Clinical Research Institutional Approval and Recruitment : Barriers and Strategies

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Clinical Research Process

Step 1
- Identify a research gap

Step 2
- Define measures & develop protocols

Step 3
- **Obtain institutional review board (IRB) approval**

Step 4
- **Recruitment & data collection**

Step 5
- Data analysis

Step 6
- Publication

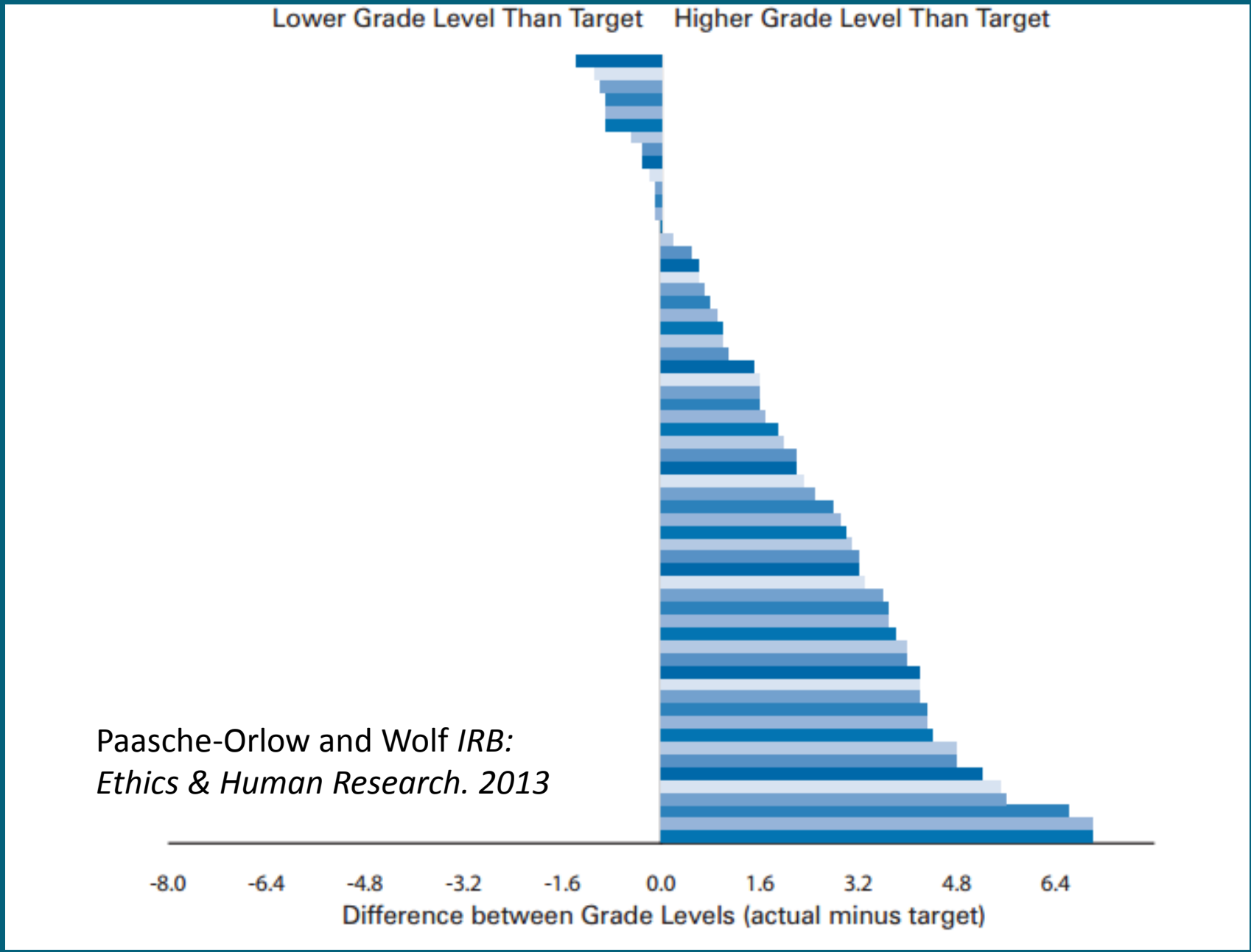
Roadmap

- Ethical considerations for ensuring
  - Informed consent
  - Privacy notification
- Navigating the IRB process
- Optimizing recruitment

Standard Informed Consent

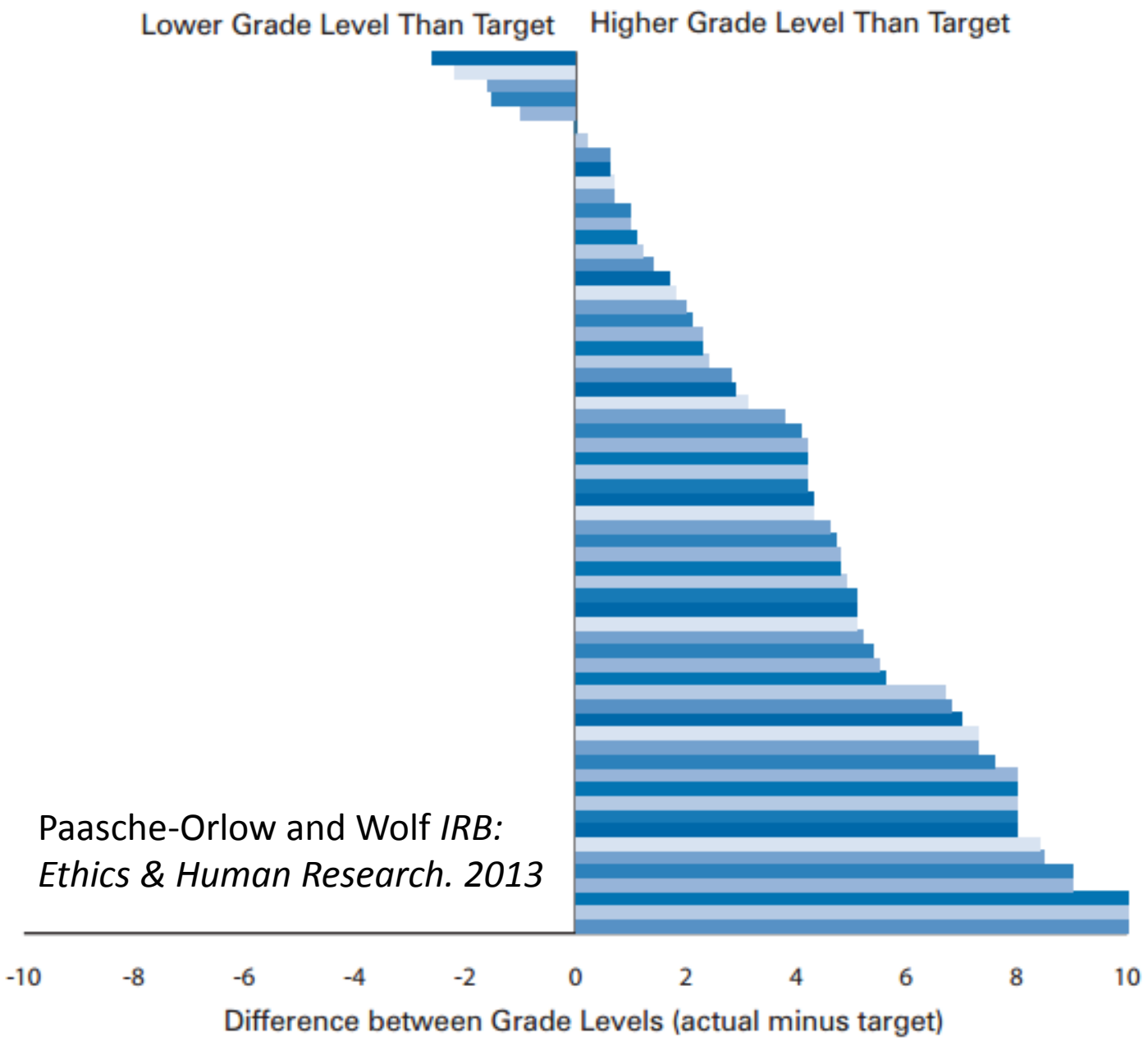
- *I understand that my participation in this study is completely voluntary and that I may either refuse to participate or withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled.*
- *Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to stop, you will not lose any of your rights*

Consent forms overestimate reading ability



Paasche-Orlow and Wolf *IRB: Ethics & Human Research. 2013*

HIPAA forms overestimate reading ability



Paasche-Orlow and Wolf *IRB: Ethics & Human Research. 2013*

Appropriate Consent & HIPAA Authorization Forms

- **Use plain language**
  - Reading level
  - Use the active voice
  - Use simple short sentence structures
  - Do not use jargon
  - definitions for technical terms & abbreviations
- **Use simple formatting**
  - At least 12-point fonts
  - Do not use ALL CAPS or *italics*.
  - Break up text into manageable chunks
- AHRQ has developed sample documents in both English and Spanish http://www.ahrq.gov/legacy/fund/informedconsent/ictoolkit2.htm#using

Example consent language

Why is this study being done?

This study is being done to create easy to understand medication labels. This research is funded by the California Health Care Foundation.

How many people will take part in this study?

About 20 people from SFGH General Medicine Clinic will take part in this study.

What will happen if I take part in this research study?

You will participate in a one-on-one interview and a focus group. During this study, you will first participate in a one-on-one interview where we will ask you questions about your health, medication habits, and demographic information. You will then be asked to join a focus group where we will show you a series of prescription medication instructions which can be used by pharmacies to increase understanding of safe and appropriate medication use. The interview and focus group will take place now and will take 2 hours to complete.

Consent Process

- Train research staff on non-verbal cues for participant discomfort
- Differentiate between clinical care and research
  - Right to refuse
- Offer to read the consent form with all research subjects
  - *Group setting may ease shame*
  - *Involve friend/ relative*
- Allot extra time to review consent document
- Verify and document that the potential research subject has understood

Verification

CONSENT VERIFICATION

Participant ID Number (PIDN): [ ]

[READ] I need to make sure that I explained this study to you clearly. So, I'm going to ask you a few questions about the study. Feel free to look over the consent form. If something isn't clear, we can look over the information together. It is OK if you don't know the answer. It just means that I didn't do my job in explaining the study to you well enough.

Ask all the questions and record the participants' first response. If information is not provided spontaneously, you can offer suggestions. When you have finished asking all of the questions once, review the relevant sections of the consent form for any questions that were answered incorrectly and then repeat the question(s) they initially got incorrect.

[READ:] You did a great job. There are a few things that I may not have made very clear. Let me repeat a few lines from the consent form so you can be sure you know what this study is about.

Use the comments section following each question to indicate whether the participant answered correctly the first time or after review (e.g., PPT subsequently answered the question correctly after reviewing the consent material one time.)

*If a participant is unable to answer one or more questions correctly after reviewing the correct answer twice, say "**I am so sorry but only patients who can correctly tell us what this study is about can be in it. Thank you for taking the time to hear about the study anyway."***

Documentation

1. **In your own words, can you tell me why we are doing this study?** *(page 1)*

Correct: ☐ 1st ☐ 2nd ☐ 3rd	• To create a handout to help patients and their friends and families make better medical decisions

2. **What will happen if you take part in this study? What will we ask you to do?** *(page 2)*

Correct: ☐ 1st ☐ 2nd ☐ 3rd	*RCT Veteran Participants:* • Review the handout and give opinions about it • You will have a 50/50 chance of being in one of two groups reviewing different handouts • In 1 week, 3 months, and 6 months, complete a phone interview about the handout • For some participants, we will audio record them talking with a doctor
Correct: ☐ 1st ☐ 2nd ☐ 3rd	*RCT Surrogates:* • Answer questions about your opinions and experience with decision-making • Answer questions about the Veteran who referred you to this study

Roadmap

- Ethical considerations for ensuring
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- Navigating the IRB process
- Optimizing recruitment

Navigating the IRB

- Challenges
  - IRB panels may lack health literacy expertise
  - Concern about recruiting vulnerable patients
  - Concern about health literacy measurement
- Strategies
  - Reference successful research approved by same institution's IRB
  - Emphasize balance of risk vs. harms
  - Engage with IRB to improve processes

A "case"

- Short-form Test of Functional Health Literacy Assessment (sTOFHLA)
  - Reading comprehension
- Passage A: s-TOFHLA: You must have an ____stomach when you come for ___.
- Options

asthma empty

incest anemia

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Recruitment Basics

- Sites
  - Public Clinics
  - Social service agencies
- Materials: visual appeal and simplicity
- Screen: *How confident are you filling out forms by yourself?*
- Retain
  - Limited transportation access
  - Limited job flexibility, time availability
  - Limited access to resources (phone, transportation)

Chew, LD et al. *JGIM* 2008

Recruitment Strategies

- The right-size incentive
  - Concern for economic coercion
- Provide travel or travel reimbursement
- Offer early morning (6-8 AM) or evening (5-8 PM) hours
- Train staff member to appropriately engage and communicate
  - Participant helping us and society
- Disconnected phone
  - Temporary, end of the month

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