AHC IE Program Update
11 October 2010, rev 8

Overall Program Goal:

Create a **fully automated platform** of systems, applications, databases and analytical tools to support the operations of research and clinical care for all of health sciences. This provides a foundation that enables secure, timely capture and exchange of information between databases in the AHC, FHS, UMP, and, perhaps, outside the University.

Program Scope:

The program, as currently defined, requires the definition, architecture, and construction of four major technical components:

- an information exchange infrastructure (for secure, consistent, and auditable data sharing),
- i2b2/Shrine (for de-identified research queries),
- research study platform (for consented study management), and a
- research clinical data repository (for analysis supporting research studies, quality improvement, accountable care organizations, etc).

A brief description of each follows.

1. **Information Exchange:** This framework provides a secure, consistent, auditable infrastructure to support the flow of information from participating partners into RSP and UM-CDR. The Information Exchange allows us to accomplish the overall mission for a robust bio-medical health informatics system (BMHI).

2. **i2b2/Shrine:** This functionality links de-identified clinical practice data among participating clinical partners, e.g. HealthPartners, Allina, Park Nicollet, University, etc. An initial pilot is in place for FHS and IHI as part of CTSI/CTSA. This solution enables self-service cohort identification and hypothesis generation. Additional data and rollout is being planned.

3. **Research Study Platform (RSP):** This architecture will contain components that capture research study data, consented clinical data, and other research data among participating partners. The functionality will provide end-to-end support for research studies including a clinical trials management system.

4. **Research Clinical Data Repository (UM-CDR):** This architecture will include an integrated **data repository** with identified research and clinical data from participating partners. The uses of such data would include analysis of research, planning, and clinical partner research collaboration.
Program Research Functionality Outcomes

Achieving the overall program goal and program scope will provide the following research functionality outcomes:

a. The ability to exchange data between the operational tools used to support clinical research and trials management, clinical and laboratory data management, tissue samples and other relevant data, e.g. genomics, proteomics, metabolomics databases, etc.

b. The ability to access data systems within the University and from other institutions such as Fairview, UMP and other relevant databases outside the University.

c. The ability to exchange data from all specific systems where data are collected, to support downstream reporting, analytics and transfer to other systems and institutions.

d. The ability to interface with other systems that collect and manage clinical information, laboratory data, patient registry information, hospital (inpatient) and outpatient electronic health records and other sources.

e. The use of state-of-the science computer-user interface principles to assure user-friendly data access and functional query of the system.

f. Compliance with all appropriate privacy and regulatory requirements.

Program Organization:

An effort such as this is only successful with proper oversight, planning, and direction. The first critical step is identifying and mobilizing an Executive Oversight Committee that will be responsible for planning, prioritizing, budgeting, staffing, and communications. The governance structure is illustrated below.

The first charges for this executive committee is the creation of an overarching program plan and the subsequent creation of the various workgroups that are required to deliver it.
Program Scope Project Management

Each of the projects in the Program Scope will be assigned its leadership and charter by the Executive Committee. Each project will need members from the four primary functional groups established by the Executive Committee.

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AHC Executive Committee Charter:

1. Responsibilities:
   
   a. Define overall program scope, goals and objectives
   b. Authorize and supervises needs assessment effort
   c. Establishes priorities for the entire program – based on needs assessment results and recommendations (which must be factually presented)
   d. Authorize and approve creation of a roadmap/plan for development and implementation (dependent upon needs assessment)
   e. Define policy and legal agreements for inter/intra organizational research efforts and data sharing
   f. Define four workgroups, identify key members, provide oversight/direction, and approves the workplans of all four workgroups
   g. Establish and approve all budgets and arranges funding
   h. Manage communications for the program

2. Membership:  Co-Chairs: Connie Delaney, BMHI and Nursing and Frank Cerra, SVP Academic Health Center (AHC)

   1. Steve Cawley, Office of Information Technology (OIT)
   2. Tucker LeBien, AHC-Research
   3. Barbara Gold, University of Minnesota Physicians (UMP)
   4. Terry Carroll, Fairview Health Systems (FHS)
   5. Bruce Blazar, Clinical Translational Science Institute (CTSI)
   6. Doug Yee, Masonic Cancer Center (MCC)
   7. Vipin Kumar, Computer Science and Engineering
   8. Tim Mulcahy, Office of the Vice President for Research (OVPR)
   9. Sarah Cooley, Clinical Research Services, MCC
   10. John Connett, Biostatistics (BDAC)
   11. Marty LaVenture, MN Dept of Health - Minnesota e-Health
   12. Terry Bock, AHC
   13. Beth Nunnally, AHC Finance
   14. Mary Koppel, AHC Communications

   Ex Officio Members:
   15. Steve Ruggles, UMN Population Center
   16. Latanya Sweeney, Privacy Consultant
Four Workgroups

A. Informatics Oversight

1. Responsibilities:

   a. Formalize overall informatics program
   b. Validate overarching needs assessment findings and recommendations
   c. Determine best-in-class models for comparison
   d. Identify pilot/prototypes and use cases with formal handoff to Research Studies Workgroup
   e. Communication plans
   f. Approve Rollout plans
   g. Approve Training plans
   h. Manage program approach across all three other sub groups
   i. Insure that all necessary requirements are detailed to meet the needs of researchers
      i. detailed data requirements for the various informatics needs
      ii. detailed system requirements for the various informatics needs
      iii. detailed tool requirements for the various informatics needs
   j. Review and endorse technical architecture, plans, and recommendations that support informatics and an integrated approach to best-practice and resource utilization.
   k. Provide reports on progress to the IE Executive Committee – monitor and evaluate outcomes/progress to overall plan

2. Membership: Chair: Connie Delaney, BMHI and Nursing

   1. Doug Yee, MCC
   2. Genevieve Melton-Meaux, Institute for Healthcare Informatics (IHI)
   3. Mark Herzberg, CTSI CRIS
   5. Badri Konety, Surgery
   6. Dan Weisdorf, MCC
   7. Terry Carroll, FHS
   8. Mary Koppel, AHC Communications
   9. Peter Radcliff, UMN
   10. Ed Deegan, AHC Information Systems (IS)
   11. Keith Dunder, AHC Legal
   12. Chris Chute - Mayo
   13. Advisor, Bruce Johnson
B. Research Studies Workgroup

1. Responsibilities:

   a. Maintain operations focus for supporting the implementation and testing of research studies
   b. Formalize needs/requirements for supporting research studies
   c. Validate needs assessment findings and recommendations on a per implementation basis
   d. Identify pilot/prototypes and use cases
   e. Identify collaboration needs/requirements
   f. Identify baseline Research study process
   g. Identify tools/approaches/processes that support baseline research (tie to architecture/solutions workgroup) – for consideration to Informatics Oversight Workgroup
   h. Implement plans as approved by Informatics Oversight Workgroup on communication, rollout and training
   i. Identify and document requirements
      i. detailed data requirements for the various Research Study needs
      ii. detailed system requirements for the various Research Study needs
      iii. detailed tool requirements for the various Research Study needs
   j. Review and test technical architecture, plans, and recommendations that support research studies
   k. Provide reports on progress to the Informatics Oversight Workgroup and IE Executive Committee

2. Membership: Co-Chairs: Sarah Cooley, MCC and Don Connelly, IHI

   1. Dan Weisdorf, Researcher
   2. Dorothy Hatsukami, Researcher
   3. Ed Greeno, Researcher
   4. Dan Garry, Researcher
   5. Terry Adam, IHI Fellow
   6. Serguei Pakhomov, IHI Fellow
   7. Ross Janssen, Institutional Privacy Officer
   8. Mark Herzberg, CTSI CRIS
   9. Kim Ott, FHS
   10. Ed Deegan, AHC IS
   11. Joe Sullivan, OIT
   12. Mary Koppel, AHC Communications
   13. Bruce Johnson, Advisor
   14. Patricia Klauer, Consultant
C. Data Governance and Security

1. Responsibilities:
   a. **Create processes** for the oversight of data (definition, capture, management, and usage/access)
   b. Validate needs assessment findings and recommendations
   c. Establish policies and procedures for cross-organizational data sharing – data exchange between AHC, Fairview, UMP, caBIG, CTSAs and other organizations to support collaborative clinical, research, and regulatory needs (incl legal documents such as; BAA, DURSA, MOU)
   d. Develop security/privacy approach for each component:
      - IE
      - I2b2/SHRINE
      - RSP
      - UM-CDR
   e. Conduct audit reviews
   f. Coordinate with Data Linkage Center (DLC)
   g. Work to define IRB review/approval process and tools
   h. Coordinate eIRB integration
   i. Develop data quality assurance process
   j. Define data access request process/policy/reporting
   k. Communication plans
   l. Training plans
   m. Identify requirements
      - detailed security requirements for the entire program
      - detailed system requirements for the information exchange
      - auditing of data access/usage
   n. Review and endorse technical architecture, plans, and recommendations ensuring that auditing and security are adequately accommodated
   o. Provide reports on progress to the IE Executive Committee

2. Membership: Co-Chairs: Stuart Speedie, IHI and Steve Ruggles, UMN Population Center
   1. Ken Hanna, OIT
   2. Nguyen H Cuong, MMC
   3. Bob Milius- MMC
   4. Ross Janssen, Institutional Privacy Officer
   5. Moira Keane, OVPR – Institutional Review Board (IRB)
   6. Adrienne Baranauskas, FHS
   7. Glen Allen, FHS
   8. Genevieve Melton-Meaux, IHI
   9. Justin Dale, AHC IS
   10. Tucker LeBien, AHC - Research
   11. Key Informatics Workgroup member
   12. Key Research Studies Workgroup member
   13. Bruce Johnson, Advisor
   14. UM-CDR Manager and Data Stewards
D. Architecture and Solutions

1. Responsibilities:

   a. Each project would have a research project owner that drives from the Informatics/Research perspective and an IT project manager/leader that coordinates the development activities.
   b. BMHI problem solving group for architecture and solutions.
   c. Ensure architecture detailing, refinement, and mapping to solutions.
   d. Definition of the technical solution that fits the requirements developed by the 3 other workgroups for each technical component/project.
   e. Definition and establishment of the necessary underlying infrastructure required to support this program.
   f. Planning, managing, and delivery of all technical efforts (as prioritized by the executive committee).
   g. Development of foundational IT processes for development and delivery.
   h. Design and development of operational reporting tools that support all needs of governance/security/auditing.
   i. Provide reports on progress to the IE Executive Committee and other 3 workgroups.

2. Membership: Chair: Connie Delaney, BMHI and Nursing

   1. Marty LaVenture, Minnesota e-Health
   2. Sarah Cooley, MCC
   3. Chief Data Steward
   4. Vipin Kumar, Computer Sciences
   5. Ray Gensinger, FHS
   6. Steve Cawley, OIT
   7. Barbara Gold, UMP
   8. Layne Johnson, IHI
   9. UM-CDR Manager
   10. RSP Manager
   11. Justin Dale - I2b2/SHRINE technical lead, AHC-IS
   12. Information Exchange technical lead
   13. Bruce Johnson, Advisor