Medical University of South Carolina (MUSC)/ Medical University Hospital Authority (MUHA) Clinical Data Warehouse

Governance Charter

Purpose of Charter

The purpose of the Charter for the Governance of the MUSC/MUHA **Clinical Data Warehouse** (CDW) is to outline the guiding principles and processes for appropriate oversight and governance in the acquisition and use of data supporting MUSC/MUHA Research, Clinical Care, Administration, and Education.

Description of the Program

MUSC and MUHA have established an **Enterprise Data Warehouse** (EDW) to support their needs in clinical, organizational, and research initiatives. The Clinical Data Warehouse (CDW) is the clinical component of the EDW.

Use of the CDW for research is focused on investigator access to data for clinical research activities such as cohort analysis, hypothesis testing, and patient recruitment via Institutional Review Board (IRB) approved processes as described in the standard operating procedure documents.

Use of the CDW also includes non-research, operational activities such as hospital performance improvement, quality assurance and patient safety projects.

Governance

CDW Governance Committee

The Vice President for Medical Affairs (MUSC) and the Associate Provost for Research (MUSC) serve as the Executive Sponsors for this project, and the Chief Medical Information Officer (MUHA) chairs the senior leadership Governance Committee. The Governance Committee consists of leadership from the University, Medical University Hospital Authority, University Medical Associates, and the Office of the Chief Information Officer as well as the Principle Investigator of the IRB approved protocol for the use of the CDW for research.

CDW Oversight Committees

Reporting to the Governance Committee are two Oversight Committees representing Clinical Care/Operations, and Research. The Committees are chaired by individuals who manage those activities for the Hospital and University Biomedical Informatics.

CDW Working Groups

Reporting to the Oversight Committees are four Working Group committees that will deal more specifically with data and operational related issues. Each of the committees has a mix of University and Hospital staff to oversee the CDW Infrastructure/Database Architecture, Security, Data Quality, and Human Research Protection (HRP). Chairs of the Working Groups are ad hoc members of the Oversight Committees.

Committee Structure

Governance Committee

- MUHA Chief Medical Information Officer, Chair
- MUSC Associate Provost for Research
- MUHA Executive Medical Director
- MUSC Vice President for Medical Affairs and Dean, College of Medicine
- UMA Chief Executive Officer
- MUSC Chief Information Officer
- MUSC Principle Investigator (PI), CDW IRB Protocol

Roles and Responsibilities:

- Sets overall direction and vision for the CDW
- Makes high-level decisions regarding financial and staff resources
- Communicates vision to MUSC enterprise

Meeting Frequency: Chair will decide

Oversight Committees

Clinical Care / Operations Oversight:

- MUHA Medical Director, CDW, Chair
- MUHA Director, Strategic Planning
- MUHA Medical Director, Quality
- MUHA Manager, Enterprise Analytics
- MUHA Director, Decision Support
- MUHA Director, Quality
- MUHA Hospital Compliance Officer
- UMA Director, Decision Support
- MUSC EDW Program Manager, OCIO
- MUSC EDW Program Support Staff, OCIO

Roles and Responsibilities

- Set priorities for clinical care use of data warehouse
- Align priorities to clinical enterprise strategic plan and quality strategic plan
- Oversee project timelines and deliverables
- Monitor/propose changes to clinical systems that affect data collection/use
- Set policy and procedures for patient data documentation changes

Meeting Frequency: Chair will decide

Research Oversight

- MUSC PI, CDW Protocol, Chair
- MUHA Medical Director, CDW
- MUHA Manager, Enterprise Analytics
- MUSC Member, Data Request Committee
- MUSC EDW Program Manager, OCIO

Roles and Responsibilities

- Develop and oversee policies and standards for CDW access and use
- Prioritization and resolution of user requests
- Develop and report metrics to Governance, Associate Provost for Research and SCTR
- Quarterly review of audits

Meeting Frequency: Chair will decide

Working Groups

Data Quality Working Group: (Chair to be identified)

- MUHA Manager, Enterprise Analytics
- MUHA Enterprise Analytics representative
- MUHA Director, Decisions Support
- MUHA Medical Director, EDW
- MUHA Medical Director, Quality
- Technical experts from each feeder system as needed (both MUHA and MUSC)
- MUSC EDW Program Manager, OCIO
- MUSC CDW Honest Broker

Roles and Responsibilities

- Oversee data quality considering sources of data
- Oversee design of user interface
- Develop data quality feedback mechanism
- Establish data validity requirements
- Establish the agreed upon medical terms, meanings and relations (ontology) as they apply to data in the warehouse.

Meeting Frequency: Chair will decide

Infrastructure and Architecture Working Group: (Chair to be identified)

- MUSC EDW Program Manager, OCIO
- MUHA Enterprise Analytics representative
- CDW System Vendor Representative (e.g. Telus)
- MUSC CDW Honest Broker
- MUSC Business Intelligence analyst
- MUSC Business Intelligence architect

MUSC/MUHA Clinical Data Warehouse Governance Charter (continued)

Roles and Responsibilities

- Develop/Maintain/Troubleshoot infrastructure
- Advise on CDW features and functionality
- Validate Extract-Transform-Load (ETL) automated process and output
- Standards and interoperability as they interface with other clinical systems
- Oversee development of clinical decision support tools
- Oversee warehouse performance and accuracy metrics
- Oversee development of user interface design and revisions as requested by Data Quality group.
- Implement metadata model based upon ontology recommendations from the Data Quality group.
- Implement ontologies (hierarchy structure) and concept mapping developed by Data Quality group.

Meeting Frequency: Chair will decide

Security Working Group

- MUSC Compliance Privacy Officer, Chair
- MUSC OCIO Security Officer
- MUSC PI, CDW Protocol
- MUSC Operations Manager, Office of Associate Provost for Research
- MUHA Hospital Compliance Officer
- MUSC CDW Honest Broker
- EDW Program Manager, OCIO

Roles and Responsibilities

- Draft policy for data security and access
- Develop audit reports for research related queries
- Ensure auditing activity

Meeting Frequency: Chair will decide

Human Research Protection Working Group:

- MUSC IRB Program Manager, Chair
- MUSC PI, CDW Protocol
- MUSC SCTR Lead Regulatory Coordinator
- MUSC Director, University Compliance
- MUSC Member, Data Request Committee
- MUSC Director, Human Research Protection Program Accreditation

Roles and Responsibilities

- Coordinate interface between CDW and Office of Research Integrity
- Provide consultation and input on CDW initiatives in the context of MUSC Human Research Protection Program

MUSC/MUHA Clinical Data Warehouse Governance Charter (continued)

Meeting Frequency: Annually

Resolution Process for Issues arising from use and maintenance of CDW

The Escalation Process for any issues will follow the Governance Hierarchy. If the issue or risk cannot be resolved at the level where it has been identified, it will be the responsibility of the respective chair to escalate the issue to the next higher-level committee in the governance structure. It is expected that these issues will be escalated at the next regularly scheduled meeting of the higher-level committee. If the issue or risk requires immediate attention, the chair of the reporting committee will note the level of urgency to the chair of the higher-level committee so that a special meeting can be called. It will be the prerogative of the higher-level committee chair to determine if the issue or risk warrants that an extra meeting be held in person or via conference call, or if the issue should be resolved via e-mail. Any issue or risk identified will be documented by the MUSC EDW Program Manager and OCIO who will keep a current status on each item. The open items will be listed on the agenda for discussion at each subsequent meeting until resolved.

Institutional Review Board (IRB) Related Policies and Procedures

The IRB policies and procedures for granting access to patient information for Clinical Studies and Research will continue to be the governing documents for related access to the CDW by MUSC/MUHA faculty, staff, residents, and students.

OFFICIAL SIGNATURE AND APPROVAL

5/23/11
Mark S. Sothmann, Ph.D. Date
Vice President for Academic Affairs and Provost

6/17/11
Etta D. Pisano, M.D. Date
Vice President for Medical Affairs and Dean, College of Medicine

5/23/11
Stephen M. Lanier, Ph.D. Date
Associate Provost for Research
Professor of Pharmacology

6/22/11
W. Stuart Smith, M.H.A. Date
Vice President for Clinical Operations
Executive Director for Medical Center

6/17/2011
Frank C. Clark, Ph.D. Date
Vice President for Information Technology and CIO

5/23/11
Lisa P. Montgomery, M.H.A. Date
Vice President for Finance and Administration