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 PHSIPO 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* 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 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 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:
June 22, 2012

Project is (choose one):

_ **New**

X_ **Revision of an earlier project** (BioSense Program)

_ **Continuance of ongoing project**

(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 Title:
BioSense 2.0

Project period:

Start: 2011

End: Ongoing

***Funding Dates** (if applicable): NA*

Start:

End:

Lead PHSIPO Staff Member:

Name: Kathleen Gallagher

User ID: kxg7

Scientific Ethics No: 14043

Branch/Unit: Director, DNDHI

Telephone: 404-498-6631

Mailstop: E 91

Please indicate your role(s) in this project:

__ **COTR (Project Officer)**

_X_ **Principal Investigator**

__ **Co-Investigator**

_X_ **Technical Monitor**

__ **Consultant**

__ **Other (please explain)**

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?

BioSense Epidemiology and Surveillance Team Activities Summary

The BioSense Program was mandated by Congress in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Program 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.

BioSense is a timely national electronic health surveillance system that receives and processes healthcare encounter data that has been stripped of individual identifiers [except patient birthdate (month/year), zip code, sex, ethnicity, race, and death date] and sent in electronic format from participating state, local, and territorial public health jurisdictions' non-federal hospital emergency departments and inpatient facilities in addition to all United States Department of Defense (DoD) and Veterans Affairs (VA) outpatient hospitals and clinics nationwide. The BioSense Program also receives pharmacy data from a private sector health information exchange firm and laboratory data from two national-level private sector clinical laboratories.

All data submitted by users in BioSense 2.0 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 platform provides public health jurisdiction users with an exclusive secure space as well as tools for posting, receiving, controlling, analyzing, and sharing their public health surveillance information with other public health jurisdictions, CDC, or other public health partners. The public health jurisdiction retains ownership of any data it contributes to its exclusive secure space within BioSense 2.0. 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 (laboratory data), and a private sector health information exchange firm (pharmacy data) to provide healthcare encounter data to CDC's secure space for the purpose of national public health situation awareness and syndromic surveillance. A small portion of the data shared with CDC also resides with the CDC's Office of Surveillance, Epidemiology and Laboratory Services' BioSense Program on encrypted hard drive for the purpose of evaluation and analysis.

Initially intended to serve as a tool for early detection and rapid assessment of potential bioterrorism-related illness, the BioSense Program has since expanded its role to detecting changes over time in predefined syndromes and sub-syndromes of public health importance (ex., injury, chronic disease, and influenza) and providing timely, national public health situation awareness throughout the course of public health emergencies (ex., 2009 H1N1).

The BioSense Epidemiology and Surveillance Team (BEST) conducts the following ongoing activities:

1. Syndrome Specific Event Detection (Routine Surveillance)
2. Spatial Cluster Detection for Chosen Syndromes and Sub-Syndromes
3. Asthma Surveillance
4. Enhanced Surveillance
5. Situation Awareness
6. Laboratory Test Data Analysis
7. Pharmacy Sales Data Analysis
8. Enhanced Methods Development Initiatives

1. Syndrome Specific Event Detection (SSED) (Routine Surveillance)

SSED is the Daily Anomaly Detection conducted Monday through Friday. This activity employs statistical algorithms to analyze the large amount of healthcare encounter data received from DoD and VA outpatient clinics and public health jurisdictions' non-federal hospital EDs to identify statistically significant increases in patient visits (i.e., anomalies). The algorithms are applied to separately categorized time series of patient visit records using categories chosen to capture 15 predefined syndromes and 78 predefined sub-syndromes of public health interest. This timely surveillance provides an

opportunity for early detection of anomalies in predefined syndromes and sub-syndromes of public health interest that could indicate increases in patient visits resulting from outbreaks caused by bioterrorism agents and other infectious diseases as well as increases in patient visits for injuries and chronic disease complaints resulting from climate and other environmental factors.

An important part of the work of the BEST is the daily identification, review, prioritization, characterization, and when necessary reporting of these anomalies. The analysts evaluate the six-month time series for each anomaly and occasionally, to further characterize an anomaly, accesses the Patient List (the de-identified list of patient visits and associated descriptive variables that compose the anomaly, for example diagnosis or chief complaint, patient state, patient zip code, patient age, and patient gender). If an anomaly is suspected to result from an event of public health importance or is associated with a documented real-world event, the analyst assigned to the territory in question writes an Anomaly Characterization Report that is reviewed by the entire team. The team will come to a final consensus regarding an anomaly's public health importance and determine whether or not to escalate the report to specific BioSense stakeholders which may include the following: CDC Emergency Operations Center, other CDC Centers, DoD, or VA.

This surveillance activity is conducted solely to provide national public health situation awareness that can be accessed by approved users through a cloud-enabled, web-based application or be fed back to public health professionals at CDC, DoD, or, VA by the BEST.

2. Spatial Cluster Detection for Chosen Syndromes and Sub-Syndromes

Monday through Friday, BioSense employs SaTScan software using the purely spatial Poisson probability model on a facility basis to evaluate clinical encounter data received from non-federal hospital EDs, DoD, or VA. This software outputs any statistically significant spatial clusters of visits (anomalies) from reporting facilities for 3 syndromes and 9 sub-syndromes. Any such anomaly is further evaluated using BioSense's statistical temporal algorithms to produce a six-month time series.

The analysts evaluate the six-month time series for each anomaly and occasionally access the Patient List to further characterize a cluster anomaly. If a cluster anomaly is suspected to be an event of public health importance or is associated with a documented real-world event, the analyst assigned to the territory in question writes a SaTScan Cluster Characterization Report that is reviewed by the entire team. The team will come to a final consensus regarding the anomaly's public health importance and determine whether or not to escalate the report to BioSense stakeholders.

This surveillance activity is conducted solely to provide national public health situation awareness that can be fed back to public health professionals at CDC, DoD, or VA.

3. Asthma Surveillance

Asthma Surveillance is conducted in collaboration with the Alabama Department of Public Health to supplement surveillance for the Alabama Asthma Program. VA and DoD outpatient, final diagnosis data is used to create quarterly reports for Alabama that summarize healthcare visit counts for the Asthma Sub-Syndrome.

This surveillance activity is conducted solely to provide an additional source of public health situation awareness regarding asthma that can be used by the Alabama Department of Public Health's Asthma Program.

4. Enhanced Surveillance (ES)

ES in BioSense is defined as targeted surveillance of specific events that pose an inherent risk to public health. Such events might include the possible threat of a terrorist act, large numbers of people in attendance, the presence of high ranking dignitaries, or historical or political implications (examples: State of the Union Address, Super Bowl, and North American Leaders Summit). Each year, the BEST establishes a calendar of known events for targeted surveillance, and may add or delete events as necessary.

This activity employs statistical algorithms to analyze the clinical encounter data received from ED, DoD, and VA facilities in the area of the targeted event to identify statistically significant increases in patient visits (i.e., anomalies) for a predetermined time before, during, and after the targeted event. The algorithms are applied to separately categorized time series of patient visit records using categories chosen to capture 33 predefined syndromes and sub-syndromes of public health interest. Additional syndromes or sub-syndromes can be added if necessary.

To conduct these activities, the analysts must evaluate the six-month time series and occasionally access the Patient List to further characterize any anomalies. During the time of ES for a targeted event, special summary reports are written and distributed on a regular basis to the appropriate parties in the CDC Emergency Operations Center and the state and local jurisdictions where the event is located.

This surveillance activity is conducted solely to provide an all-hazards public health surveillance system that can offer timely surveillance during large-scale events of national significance.

5. Situation Awareness (SA)
SA is surveillance on unplanned emergency events (e.g., disease outbreaks and severe weather events including but not limited to hurricanes, flooding, earthquakes, heat, and cold) to empower CDC and state or local partners with the knowledge to make better strategic decisions and conduct timely responses.

This activity employs statistical algorithms to analyze the clinical encounter data received from ED, DoD, and VA facilities in the area of an unplanned emergency event to identify statistically significant anomalies during and after the event. The algorithms are applied to separately categorized time series of patient visit records using categories chosen to capture the syndromes and sub-syndromes of public health interest that are specifically chosen for each event.

To conduct these activities, the analysts must evaluate the six-month time series and occasionally access the Patient List to further characterize any anomalies. During the time of SA for an unplanned emergency event, special summary reports are written and distributed on a regular basis to the appropriate parties in the CDC Emergency Operations Center and the state and local jurisdictions where the event is located.

This surveillance activity is conducted solely to provide an all-hazards public health surveillance system that can offer timely surveillance during unplanned emergency events.

6. Laboratory Test Data Analysis
Laboratory test data analysis is conducted for ILI using laboratory data received from two national-level private sector clinical laboratories. Information on influenza related laboratory test orders and results have been extracted into SAS analytic data files. Those SAS analytic files have been summarized and the aggregate results have been shared with CDC collaborators (NCIRD). These data have been used to monitor influenza related activities and outbreaks. In the future, the BEST plans to broaden the analysis beyond just ILI and make the laboratory data more widely available on the BioSense 2.0 web-based application.

Laboratory test data analysis is conducted solely to provide an additional source of public health situation awareness regarding Influenza that can be used by the subject matter experts in CDC who are charged with monitoring influenza.

7. Pharmacy Sales Data Analysis
Pharmacy sales data analysis is currently limited to the topic of influenza related medications. Influenza specific anti-viral sales data are analyzed and trending is compared to overall anti-infective sales by state and MMWR week. These data are shared with the Influenza Division and compared to both BioSense (non-federal hospital EDs) Revised Flu Syndrome visit definition and ILInet. A similar service is provided to the Maryland Department of Public Health. In the future, the BEST plans to broaden the analysis beyond just influenza.

Pharmacy sales data analysis is conducted solely to provide an additional source of public health situation awareness regarding influenza that can be used by the subject matter experts in CDC who are charged with monitoring influenza and the Maryland Department of Public Health.

8. Enhanced Methods Development Initiatives
Enhanced methods development initiatives are sometimes conducted internally within the BEST, but they are usually collaborations with state or local health departments, academia, or other areas of CDC. These initiatives serve many purposes that include but are not limited to the following: analyzing data to determine the best ways to use BioSense data for early event detection, situation awareness, and other public health purposes; developing methods for BioSense to identify possible events or concerns that warrant further follow-up investigation, or immediate public health intervention actions; and querying the source data repository for additional data or information as may be necessary to carry out critical public health functions. Examples include, creating new syndromes and sub-syndromes, conducting data analysis to further refine BioSense algorithms and anomaly investigation, assisting a state with evaluating the burden of non-traumatic oral health visits to their EDs on their Medicaid system, and providing aggregate data to other teams at CDC so they can evaluate the potential for BioSense data to be used for surveillance of their subject of interest.

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.

BioSense collects the following data elements that could apply to the concern of the identification of an individual: Date of birth (month/year), date of death (month/day/year), sex, ethnic group, race, state, zip code, date of visit, and name of facility visited.

In BioSense we receive geographic subdivisions smaller than state (zip code) and elements of dates other than year (birth dates by month/year). We do not receive any other Individual Identifiers based on Box 2 of the April 11, 2003 MMWR Supplement, HIPAA Privacy Rule and Public Health.

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)).

Patient IDs from non-federal hospitals or Accession IDs from laboratories are unique, information free, encrypted codes. It is not possible for members of the BioSense Epidemiology and Surveillance Team (CDC staff and contractors who monitor daily anomaly alerts and conduct public health practice with the data) to trace these numbers back to individually identifiable information, because 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.

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.

See Attachment 1

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/.

The Association of State and Territorial Health Officials (ASTHO) has been funded through a cooperative agreement with CDC's Division of Notifiable Disease and Healthcare Information (DNDHI) within the Public Health Surveillance and Informatics Program Office (PHSIPO) of the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) to facilitate the governance of BioSense 2.0, and through a contract with a vendor, ASTHO will offer access and use of BioSense 2.0 on a voluntary basis to state, local, and territorial health jurisdictions.

ASTHO will sign Information Sharing and Data Use Agreements with local, state, and territorial health departments that permit the use of the BioSense 2.0 cloud environment. However, when a local or state health department arranges to receive data from non-federal hospitals within its jurisdiction or have those hospitals submit data directly to the health department's space in the BioSense 2.0 cloud, the health department is responsible for creating its own data use agreements with the hospitals that are sending the data.

The CDC BioSense Program has individual Data Use Agreements with the entities that provide healthcare encounter data directly to its secure space for the purpose of national public health situation awareness and syndromic surveillance. These entities include VA, DoD, two national-level private sector clinical laboratories, and a private sector health information exchange firm.

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.

None of these activities is research. Most are public health surveillance. Some are emergency response. Some are evaluation and development of the BioSense system. None is intended to provide generalizable knowledge.

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/.

NA

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/

NA

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.

All data submitted by users in BioSense 2.0 will 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 platform will provide users with an exclusive secure space as well as tools for posting, receiving, controlling, analyzing, and sharing their public health surveillance information with other public health jurisdictions, CDC, or other public health partners. The public health jurisdiction will retain ownership of any data it contributes to its exclusive secure space within BioSense 2.0.

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 encounter 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 2.0 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.

Lastly, a small portion of the data shared with CDC also resides with the CDC's Office of Surveillance, Epidemiology and Laboratory Services' BioSense Program on encrypted hard drives.

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.

The BioSense Epidemiology and Surveillance Team consists of FTEs, general contractors, and an IPA contractor. Members of the Team 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 BioSense Epidemiology and Surveillance Team; however, they are usually collaborations with state or local health departments, academia, or other areas within CDC.

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	_X_ 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?

__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 (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.
http://www.nchhstp.cdc.gov/od/ADS/ScientificProjects/Scientific-Ethics-Training.shtml
http://intranet.cdc.gov/osels/lspppo/dur/Training/

Last Name	First Name	Scientific Ethics Number
Akaka	Loren (Kaipo)	613
Burkom	Howard	11372
Burrer	Sherry	7242
Dey	Achintya	15705
Dhakal	Sanjaya	526293
Hicks	Peter	12209
Maurice	Emmanuel	9727
McMurray	Paul	4249
Miller	Matt	17260
Park	Soyoun	4749

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/.

Primary Project Site
- CDC Century Center Campus, Atlanta, Georgia
  - Please see "1. Project summary" section activities 1–8

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. .

Approval and Signatures

Approvals (signature, position and title)	Date	Research Determination / Remarks
Kathleen Gallagher PHSIPO Lead for the project	6/26/2012	Comments:
Supervisor of PHSIPO Lead for the project		
Division Associate Director for Science (ADS)	06/26/2012	
PHSIPO ADS	6/27/12	non-research.

Attachment 1

CONTROLLED

UNCLASSIFIED

INFORMATION

BioSense 2.0 Data Security

The BioSense Program receives electronic healthcare encounter data from DoD and VA facilities, participating public health jurisdictions' non-federal hospitals, two national-level private sector clinical laboratories, and a private sector health information exchange firm. These data may include the following variables: ICD-9-CM diagnosis codes, CPT medical procedure codes, chief complaint text, laboratory test orders, drug class prescribed, reported patient age, birth Month/Year, gender, race, ethnic group, occupation, state of residence, zip code of residence, and facility identifier and zip code. Additionally, 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 Program 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.

The BioSense 2.0 application sits in the secure, private Government Cloud and has Authorization to Operate from CDC, because it has been through the CDC's Certification & Accreditation process, which meets Federal Information Security Management Act (FISMA) requirements and incorporates the use of National Institute of Standards and Technology (NIST) Special Publications. Some of the security guidance specifically incorporated can be found in:

- NIST SP 800-18: Guide for Developing Security Plans for Federal Information Systems
- NIST SP 800-37: Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach
- NIST SP 800-53: Recommended Security Controls for Federal Information Systems and Organizations
- http://csrc.nist.gov/publications/PubsSPs.html

BioSense 2.0 has a moderate system security rating according to FIPS 199 categorization. BioSense 2.0 has appropriate controls in place to meet the requirements for a system with a moderate security rating according to NIST SP 800-53 (rev.3). The following controls are in place to protect information in the system regarding the secure, private Government Cloud and CDC's Office of Surveillance, Epidemiology and Laboratory Services' BioSense Program:

- 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.

Source: BioSense O&M Baseline System Information Document (BSI) and BioSense O&M Privacy Impact Assessment (PIA)

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