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Governing Inter-institutional Research

Institute of Medicine
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Learning from the ground up...

• KP research governance
  – Research director, KP Colorado (2008-present)
  – National Research Council Chair (2014-15)

• HMO Research Network governance
  – Virtual Data Warehouse Committee (2010-11)
  – Asset Stewardship Committee (chair, 2011-12)
  – Governing Board (chair, 2013-14)

• SUPREME-DM Network
  – PI, 2011-present
  – 11-site research network with EHR data from 1.3 million persons with diabetes
Transformation of the Research Enterprise Requires Transformation of Governance

- **Bigger** – more sites and subjects, scientific and financial relationships among them
- **Better** – Trustworthy, high-quality data and methods to use it, regulatory and fiscal compliance
- **Faster** – Rapid initiation of projects, business processes and human subjects review
- **Cheaper** – Reliance on data collected through routine practice, sustained infrastructure
- **Engaged** – Integrate patient and organizational perspectives, inter-institutional scientific teams
Skillful Governance Promotes Sustainability

**Network sustainability** can be defined as:

- The development of **shared research assets** to facilitate a sequence of research studies in a specific content area or multiple areas.
- A **community of researchers** and other stakeholders who reuse and develop those assets.
- Governance of shared institutional research assets and processes requires attention to detail.
- Governance of a community of scientists requires broad principles and a light touch.
- **Precision tools, and the creativity to use them in new ways**
10 Essential Elements of Sustainability

**Shared Research Assets (precision tools)**

1. Clearly-defined network organizational structure
2. Trustworthy data and data governance
   a. Data model
   b. Data querying
   c. Approaches to assure data quality/validity
3. Shared knowledge about tools and approaches
4. Administrative efficiency
5. Physical infrastructure (e.g. biobanks)
6. Predictable infrastructure funding
10 Essential Elements of Sustainability

Community of Researchers and Stakeholders (creativity)

7. Shared mission, vision and values
8. Protection of human subjects (who are also stakeholders)
9. Strong relationship with delivery systems (which are also stakeholders)
10. Development of a culture of leadership and collaboration based on fair and transparent decision-making

All 10 of these elements have governance implications
Diversified infrastructure funding

• Single projects (R01) rarely add to infrastructure!
• HMORN infrastructure support has been a “relay race”
  – CDC Vaccine Safety Datalink (1990-present)
  – NCI Cancer Research Network (1999-present)
  – AHRQ CERTs (2000-2011)
  – NIMH Mental Health Research Network (2010-present)
  – FDA Mini-Sentinel Network (2009-present)
  – AHRQ electronic data methods (EDM) awards (2010-2013)
  – Etc.
• Research networks requires ongoing institutional support as well!
Leadership and Decisions

The culture of leadership and decision-making in research networks: leadership without control

• Decentralized organization
• Hard to enforce top-down mandates, emphasis on consensus
• Trust the capacity of researchers to self-organize and innovate
• “Hydrogen bonds, not covalent bonds”
Research Governance in Kaiser Permanente
2009-present

• Seven regional research departments that report to regional leadership rather than KP Program Office
• National Research Council (NRC) of regional directors, Program Office leaders
• Research Strategic Plan (2009)
• KP Center for Effectiveness and Safety Research (2009/11)
  – Enhance engagement with organizational stakeholders
  – Data coordinating center, enhance data model (VDW) and data quality
• Program-wide IRB coordination and metrics (2011)
• National Research Administrators Council reporting to NRC (2012)
  – Contracting, pre/post award processes, regulatory issues...
• KP National Biobank (2014) that relies on many of these processes
Conclusion: Governing Inter-Institutional Research

“Make the right thing to do the easy thing to do”
 AND
"Ruling a big country is like cooking a small fish. Too much handling will spoil it".

Lao-Tzu