



Barriers and Opportunities to Facilitate Clinical Effectiveness Research Innovation Pace & Progress

Field Advancement Working Group Paper

October 2010

Clinical Effectiveness Research Innovation Collaborative
IOM Roundtable on Value & Science-Driven Health Care

7 Considerations

- Stakeholders
- Delivery systems
- Regulation
- Methods
- Communications
- Workforce
- Funding

7 Considerations

- **Stakeholders**
 - **Patients, Providers, Payers, Purchasers, Public**
- Delivery systems
- Regulation
- Methods
- Communications
- Workforce
- Funding

7 Considerations

- Stakeholders
- **Delivery systems**
 - Venues
 - Care models
 - **Relationship to quality improvement programs**
- Regulation
- Methods
- Communications
- Workforce
- Funding

7 Considerations

- Stakeholders
- Delivery systems
- **Regulation**
 - **How should protections for human subjects of research apply?**
- Methods
- Communications
- Workforce
- Funding

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 46, 160, and 164

Food and Drug Administration

21 CFR Parts 50 and 56

Human Subjects Research Protections: Enhancing Protections for Research

Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

AGENCIES: The Office of the Secretary, HHS, and the Food and Drug Administration,

HHS.

ACTION: Advance notice of proposed rulemaking.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

“We seek comment on whether and, if so, how, the Common Rule should be changed to clarify whether or not oversight of quality improvement, program evaluation studies, or public health activities are covered.” page 45

Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

AGENCIES: The Office of the Secretary, HHS, and the Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

7 Considerations

- Stakeholders
- Delivery systems
- Regulation
- **Methods**
 - **When is observation enough?**
 - **What kinds of interventions are most suitable?**
- Communications
- Workforce
- Funding

7 Considerations

- Stakeholders
- Delivery systems
- Regulation
- Methods
- **Communications**
 - **How to build support, sustain interest**
- Workforce
- Funding

7 Considerations

- Stakeholders
- Delivery systems
- Regulation
- Methods
- Communications
- **Workforce**
 - Engaging, supporting, rewarding investigators
 - Engaging caregivers
- Funding

7 Considerations

- Stakeholders
- Delivery systems
- Regulation
- Methods
- Communications
- Workforce
- **Funding**
 - **Roles of traditional funders, new funders, the health care system**