Ethical Review and Oversight Issues in Research Involving Standard of Care Interventions: An Institute of Medicine Workshop

December 2–3, 2014
Standard of Care

• **A diagnostic and treatment** process that a clinician should follow for a certain type of patient, illness, or clinical circumstance. ([www.medicine.net](http://www.medicine.net))
  – Implies there is a single standard of care for each circumstance?

• **Treatment that is accepted** by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy. ([www.cancer.gov](http://www.cancer.gov))
  – Implicitly acknowledges more than one treatment might be acceptable?
Evidence-Based Development of the Standard(s) of Care

Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Evidence obtained from multiple time series designs with or without the intervention.

Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Evidence obtained from well-designed controlled trials without randomization.

Evidence obtained from at least one properly designed randomized controlled trial.
Comparative Effectiveness Research

• Inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatments.

• The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.
  – Researchers look at all of the available evidence about the benefits and harms of each choice for different groups of people from existing clinical trials, clinical studies, and other research. These are called research reviews, because they are systematic reviews of existing evidence.
  – Researchers conduct studies that generate new evidence of effectiveness or comparative effectiveness of a test, treatment, procedure, or health-care service.

http://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/
Constructing Clinical Trials to Compare Standard Approaches to Care

• IRB oversight (and in the case of some regulated products, FDA consultation)
• The Common Rule
  – Recruitment
  – Description of purpose of research
  – Description of methodology (including randomization)
  – Information about risks
  – Information about possible benefits
  – Information about compensation for injury, permissibility of leaving the study,
Risks

• Can (and if so, how do) the risks of participating in research that compares treatment options differ from the risks of having any one of those treatments in a non-research clinical setting?

• For randomized trials, does randomization in and of itself constitute a risk separate from the risks of the treatments?

• How can one define, identify and describe to study participants the reasonably foreseeable risks?
Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care

Draft

This guidance, when finalized, will represent the Office for Human Research Protections’ (OHRP’s) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP or the public.

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Date: October 20, 2014

Scope:

This guidance pertains to nonexempt research involving human subjects that is designed to evaluate treatments or procedures that are medically recognized standards of care. The guidance applies to such research that is conducted or supported by the Department of Health and Human Services (HHS).
Agenda

SESSION I: Randomization of Participants – Determining and Communicating Risks

SESSION II: Methodology for Evaluating the Degree of Risk & Determining Risks That Are Reasonably Foreseeable

*Ethics of Research Involving Standard of Care Interventions: Preliminary Findings*

SESSION III: Framing Risks Of Standard Of Care Interventions – What Should The Consent Form Say?

SESSION IV: Concluding Discussion