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 terns 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** BioSense
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:	SISB
Lead DHIS Staff Member:	Umed Ajani (Acting Branch Cheif)
Mailstop:	E97
Telephone:	404-498-0258
Scientific Ethics No:	
User ID:	UAA0

Please indicate your role(s) in this project (Select all that apply):

- ☐ COTR (Project Officer)
- ☐ Principal Investigator
- ☐ Co-Investigator
- ☐ Technical Monitor
- ☐ Consultant
- ☒ Other

If Other, please explain: SISB Lead (Acting)

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 BioSense Program was created by Congressional mandate as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and was launched by Centers for Disease Control and Prevention (CDC) in 2003. Funding for the BioSense Program comes directly from Congress as the BioSense Line (called the Biosurveillance Line prior to 2011) in the CDC Preparedness and Response Budget Appropriation Activity. The money is then distributed to the BioSense Program through CDC's Office of Public Health Preparedness and Response. A portion of the funds are allocated to a contract and a cooperative agreement.

BioSense provides public health officials a common electronic health information system, or platform, with standardized tools and procedures for collecting, evaluating, and analyzing health information. It increases the ability of public health jurisdictions and their healthcare partners to share healthcare-related data, cooperatively track health issues, and promote a coordinated public health response to events of public health concern including include disease outbreaks, hazardous conditions, or special public events that require enhanced public health surveillance. One goal of BioSense is to provide enhanced public health situational awareness utilizing EHR data to support public health decisions and programs at the local, state, and national level.

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 BioSense program has 4 different types of information collection: (1) collection of data needed for recruitment and onboarding of participating BioSense jurisdictions; (2) collection of data used to provide access to the BioSense application to all appropriate users in participating jurisdictions and organizations (registration), (3) collection of data needed to determine system requirements and perform a usability assessment of the BioSense application, and (4) collection of existing healthcare encounter data from electronic health records (EHRs), pharmacy data, and laboratory data.

1) Recruitment and Onboarding
CDC collaborates with ASTHO, NACCHO, CSTE, and ISDS to reach out to the public health community. The efforts focus on outreach and information, and no survey or questionnaire is performed. State, local, and territorial public health jurisdictions approach the CDC via a general email account (BioSenseProgram@cdc.gov) and request the Information Sharing and Data Use Agreement to join BioSense. Once this agreement with ASTHO is signed, the BioSense technical team begins work to onboard their data sources to the system. First and last names, email addresses, organizational affiliations, and telephone numbers of individuals responding on behalf of the public health jurisdictions are collected through BioSenseProgram@cdc.gov for contact purposes only. Further communication is conducted via email, phone, or in person meeting, in order to accommodate their needs to join BioSense. This information is maintained for as long as the jurisdiction maintains an Information Sharing and Data Use Agreement with ASTHO. No other information in identifiable form is collected for this activity. The information is stored in the form that is is received (as an email) with security provided by CDC's email system. The BioSenseProgram@cdc.gov email address is monitored by the BioSense technical team including CDC personnel.

2) Registration
Access to the BioSense application is obtained through the one-time completion of a registration form on the site that is maintained by the vendor contracted by CDC (https://biosen.se). The site is a submenu of the BioSense application. Information collected on this form contains first and last names, email addresses, organizational affiliations, security questions and passwords. This information is used only for the purpose of facilitating user approval and the setting of user data access privileges by the system. This information will be maintained for as long as the user chooses to keep an account. No other information in identifiable form is collected for this activity. Information collected for granting access to the web application will be used only internally and only to inform the granting of access to the web application and setting user permissions. Additionally, this information in aggregate form might be used to establish application use statistics, such as, the number of total users of the application or number of users of the application by state.

3) Requirements and Usability Assessment
This information collection has not yet started and the data collection and analysis procedures have not yet been finalized. When the data collection and analysis procedures are finalized, an updated research determination will be submitted.

4) EHR, pharmacy, and laboratory data

The BioSense application receives, stores, and provides the ability to analyze healthcare encounter data from EHRs, as well as pharmacy and laboratory data. All EHR, pharmacy, and laboratory data reside outside of CDC in a cloud-enabled, web-based

platform that has Authorization to Operate from CDC since it has been through the CDC's Certification & Accreditation (C&A) process. The BioSense application sits in the secure, private Government Cloud which is simply used as a storage and processing mechanism, as opposed to on-site servers at CDC. This environment provides participating health departments with easily managed on-demand access to a shared pool of configurable computing resources such as networks, servers, software, tools, storage, and services, with limited need for additional IT support. Each participant controls its data within the cloud and is provided with free secure data storage space with tools for posting, receiving, controlling and analyzing their data; an easy-to-use data display dashboard; and a shared environment where users can collaborate and advance public health surveillance practice. A public health jurisdiction may submit data it receives from non-federal hospitals (emergency departments, outpatient clinics, and inpatient facilities) in its jurisdiction to its exclusive, secure space in the cloud or it may have the non-federal hospitals in its jurisdiction submit data directly to its secure space. The health department is responsible for creating its own data use agreements with the hospitals that are sending the data, retains ownership of any data it contributes to its exclusive secure space, and is not required to share its data with any other BioSense users.

CDC maintains its own secure space to receive, store, and analyze data. CDC has data use agreements with DoD and the VA to use the clinical encounter data from DoD and VA outpatient hospitals and clinics for anomaly analysis to provide national public health situation awareness. CDC also has data use agreements with a national-level private sector clinical laboratory that voluntarily provide laboratory data from their existing data bases for the purpose of surveillance. CDC also has a contract with a private sector health IT company for data services to extract and process data from their existing pharmacy claims data base for the purpose of surveillance.

Data residing on the shared space are aggregated into pre-defined syndromes and sub-syndromes and time series are created that can be viewed on the web application dashboard by approved users. Additionally, the BioSense staff at CDC analyzes these data daily. Pharmacy and laboratory data are currently only used to provide additional data for influenza-related syndromes and sub-syndromes.

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.

1) Recruitment and Onboarding
First and last names, email addresses, organizational affiliations, and telephone numbers of individuals responding on behalf of the public health jurisdictions are collected through info@biosen.se for contact purposes only.

2) Registration
First and last names, email addresses, organizational affiliations, security questions and passwords are collected and used only for the purpose of facilitating user approval and the setting of user data access privileges by the system.

3) Requirements and Usability Assessment
This information collection has not yet started and it has not been determined which identifiable private information will be collected, if any. When this is determined, an updated research determination will be submitted.

4) EHR, Laboratory, and Pharmacy Data
Data elements collected include: ICD-9-CM diagnosis codes, CPT medical procedure codes, chief complaint text, laboratory test orders, drug class prescribed, reported patient age, birth Month/Year, date of death (month/day/year), gender, race, ethnic group, state of residence, zip code of residence, date of visit, name of facility, and facility identifier and zip code. A Patient ID# is generated from the hospital data when sent to CDC but cannot be linked to reveal the identity of the person through the system. BioSense does not allow the sharing or disclosure of personally identifiable information and adheres to the policies of CDC for retention and destruction of such information.

Data placed by state, local, and territorial public health jurisdictions on a voluntary basis into the shared space will be shared with other jurisdictions and CDC. These data are be aggregated into pre-defined syndromes and sub-syndromes and displayed as a time series that can be viewed on the web application dashboard by approved users. No individually identifiable information will be displayed on the dashboard. CDC will be able to view Patient Lists that could contain combinations of variables that can be considered individually identifiable information, but this type of data is only used internally to investigate the public health importance of an anomaly and is not shared.

VA, DoD, pharmacy, and laboratory data received by CDC are used internally to conduct anomaly analysis. These data are shared in aggregate format (containing no individually identifiable information) with the CDC Emergency Operations Center (EOC) and applicable public health jurisdictions when the BioSense Program is engaged in conducting surveillance on high profile events or public health emergencies.

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)).

1) Recruitment and Onboarding
Individual records do not have a unique identification number or code.

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

3) Requirements and Usability Assessment
This information collection has not yet started and it has not been determined which identifiable private information will be collected, if any. When this is determined, an updated research determination will be submitted.

4) EHR, Laboratory, and Pharmacy Data
Patient IDs from non-federal hospitals or Accession IDs from laboratories are unique, information free, encrypted codes. It is not possible for BioSense analysts to trace these numbers back to individually identifiable information, because the BioSense has a one-way data flow (i.e., data flows into the BioSense Program, but it cannot be traced back through the system to its source). If these codes were given back to a non-federal hospital or laboratory, their qualified staff would have the ability to de-encrypt the ID and associate BioSense patient data to the patient's medical record (the ability for this kind of follow-up does not exist for DoD or VA ID codes). Additionally, according to Data Use Agreements established with the public health jurisdictions and organizations that share data with the BioSense Program, follow-up may only include case investigation, contact tracing, exposure assessment and other activities by federal, state, or local public health agencies acting under federal, state, or local statutory authorities. Notably, no follow-up activity has ever been attempted by CDC.

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/).

1) Recruitment and Onboarding
Recruitment and onboarding data are not reported, published, or shared.

2) Registration
Data collected to grant user accounts are not reported, published or shared and reside in the BioSense 2.0 application. The BioSense application sits in the secure, private Government Cloud; passed CDC's Certification & Accreditation (C&A)process; and has Authorization to Operate from CDC. The C&A process meets Federal Information Security Management Act (FISMA) requirements and incorporates the use of National Institute of Standards and Technology (NIST) Special Publications.

The BioSense application has a moderate system security rating according to FIPS 199 categorization and has the following controls in place:
• Administrative: role based access controls (permissions granted to access data based on users', including FTEs, contractors and fellows, role/job duties);
• Technical Controls: user ID, passwords, firewall, encryption, intrusion detection system, CAC (ID Badges) , Anti-virus; and
• Physical Controls: guards, ID badges, key cards, cipher locks, and closed circuit TV.

For the security of data in transit, all external/internet connections to BioSense 2.0 must be secured by a secure sockets layer (SSL) certificate that is provided to authenticated users. SSL creates an encrypted connection between the authenticated users and the BioSense data store. In addition to the SSL connection, Internet Protocol Security (IPsec) is used to encrypt the data being transmitted through the connection.

3) Requirements and Usability Assessment
This information collection has not yet started and it has not been determined how data security, privacy, and confidentiality will be maintained. When this is determined, an updated research determination will be submitted.

4) EHR, Laboratory, and Pharmacy Data
These data are stored in the BioSense application which sits in the secure, private Government Cloud; passed CDC's Certification & Accreditation (C&A)process; and has Authorization to Operate from CDC. The C&A process meets Federal Information Security Management Act (FISMA) requirements and incorporates the use of National Institute of Standards and Technology (NIST) Special Publications.

The BioSense application has a moderate system security rating according to FIPS 199 categorization and has the following controls in place:
• Administrative: role based access controls (permissions granted to access data based on users', including FTEs, contractors and fellows, role/job duties)
• Technical Controls: user ID, passwords, firewall, encryption, intrusion detection system, CAC (ID Badges), Anti-virus, PIV compliant

- Physical Controls: guards, ID badges, key cards, cipher locks, closed circuit TV

For the security of data in transit, all external/internet connections to BioSense 2.0 must be secured by a secure sockets layer (SSL) certificate that is provided to authenticated users. SSL creates an encrypted connection between the authenticated users and the BioSense data store. In addition to the SSL connection, Internet Protocol Security (IPsec) is used to encrypt the data being transmitted through the connection.

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.

1) Recruitment and Onboarding
Agreements exist between ASTHO and each of the jurisdictions using the BioSense application.

2) Registration
All registered jurisdictions sign agreements with ASTHO during the recruitment and onboarding phase as stated above.

3) Requirements and Usability Assessment
This information collection has not yet started. No data use or sharing agreements will be used for this information collection.

4) EHR, Laboratory, and Pharmacy Data
Agreements exist between CDC and a) DoD (for EHR Data), b) VA (for EHR data), c) a national-level private sector clinical laboratory (for laboratory data), and d) a private sector health IT company (for pharmacy data). Agreements also exist between jurisdictions using the BioSense application and individual providers.

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.

1) Recruitment and Onboarding
This activity is nonresearch as the data are not used to develop or contribute to generalizable knowledge to improve public health practice but only used for outreach and information about potential users of the BioSense application.

2) Registration
This activity is nonresearch as the data are not used to develop or contribute to generalizable knowledge to improve public health practice but only used to facilitate user approval and to set user data access privileges by the BioSense application.

3) Requirements and Usability Assessment
This information collection has not yet started. It will be nonresearch as the data will not be used to develop or contribute to generalizable knowledge to improve public health practice but only used to determine the requirements for and assess the usability of the BioSense application.

4) EHR, Laboratory, and Pharmacy Data
This activity is nonresearch as the data are not used to develop or contribute to generalizable knowledge to improve public health practice but the purpose of the activity is to identify and control health problems and intended benefits of the project are primarily or exclusively for the participating jurisdiction's community. The activity is considered nonresearch surveillance as it involves the regular, ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population. Further, the activity is also considered nonresearch emergency response since it is undertaken to identify and characterize immediate health problems and the knowledge gained will directly benefit the participating jurisdiction's community.

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. **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.

1) Recruitment and Onboarding
Recruitment and onboarding data reside in the CDC email system. The BioSense technical team including CDC personnel have access to the data.

2) Registration
All registration data in the BioSense application resides in a cloud-enabled, web-based platform that sits in the secure, private Government Cloud and is in compliance with the Federal Information Security Management Act.

3) Requirements and Usability Assessment
This data collection has not yet started and it is not known where these data will reside. An updated research determination will be submitted when it is known where these data will reside.

4) EHR, Laboratory, and Pharmacy Data
All data submitted by users in BioSense reside in a cloud-enabled, web-based platform that sits in the secure, private Government Cloud and is in compliance with the Federal Information Security Management Act. The public health jurisdictions retain ownership of any data they contributes to their exclusive secure space within BioSense.

The BioSense 2.0 cloud also provides the CDC's BioSense Program its own exclusive secure space to receive, store, and analyze data. CDC has agreements with VA, DoD, two national-level private sector clinical laboratories, and a private sector health information exchange firm to provide healthcare data to CDC's secure space for the purpose of national public health situation awareness and syndromic surveillance.

In addition to providing a secure, exclusive space for use by CDC and secure, exclusive spaces for use by each participating state, local, and territorial public health jurisdiction, BioSense 2.0 provides a second secure space in the cloud for public health jurisdictions to share aggregate data with other participating jurisdictions and CDC. Whenever possible, the BioSense Program plans to share aggregate-level pharmacy and laboratory data with public health jurisdictions. To participate in the shared space, jurisdiction administrators must simply select from drop-down lists to choose their sharing permissions on the BioSense application, and they will have the right at any time to revise the level of sharing permissions regarding the data in their secure space. As part of access to the shared space, public health jurisdictions will be required to grant CDC access to, at minimum, aggregate level data (city, county, or state) from their jurisdiction that has been placed in the shared space. They must also agree that CDC may review data contributed to the shared space for public health practice and surveillance purposes.

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.

1) Recruitment and Onboarding
The BioSense technical team (which may include contract or CDC personnel from DHIS) is involved in this data collection.

2) Registration
The BioSense technical team (which may include contract or CDC personnel from DHIS) is involved in this data collection.

3) Requirements and Usability Assessment
This data collection has not yet started. It will be led by DHIS/ISB with support from an organization with a contract with CDC.

4) EHR, Laboratory, and Pharmacy Data
A team of contract and CDC personnel from DHIS are involved in this data collection. Team members are allowed access to raw VA, DoD, laboratory, and pharmacy data and aggregated non-federal hospital data from public health jurisdictions to conduct public health projects. Any person or organization who collaborates with the team on a project is allowed access to only aggregate data that is agreed upon when the project proposal is written. Sometimes projects are conducted internally within the team; however, they are usually collaborations with state or local health departments, academia, or other areas within CDC.

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:
	Emergency Response

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

Michael Coletta (Program Manager), Umed Ajani (SISB Acting Branch Chief), Achintya Dey, Sanjaya Dhakal, Peter Hicks, Maurice Emmanuel, Matt Miller, Hong Zhou, Alan Davis

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.

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: 2014.08.08 07:52:58 -04'00'

Supervisor of DHIS Lead for the project

Paula W Yoon 8/11/14

DHIS ADS

08/11/2014