agents do not intervene or interact with living individuals for research purposes.
  - ___2. CDC employees or agents do not obtain individually identifiable private information.
  - ___3. Project must be reviewed by an IRB with an FWA. (Attach a copy of the IRB approval letter from the engaged institution(s).
    - Supported Institution/Entity Name _____
    - Supported Institution/Entity FWA #_____ Expiration Date_____
    - Local IRB # _____ IRB Approval Expiration Date_____
- ___B. CDC staff provide technical support only that does not involve interaction with human subjects or with data collection.
- ___C. CDC staff are involved only in manuscript writing for a project that has closed. For this project, CDC staff were not involved with human subjects or with data collection.

Attach project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: nchstphs@cdc.gov

☐ ___ Check here if this request is an **amendment** of an existing determination of human subjects research review routing.

Approval initials & Name: SG Sam Groseclose, DVM, MPH 12/23/2008 — **Branch or Section Chief** — Date

Dr. Fred Bloom for S. Aral 12/23/08 — **ADS or Div. Director** — Date

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Project Title___ *Sexually Transmitted Disease (STD) Morbidity Surveillance*

NCHSTP ADS Review **Date received in NCHSTP ADS Office:** Dec 23 08

✓ **Concur, project does not require human research review beyond NCHHSTP**

or

___Project constitutes human subjects research that must be routed to CDC HRPO

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document human subjects research that is exempt from human subjects regulations; such research must instead be submitted to the CDC HRPO.
2. Although CDC HRPO review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not require routing to CDC HRPO, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements as adapted to the project.
4. Other:

Signed: _____ Dec 23 08

Name: Salaam Semaan Date

Associate (or Acting or Deputy Associate) Director for Science, NCHHSTP

National Center for HIV, Viral Hepatitis, ~~STD, and TB Prevention~~

Rev. October, 2007

Selected Definitions and Links

OHRP defines ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not these activities are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP defines a ***human subject*** as 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.

Intervention includes both physical procedures by which data are gathered (for example, 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. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102

OHRP considers that an institution becomes ***"engaged"*** in human subjects research when its employees or agents intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. An institution is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm. ***Agents*** include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, e.g., contractors.

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." (CDC 1986)

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

For easy access to HHS human subjects regulations, see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
For guidance on differentiating research from nonresearch, see http://www.cdc.gov/od/ads/opspoll1.htm.
For guidance on engagement of institutions in research, see http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

Information on data protection and agreement appear in OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004.

Attachment: Project description

PROJECT TITLE: ***Sexually Transmitted Disease (STD) Morbidity Surveillance***

CDC Project Officer(s) including roles and responsibilities: Hillard Weinstock, Epidemiology and Surveillance Branch, DSTDP, scientific oversight, surveillance data analysis, interpretation & dissemination; Sam Groseclose, Statistics and Data Management Branch, DSTDP, informatics and data management oversight, surveillance data analysis, presentation, and dissemination.

Project Background

The CDC is responsible for the reporting and dissemination of nationally notifiable STD morbidity information for prevention and control purposes in collaboration with state and local health departments.

Recent changes in sexually transmitted disease (STD) epidemiology in the United States indicate that the existing passive surveillance for STD does not include all the elements needed in order to control and prevent STDs in the U.S. Towards this end, CDC is proposing a new electronic information collection that will include additional information on nationally notifiable STDs that has been beyond the scope of the current collection called Weekly and Annual Morbidity and Mortality Reports (MMWR, OMB #0920-0007, expiration, January 31, 2011). The MMWR STD surveillance includes four of 60 nationally notifiable infectious conditions included in the 0920-0007.

The new STD morbidity surveillance will be epidemiologically superior to the MMWR surveillance because it will include information on laboratory confirmation of syphilis infection and risk behaviors of persons infected with syphilis and other STDs. This STD Morbidity surveillance data will identify population subgroups at increased risk for STDs, accommodate evidence-based intervention strategies, evaluate the impact of ongoing control efforts and generally enhance our understanding of STD transmission.

The proposed STD Morbidity surveillance activity is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241)

Overview of the data collection system

The surveillance case definitions used to confirm STDs is jointly developed and approved by the Council of State and Territorial Epidemiologists (CSTE) and CDC for nationally notifiable STDs. The nationally notifiable STDs include chancroid, genital *Chlamydia trachomatis* infection, gonorrhea, and all stages of syphilis. The information content of the electronic STD morbidity case reports submitted to CDC is defined in collaboration with state and local STD programs.

Physicians and other providers collect demographic, risk, and clinical (including laboratory) information from persons diagnosed with notifiable STDs during a clinical encounter or counseling session. They submit the information in hardcopy or electronic formats, to the state and local public health departments. A subset of the information reported to state health departments is reported electronically as a case report e-record to CDC's Nationally Notifiable Disease Surveillance System (NNDSS, sometimes referred to as the National Electronic Telecommunications System for Surveillance(NETSS) on a weekly basis.

In accordance with state and local laws and regulations and Health Insurance Portability and Accountability Act (HIPAA)'s public health notification exemption, both health care providers and laboratories are required to report

demographic, risk, and clinical information data elements describing notifiable STD case-patients to the local or state public health system.

State STD prevention and control programs receive federal funds to support comprehensive STD prevention programs, comprised of eight (8) essential functions – one of which is "surveillance and data management" within their jurisdiction.

Because MMWR STD surveillance does not use paper or hard-copy data collection forms, local and state programs have the flexibility to extract defined morbidity-associated data variables from commercial, locally-developed, or CDC-provided freeware information systems(STD*MIS, URL: http://www.cdc.gov/std/std-mis/). The data elements defining STD morbidity that is needed for the new surveillance will be extracted from these state and local information systems after they are posted on the CDC mainframe. The Division of STD Prevention will extract the information needed by accessing the STD data bases through the CDC mainframe.

Use of the Information Collected

The STD morbidity information is being collected in order to monitor morbidities and risk profiles of persons with specific trends in specific STDs at the local, state, and national level. The feedback to local and state departments improves local STD prevention and control efforts. Reporting selected demographic and risk behavior data on persons infected with notifiable STDs from state and local STD prevention programs to CDC allows cross-jurisdictional, regional, and national STD trends and emerging epidemiologic patterns to be identified to guide public health response.

CDC will use the STD morbidity information for intervention planning and implementation and to guide allocation of prevention resources. Without the STD morbidity information, the distribution of STDs by risk behavior group (e.g. men who have sex with men) across the United States will be unavailable. DSTDP will not be able to make data-based decisions regarding national prevention program planning and resource allocation without STD incidence data.

Data confidentiality and security considerations:

Once STD Morbidity data are reported to CDC, use and release of the data are guided by a June 1996 policy, "Data Release Guidelines of the Council of State and Territorial Epidemiologists for the National Public Health Surveillance System", which defines the subgroups of STD morbidity data that can be released. The policy for data release intends to facilitate the use of national notifiable STD morbidity data while preserving the confidentiality of the data.

This STD Morbidity information collection request includes sensitive information on sexual and drug-using behaviors associated with the case-patient and identified only as a case identification number. The only IIF category collected is date of birth, which is collected in order to assign age of the patient and also to distinguish unique vs. repeat visits of the same client. The proposed STD Morbidity data collection will have no effect on the respondent's privacy because personally-identifiable information that allows identification of an individual will not be available in the MMWR STD case reports that arrive at CDC.

At CDC, the NNDSS data including STD case reports are maintained on secure servers behind the CDC firewall. Password-protected access is required and directory-specific user access rights are assigned by a CDC data steward following review of and sign-off on a data use policy that references the CSTE data release guidelines. Restricted access to STD data is provided to Division of STD Prevention (DSTDP)/CDC scientists, researchers, and program

managers via an intranet web-based data query application called STD Net. Epidemiologists and program consultants in the DSTDP create analytic data files from the case report line listing in order to monitor trends in STDs by demographic and geographic characteristics.

Data dissemination:

In order to gain the maximum benefit for existing STD prevention and control efforts, CDC will disseminate aggregated STD morbidity reports with local and state STD prevention programs, policy makers, academia and the general public, in the form of MMWR series of publications, including the weekly MMWR, the MMWR Surveillance Summaries, the Recommendations and Reports, and the annual Summary of Notifiable Diseases, United States. Additionally, DSTDP publishes an annual STD-specific surveillance summary and supplements in hard copy on CD-ROM and on the Internet (http://www.cdc.gov/nchstp/dstd/Stats_Trends/Stats_and_Trends.htm).

Project duration:

Collection of STD surveillance data in the United States to support STD prevention efforts began prior to 1941. The Division of STD Prevention plans to continue this long tradition, but is currently seeking OMB approval for a 3-year period and plans to renew OMB approval for STD surveillance data collection and use thereafter.