



NIH Collaboratory

Health Care Systems Research Collaboratory

Update on the *Living Textbook*

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Previous Milestones

- First content drafting starts mid-2013
- Living Textbook goes live on November 1, 2013 with three topic chapters
- Grand Rounds presentation in December of 2013

The Original Version

Living Textbook >

Informed Consent in Pragmatic Clinical Trials

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Topic summary “capsule”



Informed consent describes a process for enabling individuals to make voluntary decisions about participating in research with an understanding of the purpose, procedures, risks, and benefits of the investigation, as well as alternatives to participating. As described below, the basis for informed consent—including the requirement to obtain consent, situations in which that requirement might be modified or waived, and the content of the information provided—is grounded both in ethical principles and government regulations.

Ethical Foundations of Informed Consent

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U.S. federal regulations for the protection of human research participants are founded upon a 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Known as the *Belmont Report*, this landmark document defines three fundamental ethical principles for research involving human participants:

Respect for Persons – that competent individuals should be treated as autonomous (self-determining) agents, and that persons with diminished autonomy are entitled to protection;

Beneficence – that persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being; and

Justice – that the benefits and burdens of research be distributed fairly.

Based on these principles, the Belmont Report identifies three key parts to informed consent:

Information

In this topic:

- [Ethical Foundations of Informed Consent](#)
- [Regulatory Foundations of Informed Consent](#)
- [Waiving Informed Consent Requirements](#)
- [Obtaining Informed Consent](#)
- [Special Situations and Settings](#)
- [Emerging Issues and Controversies](#)
- [Bibliography](#)



In-page navigation

Influential Documents in Human Research Ethics

Recent Developments

Then...



Model T Ford. Public domain image from [Wikimedia Commons](#).

...and now.



Jet dragster. Image credit: Gt diesel via [Wikimedia Commons](#) (CC Attribution Share-Alike license)



The New WordPress Platform

- <http://sites.duke.edu/rethinkingclinicaltrials/>

The New WordPress Platform

Rethinking Clinical Trials

A Living Textbook of Pragmatic Clinical Trials

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Welcome

Welcome to the [NIH Collaboratory's Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials!](#) The *Living Textbook* is designed to provide a complete suite of information on how to understand, design, conduct, analyze & disseminate pragmatic clinical trials (PCTs). Although structured like a textbook, its web-based formatting allows us to deliver a flexible, continuously updatable reference with high-quality, expertly curated content.

“Our goal in creating *Rethinking Clinical Trials* is to provide a living document to guide the many different people with an interest in practical (or ‘pragmatic’) clinical trials and health systems research.”

—Robert M. Califf, MD
NIH Collaboratory Principal Investigator



The *Living Textbook* is organized into chapter-like “topics” written by subject matter experts in close collaboration with writers/editors at the NIH Collaboratory Coordinating Center. Through an iterative drafting process, articles on specific topics and subtopics relating to pragmatic clinical trials are published and expanded over time. The descriptive text is designed for multiple audiences, including both new and experienced researchers and clinical trialists; clinicians; patient advocates; and patients interested in participating in clinical research.

NIH Collaboratory on Twitter

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The LT Blog

Rethinking Clinical Trials

A Living Textbook of Pragmatic Clinical Trials

Changes to Informed Consent in the Era of Learning Healthcare Systems

© February 20, 2014 Cluster Randomized Trials, Comparative Effectiveness Research, Informed Consent, Patient-Centered Outcomes Research, Pragmatic clinical trials ANPRM, Cluster randomized trials, Common Rule, Informed consent, NIH Collaboratory, Ottawa Statement, PCORnet, pragmatic clinical trials Edit

In 2007, a seminal report from the Institute of Medicine (IOM) threw a sharp spotlight on a series of problems facing the broader U.S. healthcare system:

Evidence on what is effective, and under what circumstances, is often lacking, poorly communicated to decision makers, or inadequately applied, and despite significant expenditures on health care for Americans, these investments have not translated to better



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AcademyHealth ANPRM Cluster randomized trials Common Rule Informed consent learning health system mHealth mobile health NIH Collaboratory Ottawa Statement Patient-reported outcomes PCORnet pragmatic clinical trials PROs

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The New Site

- Easier and more appealing for users
- Content can be loaded and modified much faster thanks to user-friendly interface
- Better compatibility across browsers
- Works well on mobile

New Milestones

- Existing content ported to WordPress
- New site going live in days
- Two new topic chapters (Patient-Reported Outcomes and Regulatory Issues “stub” article) completed and in final stages prior to release
- Other topics in active development
- “LT Blog” added to capture fast-moving developments
- Two new FTE writers/editors coming on board
 - One hired; starting March 1
 - Second position open and expected to be filled by April 1
- Moving to dedicated “Living Textbook” domain?



What's Next?

- Work with us!
 - Whether you've got a little time or a lot, we're eager to work with Collaboratory leadership and partners in developing content
- Feed us!
 - Even if you don't have bandwidth for writing, we are gratefully for any pointers to new developments, articles, news, etc.



Thank You!

- Karen Staman, MS
- Laura Beskow, MPH, PhD
- Rob Califf, MD
- Ross McKinney, MD
- Tracie Locklear, PhD
- Kevin Weinfurt, PhD
- Amy Abernethy, MD, PhD
- Kathryn Flynn, PhD
- William Riley, PhD
- Laura Lee, PhD
- Brad Hirsch, MD, MBA
- Kim Best
- Cheri Janning, MS
- Debra Marion