Division of Health Informatics and Surveillance/Center for Surveillance, Epidemiology, and Laboratory Services

DETERMINATION OF RESEARCH STATUS

INSTRUCTIONS

- The *Determination of Research Status Form* is to be completed by the DHIS staff member with lead responsibility for the project (or activity).
- This form is to be completed for **any project (or activity),** research or nonresearch, at DHIS for which there is any information/data collection or collection of a data set. See DHIS Guidance on Research Determination for Data Collection 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) whether the project is classified as research, non-research or both, involves human, or is exempt.
- Note that a project can be both non-research and research. In that instance, different CDC policies apply to the non-research and research components.
- Before completing this form, review the DHIS Guidance specified above and the CDC's related guidance on the OADS Information Collection Review Office Intranet. 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.

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SECTION 1: Project Information

Project is (Select one): Continuation of ongoing project	**Project Title:** National Notifiable Diseases Surveillance
NOTE: Revision refers to any substantive change made to the roles of CDC staff, the types or forms of data or type of project.)	**Project Funding Number (if known):**
	PGO Tracking Number (If external funding is part of project or activity):

Period of Performance:	**Funding Dates (if applicable):**	**Type of Project (Select one):**
Start	Start	Extramural: Contract (specify collaborating organization(s))
End	End	

Branch/Unit: OD	**Please indicate your role(s) in this project (Select all that apply):**
Lead DHIS Staff Member: Umed Ajani	☐ COTR (Project Officer)
Mailstop: E-97	☐ Principal Investigator
Telephone: 404-498-0258	☐ Co-Investigator
Scientific Ethics No:	☐ Technical Monitor
User ID: UAA0	☐ Consultant
	☒ Other
	If Other, please explain: DHIS Associate Director for Surveillance
	Staff involved in the project: See list in Section 3.

SECTION 2: Project Description

1. **Project Summary:** Briefly summarize the proposed project. Describe (1) CDC, OPHSS, and CSELS priorities that the project addresses; (2) sources of funding; (3) purpose and rationale; (4) goals and objectives ;(5) methods; and (6) expected output(s), e g., manuscript, training module, web application, IT service, etc.

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 NNDSS in collaboration with the Council of State and Territorial Epidemiologists (CSTE). NNDSS facilitates aggregating data from 57 reporting jurisdictions (including health departments in every state in the U.S., New York City, Washington D.C., 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 disease 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 health policy. 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 healthcare practices.

A key NNDSS activity is the NNDSS Modernization Initiative (NMI). NMI is an effort to enhance the system's surveillance capabilities to provide more comprehensive, timely, and higher quality data than ever before for public health decision making. Through this multi-year initiative, CDC seeks to increase the robustness of the NNDSS technological infrastructure so that it is based on interoperable, standardized data and exchange mechanisms. Key components of NMI include (1) the development of prioritized Message Mapping Guides for case notification; (2) the development of the Message Validation, Processing, and Provisioning System (MVSPS) to validate and process nationally notifiable disease (NND) data messages sent by jurisdictions and provision the data to the CDC programs; and (3) technical assistance for implementation of HL7 case notification messages in jurisdictions submitting case notifications to NNDSS. NMI is one of four initiatives to address goal three of the CDC Surveillance Strategy:improve surveillance by addressing data availability, system usability, redundancies, and incorporation of new information technologies in major systems or activities.

2. **Description of Data Collection and Analysis**: Describe what information and what types of data are collected about or from what people and by whom. Explain 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. Describe 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. Describe whom at what institutions is going to do what with what information about what people - when, where, and how?

While the list of reportable conditions varies by state, CSTE recommends that health departments report cases of selected diseases and conditions to NNDSS; these selected diseases are referred to as notifiable diseases and conditions. States and territories collect various types of data about reportable disease cases. It is mandatory that reportable disease cases be reported to state and territorial jurisdictions when identified by a health provider, hospital, or laboratory. It is voluntary that notifiable disease cases be reported to CDC by state and territorial jurisdictions for nationwide aggregation and monitoring of disease data. 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). Data for some notifiable diseases and conditions come directly to DHIS from reporting jurisdictions' health departments and some CDC programs use specific reporting systems related to a particular disease to receive other notifiable condition data. DHIS then uses the data that they receive directly from reporting jurisdictions and data from CDC programs to compile and publish in MMWR and WONDER. For example, data on influenza-associated pediatric mortality, HIV, varicella deaths, and arboviral disease are shared with CDC through differing reporting systems. Sexually transmitted disease (STD) data are reported through STD program-specific reporting systems, as well as through NNDSS directly to DHIS.

3. **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 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. Four personal identifiers are submitted to NNDSS. For all conditions, the name of the person submitting the case report to CDC and the date of birth (month, day, and year) of the person with the condition are submitted. The Malaria program accepts reporting of the name of the individual diagnosed with malaria in order to link with other information and to avoid duplication of records. Some OID and CGH programs collect medical identification numbers, e.g., hospital identification number. In addition, a unique Case ID for the specific disease or condition for a given patient and a Subject ID for that patient are submitted to NNDSS. Some combinations of submitted data elements, including date of birth, date of death (month/day/year), sex, ethnic group, race, state, county, and ZIP code could potentially be used to identify individuals.

4. **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)).

As stated above, some OID and CGH programs collect medical identification numbers, e.g., hospital identification number. In addition, a unique Case ID for the specific disease or condition for a given patient and a Subject ID for that patient are submitted to NNDSS. The subject ID 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 that are being submitted to CDC about a new case. However, the subject ID is not attached to any data items received by CDC that make the individual readily identifiable (except for those records for the Malaria program where the name of the individual diagnosed with malaria is submitted along with the subject ID).

5. **Data Security - Protecting Private Information**: Describe how security of data, both electronic and hard copy will be maintained both for internal data sets and for any data sets released to the public or shared through an agreement. 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 (http://intranet.cdc.gov/od/oads/osi/privacy/policies-laws-guidelines.htm/). If required for the project, complete a Privacy Impact Assessment (PIA) and list the PIA number obtained from OCISCO (http://intranet.cdc.gov/ociso/privacy/).

The security of private information during electronic transmission to DHIS is maintained by technologies (computers and servers) that use national public health standards for messaging systems which provide security mechanisms for jurisdictions to use when submitting data. Most case records are encrypted and submitted to DHIS electronically from already existing databases via automated electronic transfers through a secure network. Electronic data are transmitted to and processed within the electronic information system platforms. The electronic data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA). These systems are also in compliance with more recent standards to protect information: the NIST Recommended Security Controls for Federal Information Systems and Organizations, Special Publication 800-53, Revised May 1, 2010.On occasion, when electronic transmission is not possible or when public health departments prefer, weekly case counts are provided by telephone, fax, mail, and email, primarily to meet weekly deadlines for publication in the MMWR. For these non-electronic transmissions, no identifiers are included, and safeguards are implemented to ensure that information is received only by the appropriate staff at DHIS. DHIS provides nationally notifiable infectious disease data to CDC programs through secure electronic platforms. The platforms are subject to CDC's Certification and Accreditation process, in which these controls are examined and validated by the CDC's Office of the Chief Information Security Officer.

All hard copy materials submitted to CDC are stored in locked cabinets in restricted access areas in buildings that require card key access.

The nationally notifiable infectious disease data received by DHIS contain sensitive personally identifiable health information (PII), which are subject to the Privacy Act. As noted above, Office of Management and Budget (OMB) Memorandum M-07-16 defines personally identifiable information as "information that can be used to distinguish or trace an individual's identity either alone or when combined with other personal or identifying information that is linked or associated with the individual." The Privacy Act is a Federal law that protects PII held by a federal agency in a system of records from which information is retrieved by an individual's name, an identification number, or some other unique identifier assigned to the individual. The CDC Privacy Act System of Records Notice that covers NNDSS is 09-20-0136. This notice provides information to the public about the existence of the CDC research and surveillance systems covered by the notice, how data are used, how data are safeguarded, and how information may be disclosed (http://www.cdc.gov/SORNnotice/09-20-0136.htm/).

The nationally notifiable infectious diseases electronic records received by DHIS are stored at DHIS indefinitely.

DHIS implements a number of safeguards to prevent the disclosure of PII and to prevent the identification of individuals when data are published, released or shared; see the document, Data Processing and Security Procedures for Nationally Notifiable Diseases Data, for more information.

PII information will not be disclosed unless otherwise compelled by law.

6. **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 DHIS intranet or SharePoint site.

In early 2015, DHIS developed a document outlining the data processing and security procedures for nationally notifiable diseases data. That document describes the DHIS procedures for receiving, securing, provisioning, publishing, and releasing nationally notifiable infectious diseases data received at CDC by information systems administered by DHIS. Surveillance programs in NCEZID, NCHHSTP, NCIRD, and CGH have primary responsibility at CDC for surveillance of the infectious

diseases and conditions covered by each Center. Programs within the Centers receive nationally notifiable infectious disease data from DHIS and use, release and/or share their programs' data according to guidance established by CDC, their Centers and programs.

7. **Research vs. nonresearch**: Review the CDC policy, Distinguishing Public Health Research and Public Health Nonresearch, to determine whether a data collection and use is research or nonresearch. State whether the project is research or not, and state why and how. Note that surveillance, emergency response, and evaluation activities may be research or nonresearch depending on the purpose of the project. If the purpose of the project is to develop or contribute to generalizable knowledge, then the project is research but if the purpose of the project is to prevent or control disease or injury or to improve a public health program, the project is nonresearch.

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

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

N/A

9. **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/

N/A

10. **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 CSELS 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 OID (NCIRD, NCHHSTP, NCEZID), and CGH use NNDSS data.

11. **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.

CSELS 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 from NCIRD, NCHHSTP, NCEZID, and CGH and our external partners and statkeholders from CSTE, the 50 U.S. states, NYC, Washington DC, and 5 territories have input into the programmatic and technical decisions made about NNDSS.

CSELS, 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. CSELS, OID and CGH staff also interact with reporting jurisdictions on manuscript preparation.

Section 3: Research Determination

1. Is the intent (purpose) of any of the data collection, analysis, and interpretation of this project to contribute to generalizable knowledge (i.e. research)?

☐ Yes
☒ No

If YES, list those activities which are research:

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

Research	Nonresearch
Check all that apply:	Check all that apply:
☐ Human Subjects involved	☒ Surveillance
☐ Human Subjects not involved	☐ Program Evaluation
☐ Other	☐ Other
If Other, please explain:	If Other, please explain:

3. If research involving human subjects, does the project qualify as exempt research?

☐ 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?

☐ a. NO, project not yet submitted. Will submit HRPO forms and protocol on

☐ 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

☐ 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

Lesliann Helmus, NNDSS Program Manager; Data Operations Team; Surveillance Operations Team; Message and Vocabulary Team; Message Validation, Processing and Provisioning Team; NEDSS Base System Team; Common Data Store Team; Data Message Brokering Team; and PHIN Messaging System Team

6. 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

2500 Century Center, Atlanta GA

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.

Section 4: Approval Signatures

DHIS Lead for the project

Umed A. Ajani -S

Digitally signed by Umed A. Ajani -S
DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Umed A. Ajani -S, 0.9.2342.19200300.100.1.1=1001352008
Date: 2015.05.05 09:44:52 -04'00'

Supervisor of DHIS Lead for the project

Paula W. Yoon

DHIS ADS