HEALTHCARE-ASSOCIATED AND RESISTANT PATHOGENS SURVEILLANCE AND PREVENTION PROJECT

Data Use and Confidentiality Agreement
Between
The Michigan Department of Community Health
And

_____ Hospital

The Michigan Department of Community Health ("MDCH" or "Data Recipient") and _____ ("Health System") enter into this Data Use and Confidentiality Agreement (the "Agreement") effective _____/_____/_____ ("Effective Date"). The Health System and the MDCH shall be referred to individually as a "Party," or collectively as the "Parties."

RECITALS

A. The MDCH is a Public Health Authority, as defined by the HIPAA Privacy Rule, that is authorized by the Public Health Code to collect or receive protected health information for the purpose of preventing or controlling disease, injury, or disability, and conduct public health surveillance, public health investigations, and public health interventions. MCL 333.2221, 45 CFR 164.512(b)(1)(i).

B. The Health System is a health care provider that participates in the National Healthcare Safety Network (NHSN) and has been invited by the MDCH to participate in the Michigan Healthcare-Associated and Resistant Pathogens Surveillance and Prevention Project (the "Project").

C. As a Public Health Authority, the MDCH has developed the Michigan Healthcare-Associated and Resistant Pathogens Surveillance and Prevention Project, using modules within the National Healthcare Safety Network (the "Data System"), and following guidance within the *HHS Action Plan to Prevent Healthcare-Associated Infections*.

D. NHSN fulfills the data system components of the cooperative agreement administered by the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) pursuant to the American Recovery and Reinvestment Act (ARRA) of 2009, Public Law 111-5.

E. Pursuant to such cooperative agreements, CDC and HHS have provided funding to the State of Michigan to enhance surveillance and prevention of health-associated infections to further the objectives of improving patient safety and reducing healthcare costs.

F. The parties shall abide by all applicable federal and state laws, rules and regulations, including without limitation all patient confidentiality and medical records requirements, and any applicable Institutional Review Board ("IRB") requirements.

I. PURPOSE

A. This Agreement sets forth the terms and conditions pursuant to which the Data Recipient will access and use Health System Data covered by this Agreement.

B. Data Recipient represents and warrants that Health System Data will be used solely for the purposes as stated below:

1. To permit valid estimation of the magnitude of adverse events (i.e. healthcare-associated infections) among Michigan patients;

2. To permit recognition of trends in adverse event rates, antimicrobial use and resistance, and pathogens associated with healthcare-associated infections;

3. To utilize this data to prepare aggregate reports to show the occurrence of these infections and organisms in the state;

4. To provide facilities with risk-adjusted adverse event data that can be used for comparison purposes;

5. To assist facilities in developing surveillance and analysis methods that permit timely recognition of patient problems and prompt intervention with appropriate measures;

6. To use aggregate, de-identified data to educate healthcare providers and the general public on the importance of using antibiotics appropriately.

II. DEFINITIONS

A. "*HIPAA Privacy Rule"* means regulations adopted by the United States Department of Health and Human Services pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, which establishes national

standards for the use and disclosure of health information. The HIPAA Privacy Rule is set out at 45 CFR Parts 160 and 164.

B. *"Health System Data"* is (1) protected health information that has all direct identifiers removed so that it meets the criteria of a "limited data set," as set out in the HIPAA Privacy Rule, 45 CFR 164.514(e)(2), and (2) includes the NHSN data element(s) that the Health System elects to make available to the Data Recipient as part of the Project.

C. "*Confidential Information"* shall consist of (1) all the Health System Data made available to MDCH under this Agreement, as necessary for the performance of the Project, and (2) all other written or orally disclosed information or electronically exchanged information of any Party provided to any other Party, directly or indirectly, pursuant to the Project which is clearly designated in writing as "Confidential", or in the case of oral disclosure, is identified in writing as "Confidential" within ten days, with the exception of any information that:

a) was in the recipient Party's lawful possession prior to disclosure by the owner Party; or
b) is lawfully received by a Party without restriction regarding use or confidentiality from an independent third party who, to the recipient Party's best knowledge, is in lawful possession of said information; or
c) is now or hereafter becomes generally available to the public through no action, inaction, or fault of any Party hereto.

D. "*Use*" means the sharing, employment, application, utilization, examination or analysis of individually identifiable health information (as defined by the HIPAA Privacy Rule) within the entity that maintains such information.

E. "*Disclosure*" means the releases, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

F. *"Limited Data Set"* means protected health information that does not contain any direct individual identifiers, as defined by the HIPAA Privacy Rule.

III. ASSURANCES OF CONFIDENTIALITY

A. The Health System Data provided to Data Recipient through the NHSN pursuant to this Agreement will constitute a Limited Data Set, and use or disclosure of this data will be in strict conformance with the provisions of this Agreement. Any other Confidential Information to be disclosed pursuant to the Project will be held in strict confidence, as provided by this Agreement.

B. The Confidential Information and Health System Data will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, and/or the institution in accordance with this Agreement and Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

C. No party shall release any Confidential Information of any other party without the express written consent of the other Parties, or without notice to the other Parties, where release is required by law or by court order.

D. Each Party shall strictly limit access to the relevant portions of the Confidential Information of the other Parties to such of its employees as delineated herein who have a need to know such portions of the Confidential Information regarding the Project.

E. The Health System, as a "covered entity" under HIPAA Privacy Rule, is authorized to release a Limited Data Set to the MDCH, without individual patients' authorization, for research or public health purposes, subject to assurances of confidentiality, as provided by the Privacy Rule. 45 CFR 164.514(e)(3)(i), 164.514(e)(4), 164.512(b)(1)(i).

F. Consistent with this Agreement, the MDCH shall exercise its discretion to exempt from public disclosure the Health System Data, which is provided voluntarily by the Health System pursuant to this Agreement, as permitted under Section 13(1) under the Michigan Freedom of Information Act (FOIA) MCL 15.231 et seq.

G. Pursuant to Part 26 of the Public Health Code, MCL 333.2601 et seq., this project has been designated by MDCH's Chief Medical Executive as a designated medical research project, and thus, information voluntarily provided by the Health System pursuant to this Agreement is confidential pursuant to MCL 333.2631 and 333.2632.

IV. PENALTIES FOR NON-COMPLIANCE

A. The unauthorized use or disclosure of Confidential Information may be punishable by imprisonment or fine, or both, under Michigan and federal laws specific to the type of information released.

V. OBLIGATIONS OF HEALTH SYSTEM

A. The Health System agrees to voluntarily participate in the MDCH-SHARP Unit User Group of the National Healthcare Safety Network (NHSN) Surveillance System. By participating, the Health System agrees to confer rights to the Data Recipient to view the Limited Data Set and utilize de-identified data from one or more of the following modules from NHSN:

1. Patient Safety Component
   a) Multi-drug-Resistant Organisms/*Clostridium difficile*-associated Disease (MDRO/CDAD) Module
      i. MDRO Infection Surveillance
      ii. Laboratory Identified Event
      iii. Prevention Process Measures
         a. Hand Hygiene
         b. Gown & Glove Use
         c. Active Surveillance Testing
         d. Active Surveillance Testing Outcome Measures
      iv. CDI Measures
         a. CDAD Infection Event
         b. Laboratory-Identified CDAD Event

   b) Device-Associated Module
      i. CLABSI – Central line-associated bloodstream infection
      ii. CLIP – Central line insertion practices
      iii. VAP – Ventilator-associated pneumonia
      iv. CAUTI – Catheter-associated urinary tract infection

   c) Procedure-Associated Module
      i. SSI—Surgical site infection
      ii. PPP – post-procedure pneumonia

   d) Medication-Associated Module
      i. AUR – Antimicrobial use and resistance options

   e) High Risk Inpatient Influenza Vaccination (HRIIV) Module

2. Healthcare Personnel Safety Component
   a) Blood/Body Fluids Exposure Module
   b) Influenza Vaccination and Exposure Management

B. The Health System Data collected and submitted to NHSN and accessed by the MDCH will not contain the patient name or any other direct individual identifier (as defined by the HIPAA Privacy Rule). The data will include only

a patient ID number that is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, as allowed by 45 CFR 164.514(c).

C. The Health System Data may contain the following **indirect** patient identifiers:

1. Patient symptoms, lab or diagnostic testing results, hospital location;
2. Gender, age, ethnicity, type of infection;
3. Dates directly related to the patient, such as birth date, date of death, admission date, discharge date, visit date, diagnosis date, etc.

D. The Health System will consider offers of support from MDCH to assist with data validation activities.

VI. OBLIGATIONS AND ACTIVITIES OF DATA RECIPIENT (MDCH)

With regarding to data provided under this agreement, the MDCH agrees to:

A. Use and disclose Health System Data only for public health purposes as stated herein, except as otherwise required by applicable state or federal law;

B. Limit access to Health System Data only to the following:

1. The Michigan Department of Community Health (MDCH), Division of Communicable Diseases, Surveillance of Healthcare-Associated and Resistant Pathogens (SHARP) Unit;
2. The Michigan Department of Community Health (MDCH), Bureau of Laboratories, Infectious Disease Division, Microbiology Section.

C. Use appropriate safeguards to prevent use or disclosure of Health System Data other than as provided for by this Agreement;

D. Provide written notice to Health System of any use or disclosure of Health System Data not provided for by this Agreement;

E. Ensure that any agent(s) or subcontractor(s) who accesses Health System Data agrees to the same restrictions and conditions that apply to the Data Recipient;

F. Make reasonable efforts to limit the use or disclosure of Health System Data to the minimum amount necessary to accomplish the intended purpose of the use or disclosure of the Data;

G. Make no attempt to contact or identify any individuals or entities whose health or provider information may be represented in Health System Data;

H. Return or destroy all originals and copies of any potentially identifiable information upon completion of project, or upon request, unless otherwise approved in this Agreement;

I. Not use the data provided to engage in any method, act, or practice which constitutes a commercial solicitation or advertisement of goods or services to consumers; and

J. Not use the data provided as a basis for legal, administrative or other actions which may affect particular individuals or establishments as a result of their specific identification in this project.

VII. PROVISION AND MANAGEMENT OF HEALTH SYSTEM DATA

A. The Health System shall provide Health System Data access to the MDCH for use in connection with surveillance of healthcare-associated infections. The Health System shall transmit the data electronically through the National Healthcare Safety Network (NHSN).

B. Some of the Health System Data may be extracted and stored in a computer maintained by the MDCH, and/or the Michigan Department of Information Technology (DIT), serving as the MDCH's agent.

C. The MDCH and its agent, the Michigan Department of Information Technology (DIT), shall use all reasonable administrative, physical and technical safeguards (based on industry best practices) to secure, protect and manage the Health System Data in compliance with the terms of this Agreement.

D. Throughout the term of this Agreement, the MDCH shall make the Health System Data and all aggregated data provided by other participants in the Project, including data summaries and analysis produced by the Project, available to designated personnel of the MDCH and local health departments, as required in order to carry out the public health surveillance functions of the Project.

E. Participants in the Project will receive regular updates on the status of the Surveillance and Prevention Project. Further, an Advisory Group will determine the most appropriate presentation of data for participants.

F. All the Health System Data shall at all time remain the property of the Health System and shall be returned to the Health System in its original form, and any aggregated or derivative form, immediately upon request.

VIII. GOVERNANCE

A. This Project will be directed by a board comprised of representatives of the state of Michigan, medical professionals, the state hospital association, hospital quality assurance and safety agencies, and consumer representatives (the "HAI Prevention Advisory Group").

B. The Advisory Group shall be responsible for oversight of the Project.

IX. INSTITUTIONAL REVIEW BOARD (IRB) APPROVALS

As relevant and appropriate, the Parties shall abide by all applicable IRB requirements and/or requirements of the Health System Information Security Committee ("ISC"). Where IRB and ISC oversight is required, the Parties shall provide such documentation of compliance to each other.

X. MISCELLANEOUS

A. The terms and conditions of this Agreement supersede all previous oral or written representations, understandings or agreements not incorporated into this Agreement.

B. This Agreement shall not be amended or modified, unless approved in writing by the Parties.

C. If any provision of this Agreement shall be held illegal or unenforceable by a court having jurisdiction, such provision shall be modified to the extent necessary to render it enforceable by a court having jurisdiction. Such provision shall be modified to the extent necessary to render it enforceable without losing its intent, or severed from this Agreement if no such modification is possible, and other provisions of this Agreement shall remain in full force and effect.

D. The relationship between the MDCH and the Health System is that of independent contractors and neither Party, nor its agents, shall have any authority to bind the other Party in any way.

E. Nothing express or implied in this Agreement is intended to confer, nor shall anything in this Agreement confer upon any person, other than the MDCH and the Health System, and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

XI. TERM AND TERMINATION OF AGREEMENT

A. This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement is terminated in writing by either Party.
B. Termination Without Cause. Health System may terminate this Agreement without cause upon thirty (30) days written notice to Data Recipient.
C. Termination With Cause. Upon Health System's knowledge of a pattern or practice that constitutes a material breach of this Agreement by Data Recipient, Health System will take, and Data Recipient will cooperate in taking, reasonable steps to cure the breach and mitigate any reasonably anticipated consequences of such breach. If such steps are unsuccessful, Health System may, in addition to any other rights Health System may have under this Agreement or by operation of law, immediately terminate this Agreement; discontinue authorization for disclosure of Health System Data to Data Recipient; and report the problem to the Secretary of the U.S. Department of Health and Human Services.

[Signatures to follow]

NOW, THEREFORE, by signing below, the parties agree that they have read, understand, and agree to the conditions set forth above:

DATA RECIPIENT:

Michigan Department of Community Health (MDCH)
Bureau of Epidemiology
Division of Communicable Diseases
Surveillance and Infectious Disease Epidemiology (SIDE) Section
Surveillance of Healthcare-Associated & Resistant Pathogens (SHARP) Unit
201 Townsend
Capitol View Bldg, 5th Floor
Lansing, MI 48913
Phone: 517-335-8165
Fax: 517-335-8263

_____	_____
Corinne Miller	James Collins
Director, Bureau of Epidemiology	Manager, SIDE Section
MDCH	MDCH
Date: _____	Date: _____

HEALTH SYSTEM:

Hospital Name: _____

Signature: _____
Name: _____
Title: _____
Date: _____
Address: _____
_____
_____
_____
Phone: _____
Fax: _____
E-Mail: _____

Authorization of Promise of Confidentiality

I authorize the promise of confidentiality that is made to the Health System, as set out in this agreement, pursuant to the Michigan Freedom of Information Act, MCL 15.243(1)(f).

_____

Janet Olszewski
Director
Michigan Department of Community Health

Date: _____