Public Health Surveillance and Informatics Program Office
REQUEST FOR DETERMINATION OF RESEARCH STATUS (11/30/2011)

INSTRUCTIONS

- The *Determination of Research Status Form* is to be completed by the PHSPO staff member with lead responsibility for the project.
- This form is to be completed for **any project** at PHSIPO for which there is any data collection or collection of a data set. See PHSIPO *Guidance on Research Determination for Data Collection (add hyperlink)* on determining whether a project is research or nonresearch.
- This form is completed at the beginning of a project, not annually. However, a new research determination form is to be completed if there are changes in 1) the type of involvement of CDC staff in the project, 2) the types of data or form of data being collected, or 3) the whether the project is classified as research, non-research or both, involves human subjects,or is exempt.
- Note that a project can be both nonresearch and research. In that instance, different CDC policies apply to the non-research and research components.
- Before completing this form, review the PHSIPO Guidance (***add hyperlink***) and CDC's related guidance. The CDC guidance also defines terms used in this form. http://intranet.cdc.gov/od/oads/osi/hrpo/steps/1-review-type.htm/.
- Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

==========

DETERMINATION OF RESEARCH STATUS FORM

Date submitted:

Project is (choose one):	***Project Title:***
_ New **_ Revision of an earlier project** **X_Continuation of earlier project without revision** *(NOTE: Revision refers to any substantive change made to the roles of CDC staff, the types or forms of data or type of project.)*	**National Notifiable Diseases Surveillance System**

Project period:	***Funding Dates*** *(if applicable):*	***PGO Tracking number:*** *(if external funding is part of activity).*
Start: 1961 **End:**	**Start: ~ 2003 (NEDSS funding)** **End:**	

Lead PHSIPO Staff Member:	***Please indicate your role(s) in this project:***
Name: Ruth Jajosky **User ID: raj3** **Scientific Ethics No: 10519** **Branch/Unit: Division of Notifiable Diseases and Healthcare Information, PHSIPO, OSELS** **Telephone: 404.498.6274**	**__ COTR (Project Officer)** **__ Principal Investigator** **__ Co-Investigator** **__ Technical Monitor** **__ Consultant** **X Other (please explain) NNDSS Team Lead**

Mailstop: E-91	

Preliminary Description of Project

1. Project summary: Briefly summarize in the following space the proposed project or activity. Include the related CDC goals or objectives and source of funding. Briefly describe the purpose and rationale of the activity. Include what information and what types of data are collected about or from what people and by whom. Note how data will be transferred from the original data collector to each of the other users and how data will be stored by each user. Note who will analyze data and what kinds of data or analytic output or aggregated data will be provided to whom and in what formats, including publications. Include in this summary information about whom at what institutions is going to do what with what information about what people, when, where, and how?

The National Notifiable Diseases Surveillance System (NNDSS) is a state-based surveillance system that enables all levels of public health (local, state, federal, and international) to monitor the occurrence and spread of nationally notifiable diseases in the U.S. CDC administers the NNDSS in collaboration with the Council of State and Territorial Epidemiologists (CSTE). The NNDSS facilitates aggregating data from 57 reporting jurisdictions (i.e., health departments in every U.S. state, New York City, Washington DC, and 5 U.S. territories), as well as managing, analyzing, interpreting and disseminating data on nationally notifiable diseases. The data are used to monitor impact of notifiable conditions, measure diseases trends, assess the effectiveness of control and prevention measures, identify populations or geographic areas at high risk, allocate resources appropriately, formulate prevention strategies, and develop public health policies. Monitoring surveillance data enables public health authorities to detect sudden changes in disease occurrence and distribution, identify changes in agents and host factors, and detect changes in health-care practices.

A key component of the NNDSS is the National Electronic Disease Surveillance System (NEDSS). NEDSS provides data and information technology standards, support, and leadership to local, state, and territorial health departments in order to perform surveillance on conditions deemed important to public health and reportable by law or regulation by healthcare providers, laboratories, hospitals and other public health entities within the relevant jurisdiction. This effort includes creating standards and providing technical support to local and state health departments in establishing electronic standards-based messaging of data streams from health care providers to local and state public health, needed for the process of public health surveillance case ascertainment and case confirmation. A subset of these data (without direct personal identifiers) are sent by NNDSS reporting jurisdictions to CDC as case notifications through HL7 messages, NETSS legacy data files, and the NEDSS Base System Master Message.. NEDSS also provides funding through the ELC Cooperative Agreement to states in order to implement electronic laboratory reporting.

Another component of the NNDSS includes the work CDC does to assist CSTE when CSTE administers the State Reportable Condition Assessment (SRCA). CSTE performs an annual national assessment to ascertain which conditions are reportable in each U.S. state and territory. The NNDSS provides technical support to CSTE in reviewing data quality and analyzing results of the SRCA. Analyzed results of the SRCA appear as "N" indicators in the MMWR tables, representing nationally notifiable diseases that are not reportable in a given state and year.

2. Identifiable information: Specifically address whether any identifiable private information will be collected. Specify whether personal identifiers are collected, stored by anyone involved in the project, and/or made available in any data sets for the project See Box 2 of the April 11, 2003 MMWR Supplement, HIPAA Privacy Rule and Public Health for a list of HIPAA personal identifiers. Also, address the issue of whether with a combination of data elements, e.g., an age category – race – sex –geographic location, individuals can be identified.

States and territories collect various types of data about reportable diseases cases. The information states and territories collect includes demographic data, clinical information (e.g., diagnosis, treatment information, vaccination history), laboratory tests and results, and epidemiologic data (such as risk factor data, travel history). In addition, states and territories collect personal identifiers such as name, address, and phone number on reportable disease cases in their jurisdiction. CDC's NNDSS receives only a subset of data collected by the states and territories for public health surveillance. However, NNDSS reporting jurisdictions do not send personal identifiers, such as names, social security numbers, addresses, or phone numbers, in the case notifications they submit to CDC. The NNDSS does include data on age, sex, race, ethnicity, and state and county of residence of the case which taken together could potentially represent a re-disclosure risk. However, NNDSS enforces cell suppression rules and data aggregation rules (e.g., age is aggregated in categories) in its tables, reports, data releases, and data release agreement to reduce the potential risk of re-identification. The rules in place for confidentiality protection were negotiated with state epidemiologists.

3. Coded information: State whether individual records have a unique identification number or code. Specify whether the identification code is attached to any data items that make the individual readily identifiable (this includes cases where there exists a master list connecting individuals and unique identification numbers (i.e. coded information)).

Because there are no names of case-patients in the NNDSS data sent to CDC, the health department generates codes (which are sent to CDC) for each case the health department sends to CDC. This code is used by the health department to cross reference the case-records mentioned in the CDC data validation report, with the actual record in the health department's surveillance information system. Thus, if errors are found by CDC during data validation, the health department can readily locate the record they need to correct and resubmit the data to CDC. This code is also used so CDC knows when updates to a record are made for an existing case, versus data are being submitted to CDC about a new case.

4. **Data Security**: Describe how security of data, both electronic and hard copy will be maintained. If personal identifiers are collected or a combination of personal characteristics could lead to identification of individuals, describe how privacy and confidentiality will be maintained during data collection, transfer, analysis, and use.

CDC has been aggregating NNDSS data from 1961-1989 in summary data format and since 1990 in case-specific format. The NNDSS staff are not aware of any breaches in data security or confidentiality to date.

The NNDSS electronic data are stored in data bases and applications that have undergone CDC security and vulnerability tests. There is controlled access to the data sets, based upon need and role of the users. Only staff having an authorized responsibility to access and use the data can access the NNDSS data sets. Each NNDSS data user signs a data use restrictions agreement which includes the following statements related to security and confidentiality. The below information is within a form titled "Registration Information and Data Use Restrictions Agreement form for the NNDSS" within the "Data Release Guidelines for the NNDSS" document. Each data user and his/her supervisor is required to agree to the following actions:

In accepting access to the NNDSS data, I agree to the following:

1. I am permitted to release final but not provisional national and regional tabulations from the NNDSS case data base (excluding AIDS/HIV, STD, and TB case data) in either narrative or tabular format.
2. I am permitted to include in presentations, slides, interviews, and publications final NNDSS data in tabular or narrative format that reports information on the following variables: disease/condition; year; event month; age grouped as <1 yr, 1-4 yrs, and by 5 year intervals thereafter; sex; race; ethnicity; and state. If the total number of cases in a state in a year for a given disease/condition is <=3, then race and ethnicity at a minimum will be suppressed for all cases in that state in that year.
3. I will not disclose or otherwise make public NNDSS county level data or data on any geographic unit smaller than state from case-specific NNDSS data files.
4. I understand that release of data not specifically permitted by this agreement is prohibited unless an exemption in writing is first obtained from the Division of Notifiable Diseases and Healthcare Information (DNDHI), PHSIPO *(proposed)*/OSELS/CDC.
5. I agree that access to NNDSS data is limited to the "Requestor" named within this RIDURA form. I agree to refer all requests for access to NNDSS data sets to the Data Operations Team.
6. I agree to use the data in the NNDSS data sets for statistical reporting and analysis only.
7. I agree to make no disclosure or use of the identity of a person discovered inadvertently and will advise the DNDHI/PHSIPO NNDSS team of any such discovery.
8. I agree not to deliberately combine NNDSS data sets or alternatively, combine an NNDSS data set with a non-NNDSS data set for the purpose of matching records to identify individuals.
9. I also agree to the following security practices:
    a) I will password protect the NNDSS data file(s) I receive. In addition, any temporary or permanent analysis files, such as those produced by SAS or other statistical package, will be password protected as well.
    b) I will treat all data at my desk site confidentially and will not give other persons access to this data.
    c) I will keep all hard copies of data runs containing small cells (i.e., counts <=3) locked in my desk when not in use, shredding them when they are no longer necessary to my analysis. In addition, I will review all printed or electronic output and delete or blackout any direct or indirect identifiers and

any small cell counts (<=3) that involve race or ethnicity.

d) I will not produce any copies of the data file(s), even for back-up purposes.
e) I am responsible for obtaining IRB review of projects when appropriate.

5. Data sharing/use: Identify data sharing and data use agreements in place following CDC guidance on data release and data sharing and following the CDC-CSTE guidance on re-release of state-provided data. If data sharing and data use agreements are not in place, describe how and when such plans will be developed and made available on the PHSIPO intranet or SharePoint http://intranet.cdc.gov/od/oads/osqt/science-policies/data.htm/.

In 1996, CDC developed a data release agreement for NNDSS, which was negotiated in collaboration with the Council of State and Territorial Epidemiologists (CSTE). This agreement pre-dates the development of the 2005 CDC-CSTE guidance on re-release of state-provided data. The NNDSS data release agreement document is posted to the NNDSS section of the DNDHI SharePoint -–the relevant document is titled "Data Release Guidelines for the National Notifiable Diseases Surveillance System". This document outlines the data file formats that CDC's NNDSS can release, alternative methods of accessing the NNDSS surveillance data (e.g., through WONDER data sets, MMWR data tables, and MMWR Summary of Notifiable Diseases), and restrictions on the use of the data, as specified in section 4 (about Data Security, above).

6. Research vs. nonresearch: Review the CDC guidance on determining whether a data collection and use is research or public health practice. State whether the project is research or not, and say why and how. If the data collection and use is public health practice (i.e. nonresearch), state what kind of practice it is, why and how.

The NNDSS data collection and use is for public health practice. The purpose of the NNDSS is to prevent or control disease and improve health, or to improve a public health program or service. The NNDSS is focused on controlling health problems in the population from which the information is gathered.

7. Research – No Human Subjects: If the data collection or analysis is research, but is not human subjects research, describe why that is the case. http://intranet.cdc.gov/od/oads/osi/hrpo/steps/1-review-type.htm/.

8. Human Subjects Research – Exempt: If the data collection or analysis is human subjects research but is exempt research, describe why that is the case.http://intranet.cdc.gov/od/oads/osi/hrpo/steps/1-review-type.htm/

9. Data storage: State where data will reside (with what organizations) and whether CDC will have the data and, if so, what organizations at CDC will have it.

The NNDSS data reside within OSELS servers and in CDC's Mid-Tier Data Center. The data are also shared with CDC programs having prevention and control responsibilities for the NNDSS conditions, through CDC's Consolidated Statistical Platform and through NNDSS Link. NNDSS Link is a SAS Intranet application which allows authorized CDC staff to perform ad-hoc queries on the data without the need to write analytical programs. Public Use Data NNDSS data are on servers controlled by CDC's WONDER Team. Staff from the following Offices and Centers use NNDSS data:

Office of Infectious Diseases (OID)
Office of the Director

National Center for Immunization and Respiratory Diseases
Immunization Services Division
Influenza Division
Division of Viral Diseases
Division of Bacterial Diseases

National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Division of HIV/AIDS Prevention
Division of Viral Hepatitis
Division of STD Prevention

Division of TB Elimination

National Center for Emerging and Zoonotic Infectious Diseases
Division of Foodborne, Waterborne and Environmental Diseases
Division of Vector-borne Diseases

Center for Global Health (CGH)
Division of Parasitic Diseases and Malaria

10. Project personnel: Briefly describe who in general at CDC will be involved in each of the following aspects of the project: project design decisions, participation in data collection or engagement with subjects or primary data, oversight or review of data collection and interactions with other individuals who collect or provide data, data transfer, data storage, data analysis, and manuscript preparation; and how they will be involved.

OSELS programmatic and technical staff are involved in making project design decisions, which includes programmatic and technical decisions about the overall operation of the system. Our internal partners (i.e., the NNDSS Governance Council, staff from the OID and CGH Offices specified above in Section 9) and our external partners and stakeholders (i.e., CSTE, the 50 U.S. states, NYC, Washington DC, and 5 territories) have input into the programmatic and technical decisions made about the NNDSS and NEDSS.

OSELS, OID, and CGH staff interact with reporting jurisdictions collecting the data in an effort to verify the accuracy of core and disease-specific data reported to CDC. In addition, OID and CGH staff interact with reporting jurisdictions on prevention and control activities and writing analytical reports and preparing surveillance indicators. OSELS, OID, and CGH staff also interact with reporting jurisdictions on manuscript preparation.

Research Determination

*1. Are any or all of the data collection activities within this project **DESIGNED** to contribute to generalizable knowledge (i.e. research)?*

__YES _X_ NO

If YES, list those activities which are research:

*2. Is this data collection activity **research or public health practice**? (Check all that apply)*

__ Research	_X_ Public Health Practice
Check one:	*Check one:*
__ Human Subjects involved	__ Emergency Response
__ Human Subjects not involved	_X_ Surveillance
__ Other (please explain)	_X_ Program Evaluation

3. If research involving human subjects, does the project qualify as exempt research?
Not applicable

__YES __ NO

If YES, give reason:

4. If the project is research involving Human Subjects, has the project or research activities been submitted to CDC Human Research Protection Office (HRPO) for review, as needed, by the CDC IRB for human subjects protection?

Not applicable

__ a. NO, project not yet submitted. Will submit HRPO forms and protocol on (date)_____

__b. NO, project is research, but there is no CDC investigator, so CDC IRB approval is not required.

__c. YES, HRPO forms and protocol submitted on (date)_____

__ d. Yes, reviewed and approved by CDC IRB, Protocol number:_____, expiration date _____

5. List any other CDC staff involved in this project; include their name, role (e.g. COTR, PI, Consultant, etc), and scientific ethics number.

Kathleen Gallagher – Director, Division of Notifiable Diseases and Healthcare Information), #14053
Enrique Nieves -- COTR and Acting Branch Chief, Information Systems and Statistical Support Branch, #5018
Jennifer Ward – Health Scientist, Data Operations Team Lead (Team responsible for producing MMWR tables and Annual Summary), Diana Onweh – Information Technology Specialist, Data Operations Team
Willie Anderson – Computer specialist, Data Operations Team
Michael Wodajo – IT specialist, Data Operations Team
Deborah Adams – Computer Specialist, Data Operations Team
Michelle Mayes – Computer Specialist, Data Operations Team
Pearl Sharp – Computer Specialist, Data Operations Team
Aaron Aranas – Health Scientist, NNDSS Team, #3185
Nelson Adekoya – Epidemiologist, NNDSS Team
Susan Katz – Communications Specialist, NNDSS Team
Anna Grigoryan – Medical epidemiologist, NNDSS Team, #373
Marion Anandappa – Computer Scientist, NNDSS Team
Jeremy Miller – Statistician, NNDSS Team, #7502
John Abellera – Health Scientist, ELC cooperative agreement

There are about 80 OID and CGH subject matter experts and technical staff who have prevention and control responsibilities for the NNDSS conditions. The CDC subject matter experts change frequently and the list of subject matter experts is updated about twice per year. The list is available upon request.

DISO technical contract staff for CDC's Common Data Store have access to the data.

6. Please list the primary project site and all collaborating site(s) and include a brief explanation of the project components at each site. If human subjects research, please include the assurance number granted to the institution by the HHS Office of Human Research Protection. http://www.hhs.gov/ohrp/assurances/index.html/.

The primary project site is the Office of Surveillance, Epidemiology and Laboratory Services; Public Health Surveillance and Informatics Program Office (proposed); Division of Notifiable Diseases and Healthcare Information. At this site, case notifications are received from reporting jurisdictions; messages from reporting jurisdictions undergo testing and are put into production; messages are parsed and translated to the relevant vocabulary standard; then, the messages are error-checked, validated (application of low-incidence verification protocol and validity checks with reporting jurisdictions), and the data are tested for compliance with data mart requirements. OSELS/PHSIPO/DNDHI also analyzes the data to create the weekly NNDSS MMWR tables, the MMWR Early Release Tables, the MMWR Summary of Notifiable Diseases, and subsets of the data are created and shared with OID and CGH partners involved in analyzing the data. This site is also responsible for NNDSS Link (an Analysis, Visualization and Reporting tool) which is a SAS intranet application for performing ad-hoc queries on the data by CDC staff (the application resides within the CDC firewall). This site also reviews the ELC cooperative agreement applications for NEDSS funding and provides funding to OID to include in the ELC cooperative agreement awards to NNDSS reporting jurisdictions which support development of integrated surveillance information systems. In addition, OSELS/PHSIPO/DNDHI is responsible for performing data quality review on the CSTE SRCA data, analysis of the SRCA data, and preparation of SRCA data to be used as "N" indicators (i.e., not reportable indicators) in NNDSS MMWR data tables. In addition, OSELS/PHSIPO/DNDHI staff work with the NEDSS Base System contract team to develop and support the NEDSS Base System as well as provide technical data integration services to reporting jurisdictions via the CDC-provided Message Subscription Service.

OID and CGH staff utilize the NNDSS data to monitor data quality, monitor disease incidence, track disease trends, identify high risk demographic groups or geographic areas, and plan prevention and control activities with state

partners. OID and CGH staff also use the data to prepare surveillance reports and manuscripts.
7. If project is research involving human subjects that is funded through grant, cooperative agreement, contract or other mechanism with another or other institutions, list amount of award that should be restricted, for each site, pending IRB approval and describe which project components will be affected.

Approval and Signatures

Approvals (signature, position and title)	**Date**	**Research Determination / Remarks**
Kathleen Gallagher Director, DNDHI and PHSIPO Lead for the project	3/26/2012	_X__ Public health practice ___ Research not involving human subjects ___ Research involving human subjects, no CDC investigators ___ Research involving human subjects, CDC investigators, exempt ___ Research involving human subjects, CDC investigators, not exempt (check if applicable) ___ Local IRB approval required ___ CDC Exemption approval or IRB approval required Comments:
Ralph Coates Division Associate Director for Science (ADS)	3/26/2012	DH Practice
Fred Shaw PHSIPO ADS	3/26/2012	PH Practice.

Ruth Ann Jajosky 3/26/2012
NNDSS
Epidemiologist