Division of Health Informatics and Surveillance (DHIS) /
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

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)** at DHIS for which there is any information/data collection or collection of a data set.
- 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 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 CDC related guidance on the OADS Human Research Protection Office (HRPO) Intranet. The CDC guidance also defines terms used in this form.

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SECTION 1: Project Information	
Project Title: National Syndromic Surveillance Program (NSSP)	
Branch/Unit: DHIS/OD **Lead DHIS Staff Member:** Michael Coletta	**Staff involved in the project:** Alan Davis Robert Brown

SECTION 2: Project Description

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

The National Syndromic Surveillance Program (NSSP) promotes and advances development of a syndromic surveillance system for the timely exchange and analysis of syndromic data. NSSP features the BioSense Platform and a collaborative Community of Practice. The cloud-based BioSense Platform is a secure integrated electronic health information system with standardized analytic tools and processes. These tools enable state and local health department syndromic surveillance practitioners to rapidly collect, evaluate, share, and store syndromic surveillance data.

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?

The following data are collected from state and local health departments through the BioSense Platform Access and Management Center (AMC): 1) onboarding data about healthcare facilities needed for state, local, and territorial public health departments to load electronic health record (EHR) data to the BioSense Platform, 2) registration data needed to allow users access to the BioSense Platform tools and services, and 3) data sharing permissions granted by the state and local health departments so that they can share data with other state and local health departments and CDC. No data are reported or published.

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.

Registration data for system users includes first name, last name, email address, and office phone.

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)).

Individual records do not have a unique identification number or code.

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/ocio/information-systems-security/privacy-information-security/it-systems/).

The BioSense Platform Access and Management Center (AMC) sits in the secure, private Government Cloud. All information storage and processing occur in this secure cloud environment.

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.

State and local health departments that use the BioSense Platform have data use agreements with CDC. These data use agreements do not allow CDC to share the data.

7. **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.

Nonresearch. The data are not used to develop or contribute to generalizable knowledge. Collected data are only used to provide authorized state and local health department users with access to the BioSense Platform and maximize the use of the BioSense tools and services.

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/.

NA.

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/

NA.

10. **Records Management:** 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. State the plans for data disposition per the CDC Records Management policy (contact Mary K. Wilson, CDC Records Office, MASO, 770-488-4906).

All data reside on the BioSense Platform in the secure, private Government Cloud.

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.

The NSSP Team is involved in and responsible for all aspects of project design and management.

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:

Click here to enter text.

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

☐Research	■Public Health Practice
Check all that apply:	*Check all that apply:*
☐ Human Subjects involved	☐ Emergency Response
☐ Human Subjects not involved	■ Surveillance
☐ Other	☐ Program Evaluation
If Other, please explain	☐ Other
	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. NSSP 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 Primary project site is CDC in 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. NA.

SECTION 4: Approval and Signatures

DHIS Lead for the project

X Michael A. Coletta -S

Digitally signed by Michael A. Coletta -S
Date: 2019.04.08 08:05:40 -04'00'

Supervisor of DHIS Lead for the project

X Lesliann E. Helmus -S

Digitally signed by Lesliann E. Helmus -S
Date: 2019.04.08 08:10:45 -04'00'

DHIS ADS or Human Subjects Contact

X Kim D. Gadsden-knowles -S

Digitally signed by Kim D. Gadsden-knowles -S
Date: 2019.04.08 10:15:59 -04'00'