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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



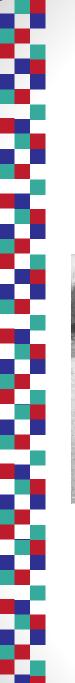
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The Original Version

Lara M. Beskow, MPH, PhD Asociate Professor Dake Clinical Research Institute Durham, NC Informed consent describes a process for enabling individuals to make voluntary decisions about participating in research with an understanding of the purpose, procedure 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. Intel for the investigation of the protection of human research, known as the element papert, this landmait document defines three fundamentar 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; Beneficer – that persons are treated in an ethical manner not only by respecting their decisions and protecting them from ham, but also by making efforts to secure their well-being; and Justice – that the benefits and burdens of research be distributed fairly. Beneficer – that persons are treated in an ethical manner not only by respecting their decisions and protecting them from ham, but also by making efforts to secure their well-being; and Justice – that the benefits and burdens of research be distributed fairly. Beneficer – that persons are treated in an ethical manner not only by respecting their decisions and protecting them from ham, but also by making efforts to secure their well-being; and Justice – that persons are treated in an ethical manner not only by respecting their decisions and protecting them from ham, but also by making efforts to secure their well-being; and Justice – that the benefits and burdens of research be distributed fairly.	Informed Consent in Pragmat	ic Clinical Trials Topic summary "capsule"
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	andmark document defines three fundamental thical principles for research involving human participa <i>Respect for Persons</i> – that competent individuals <i>Beneficence</i> – that persons are treated in an eth <i>Justice</i> – that the benefits and burdens of resear	s should be treated as autonomous (self-determining) agents, and that persons with diminished autonomy are entitled to protection; ical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being; and rch be distributed fairly.



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Recent Developments

Then...

...and now.



Model T Ford. Public domain image from Wikimedia Commons.



Jet dragster. Image credit: Gt diesel via <u>Wikimedia</u> <u>Commons</u> (CC Atribution Share-Alike license)

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The New WordPress Platform

http://sites.duke.edu/rethinkingclinicaltrials/



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The New WordPress Platform

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Rethinking Clinical Trials

A Living Textbook of Pragmatic Clinical Trials

Conflict of Interest Informed Consent Introduction LT Blog Patient-Reported Outcomes Regulatory Issues* Site Map Welcome Q

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 clin-



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Follow the NIH Collaboratory on Twitter at: https://twitter.com/Collaboratory1.

Tags

AcademyHealth ANPRIX 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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Rethinking Clinical Trials



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The LT Blog

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Rethinking Clinical Trials

A Living Textbook of Pragmatic Clinical Trials

Conflict of Interest Informed Consent Introduction

Systems

PCORnet, pragmatic clinical trials @Edit

Changes to Informed

Consent in the Era of

Learning Healthcare

series of problems facing the broader U.S. healthcare system:

communicated to decision makers, or

inadequately applied, and despite significant

these investments have not translated to better

expenditures on health care for Americans,

© February 20, 2014 E Cluster Randomized Trials, Comparative Effectiveness Research, Informed

In 2007, a seminal report from the Institute of Medicine (IOM) threw a sharp spotlight on a

Consent, Patient-Centered Outcomes Research, Pragmatic clinical trials # ANPRM, Cluster

randomized trials, Common Rule, Informed consent, NIH Collaboratory, Ottawa Statement,

IT Blog Patient-Reported Outcomes

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Pages Conflict of Interest

- Patient-Reported Outcomes

Regulatory Issues

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Rethinking Clinical Trials



Evidence on what is effective, and under what circumstances, is often lacking, poorly

Informed Consent Introduction

- LT Blog



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



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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?



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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.



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Thank You!

- Karen Staman, MS
- Laura Beskow, MPH, PhD
- Rob Califf, MD
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