INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

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CLINICAL EFFECTIVENESS RESEARCH INNOVATION COLLABORATIVE: EXPLORING THE ETHICAL FRAMEWORK FOR THE LEARNING HEALTH SYSTEM

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MARCH 28, 2013

THE NATIONAL ACADEMY OF SCIENCES
ROOM 120
2101 CONSTITUTION AVENUE, NW
WASHINGTON, DC

Meeting goals

1. Discuss conceptual, ethical, and practical issues in continuous health care learning and improvement reviewed in the Hastings Center Report learning health system supplement.
2. Highlight examples of continuous improvement efforts that have run into issues due to the current oversight framework.
3. Identify areas in which the field is in need of practical guidance, and suggest approaches to developing that guidance.

8:30 am **Coffee and light breakfast available**

9:00 am	**Welcome, introductions, and meeting overview**

Welcome from the IOM
Michael McGinnis, Institute of Medicine

Opening remarks and meeting overview by Collaborative Chair
Richard Platt, Harvard Pilgrim Health Care Institute

Brief thanks from Hasting Center
Millie Solomon, Hastings Center

9:15 am	**Issues framing**

This session will include presentations from the authors of articles published in the recently released Hastings Center Report learning health system supplement.

An ethical framework for learning health systems
Ruth Faden and Nancy Kass, Johns Hopkins University

Learning as part of operations
Deven McGraw, Center for Democracy & Technology

Current challenges and opportunities
Barbara Bierer, Brigham and Women's Hospital

Q&A and Open Discussion

10:45 am	**Break**

11:00 am	**Highlighted examples**

This session will highlight case studies of learning activities embedded in the routine delivery of care – some originally framed as research community and others as quality improvement. The presentations and discussion will focus on areas of overlap and difference in intent, methods, engagement of patients, and oversight.

- **Disclosure and consent in cluster randomized studies**
  Susan Huang, University of California Irvine

- **Use of routinely collected information and/or biospecimens**
  Rex Chisholm, Northwestern University

- **Formal evaluation of QI projects at large health system**
  Lucy Savitz, Intermountain Healthcare

Q&A and Open Discussion

1:00 pm	**Lunch**

1:30 pm	**Exploration of issue areas**

This session would include presentations that would dig deeper into the issues highlighted by the previous examples. They could include discussion of practical as well as legal and ethical issues and approaches.

- **Privacy and confidentiality: implications of HIPAA and beyond**
  Mark Barnes, Harvard University

- **What about consent?**
  Jeremy Sugarman, Johns Hopkins University

- **Federal oversight of knowledge generation in the context of care**
  Jerry Menikoff, Office for Human Research Protections

Q&A and Open Discussion

2:30 pm	**Need for guidance and next steps**

This session would be a panel discussion that would reflect back on the day's presentations and discussions and identify areas in which the field is in need of practical guidance, and suggest concrete next steps for progress.

- *Joanne Lynn*, Altarum Institute
- *Hugh Tilson*, PRIM&R
- *Greg Koski,* Alliance for Clinical Research Excellence and Safety
- *Stephan Fihn*, University of Washington and Veterans Administration
- *Steven Joffe,* Dana Farber Cancer Institute
- *Millie Solomon,* Hastings Center

Q&A and Open Discussion

4:30 pm	**Summary and next steps**

Comments and thanks from the IOM
Michael McGinnis, Institute of Medicine

4:45 pm **Adjourn**