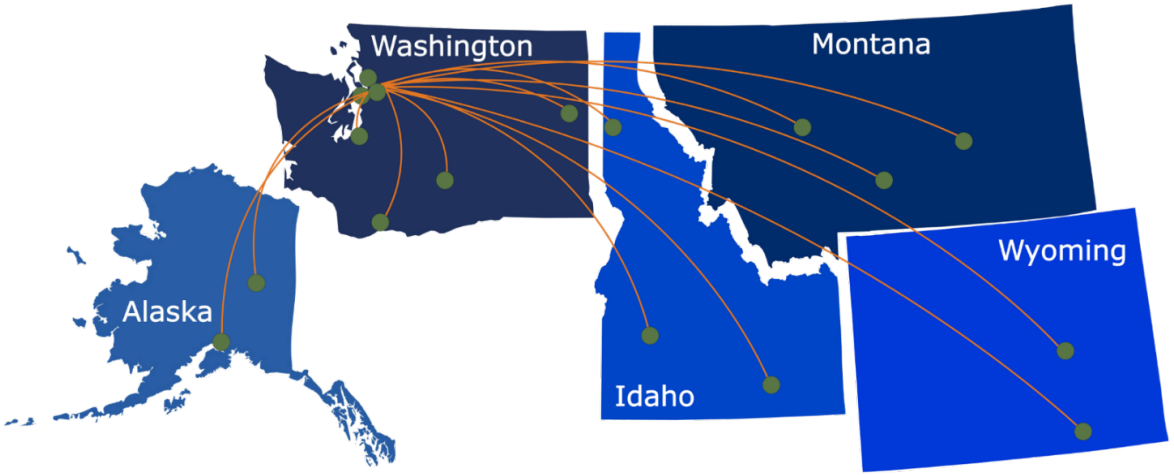

Introduction to Clinical Research
Boot Camp 2020
RESEARCH STAFF TRACK
Day 1
Monday, July 20, 2020
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

UNIVERSITY of WASHINGTON

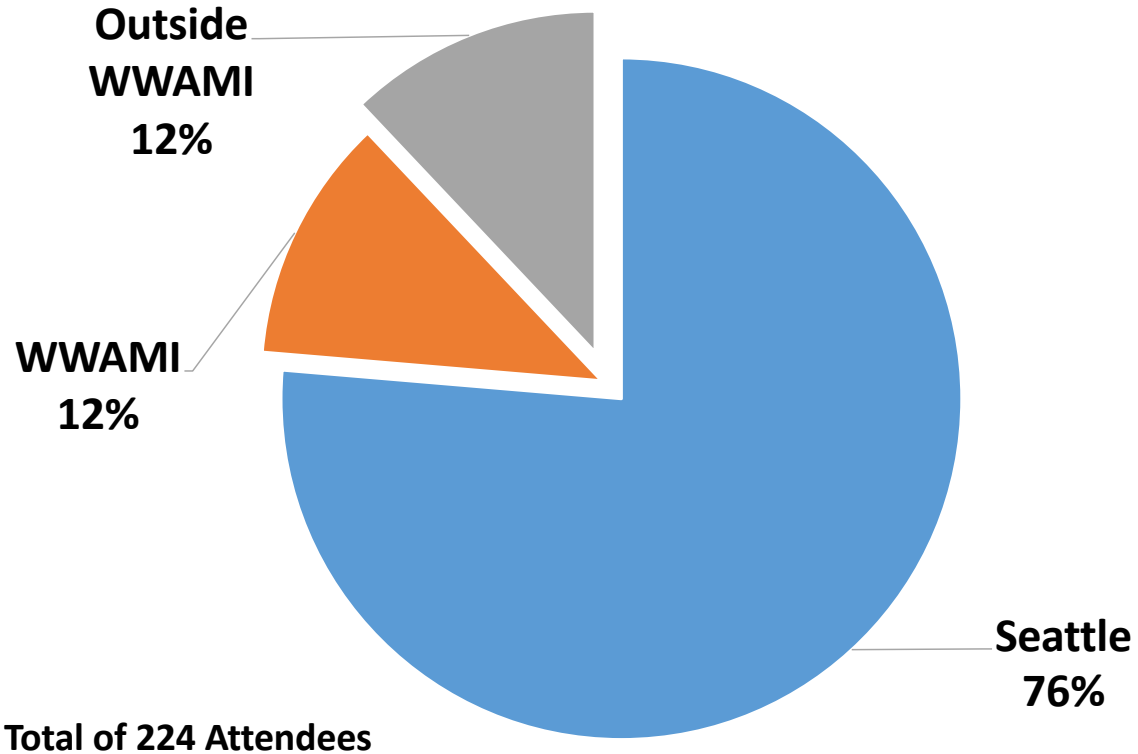
FRED HUTCH
CURES START HERE®

Seattle Children's®
HOSPITAL · RESEARCH · FOUNDATION

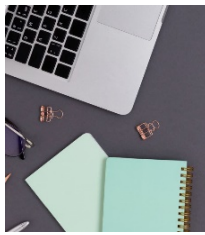


THS

Who is with us this week?



Total of 224 Attendees



Introduction to Clinical Research Boot Camp 2020

An Ethical Framework for Clinical Research: Rethinking and Going Beyond Informed Consent

Stephanie Kraft, JD

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Learning objectives

In this session you will learn about eight ethical benchmarks for clinical research and practice applying them to real-life case examples, with a focus on the role of researcher-participant interactions.

By the end of this session you will be able to:

- Describe the eight ethics benchmarks for ethical clinical research.
- Discuss how empirical data illustrate challenges with informed consent.
- Describe the role of researcher-participant interactions in the ethical conduct of research.

Overview

- Beyond informed consent
- A framework for ethical clinical research
- Respect for participants in research interactions
- Case studies

Poll

How long have you been professionally involved with research?

- 0-2 years
- 2-5 years
- 5-10 years
- 10+ years

Poll

Which of the following activities are you involved with as part of your current job? Select all that apply.

- Grant writing/study design
- Regulatory management (IRB protocols, FDA review, etc.)
- Recruitment/consent
- Data management
- Data analysis
- Manuscripts/presentations
- Reporting to funders

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Poll

Have you ever raised an ethical question about a study you were involved with? Select all that apply.

- Yes, to a PI
- Yes, to a trusted colleague or friend
- No, never

Why research ethics?

- Not just about preventing egregious violations – also offers guidance and tools to identify potential pitfalls
- Important for all research team members to be comfortable thinking about ethical challenges
- Fleshes out responsibilities above the regulatory floor

Poll

Are you involved in obtaining consent from participants?

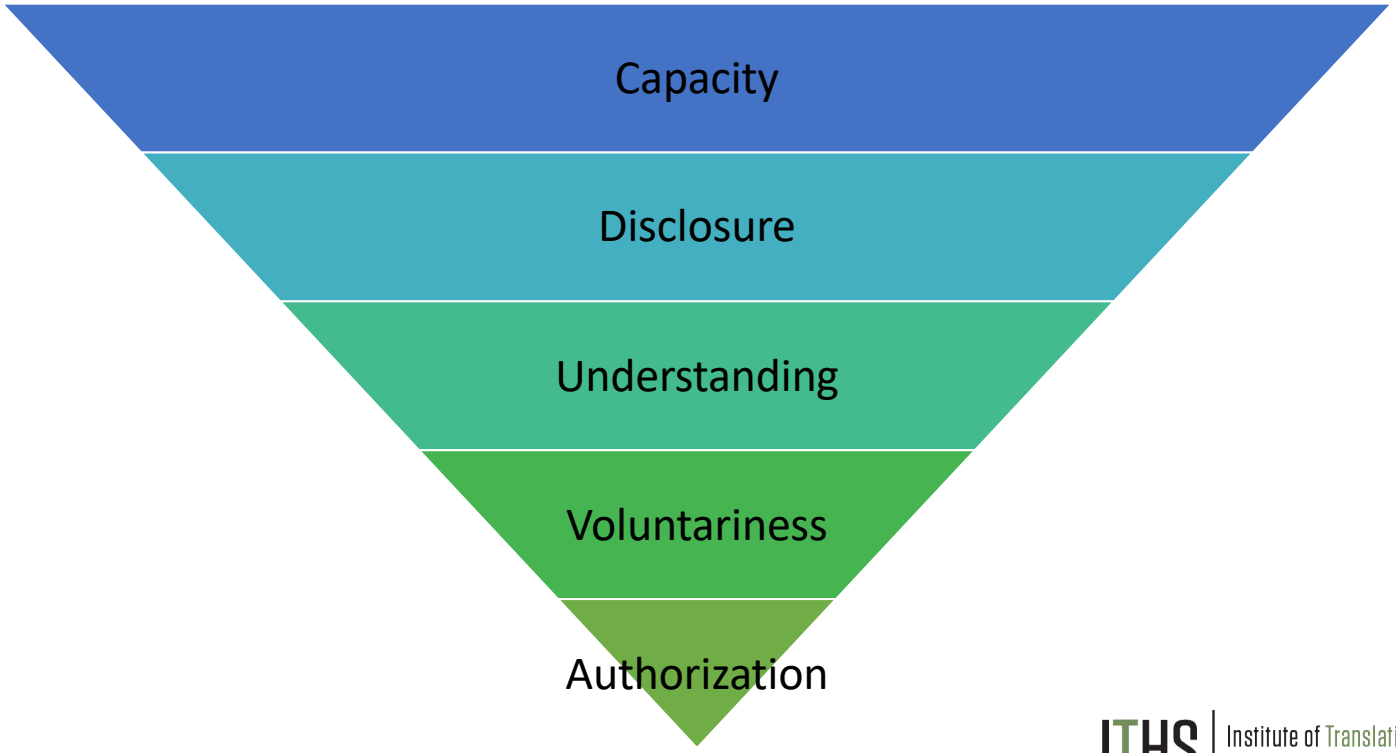
- Yes, regularly
- Yes, occasionally or on past studies
- No, never

Poll

What challenges have you faced when obtaining consent? Select all that apply.

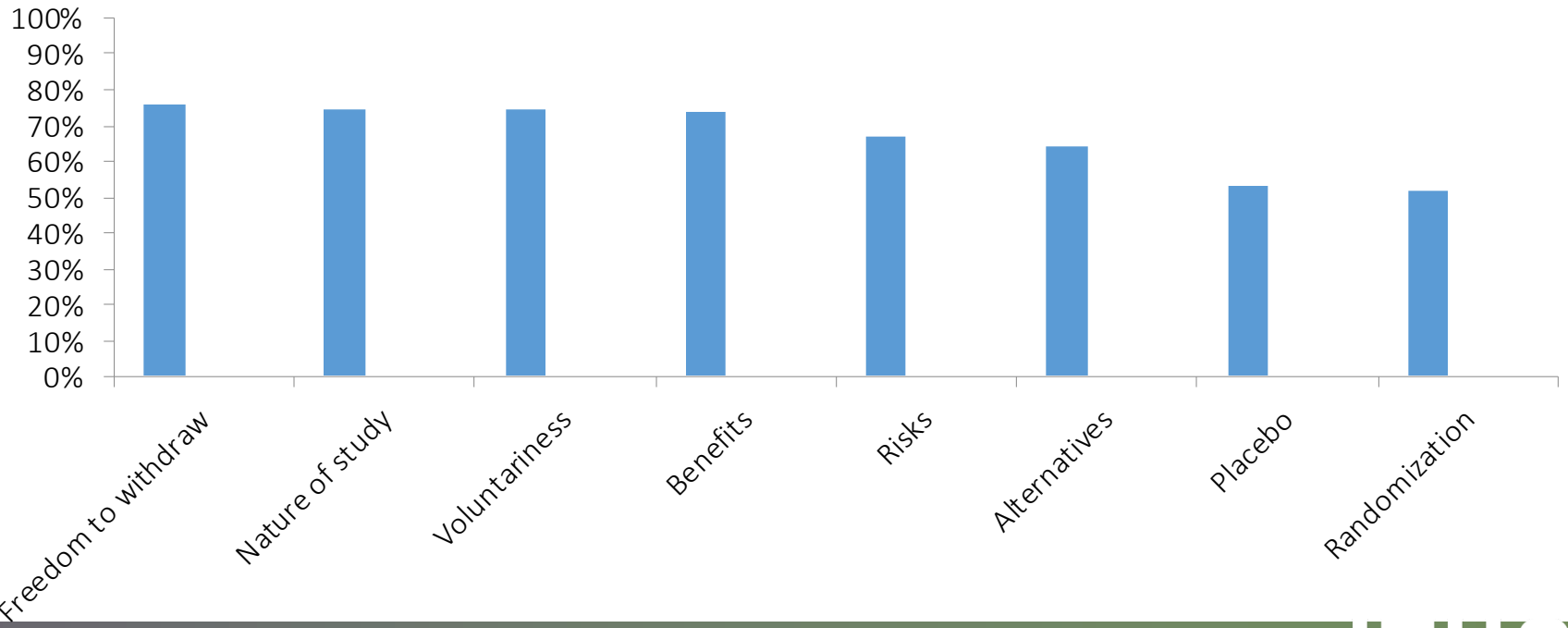
- Some concepts are hard to explain
- Complex language in consent forms
- Hard to tell if people understand everything
- Not enough time for discussion
- Overly detailed information
- Questions about people's true motivations

Five elements of informed consent



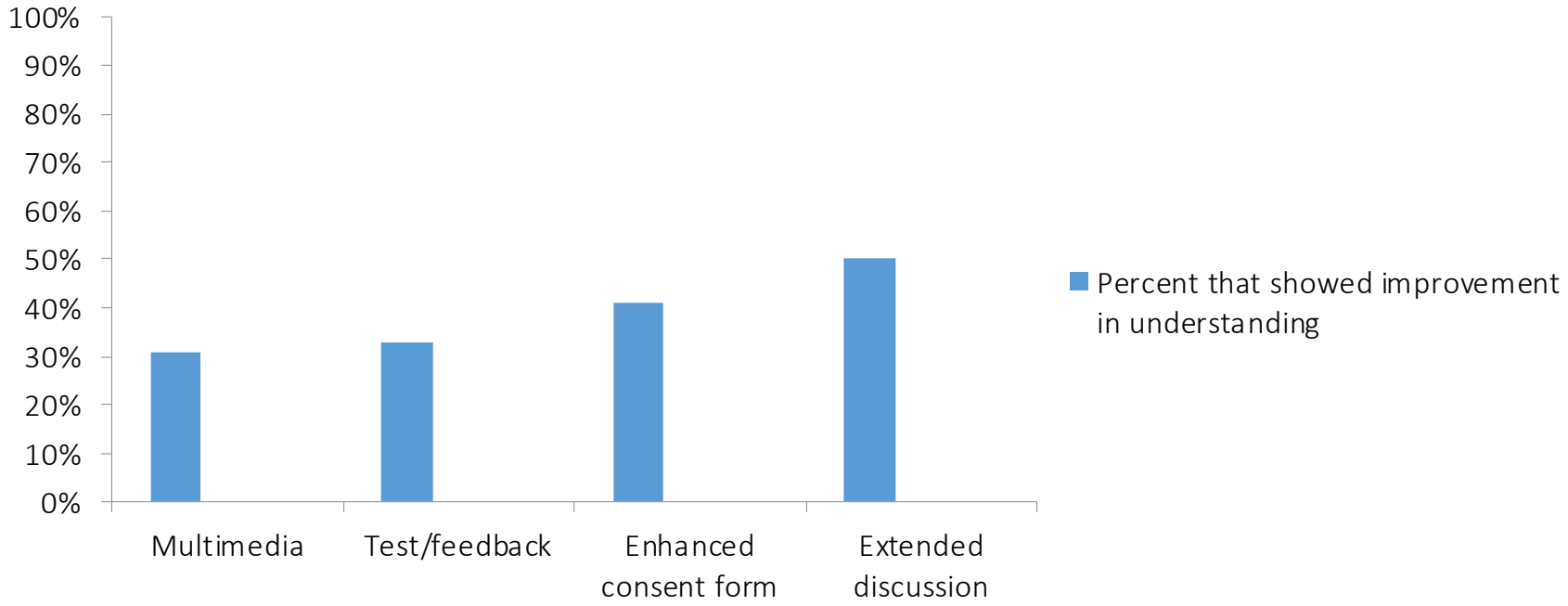
ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Systematic review of participant understanding of consent elements



Nguyen TT et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. *Bull WHO* 2015.

Meta-analysis of interventions to improve understanding



Nishimura et al. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. *BMC Med Ethics* 2013.

Informed consent is hard

- Understanding is limited and hard to improve
- Maybe we need to focus *earlier* in the process
  - Emerging evidence that people decide whether to enroll before receiving consent form
- Systematic, comprehensive look at the overall study design can contextualize the role of informed consent

Eight benchmarks for ethical research

Collaborative partnership	Social value	Scientific validity	Fair participant selection
Favorable risk/benefit ratio	Independent review	Informed consent	Respect for participants and communities

Emanuel et al. What makes clinical research ethical?
JAMA 2000;283:2701-11; *JID* 2004;189:930-37.

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Collaborative partnership

Does the research appropriately partner with the community (in research design, conduct, oversight, implementation, etc.)?

Improves research quality:

- Transparency and buy-in
- Understanding community needs

Who is the relevant community?

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Social value

Will the research lead to improvements in health or generalizable knowledge?

Limited social value includes:

- Unimportant questions
- Non-generalizable research
- Non-disseminated findings

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Scientific validity

Is there a reasonable possibility the research will produce valid scientific results?

Necessary to justify:

- Resources used
- Risks and burdens undertaken by participants

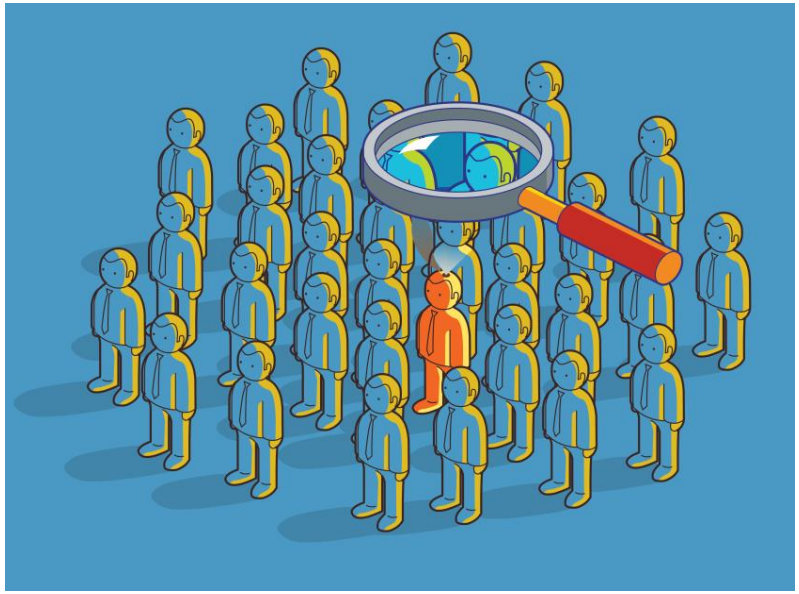
ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Fair participant selection

Are the study's scientific objectives, not vulnerability or privilege, guiding inclusion criteria and targeted populations?

Consider distribution of burdens and benefits of research:

- Burden → need protection
- Benefit → need access



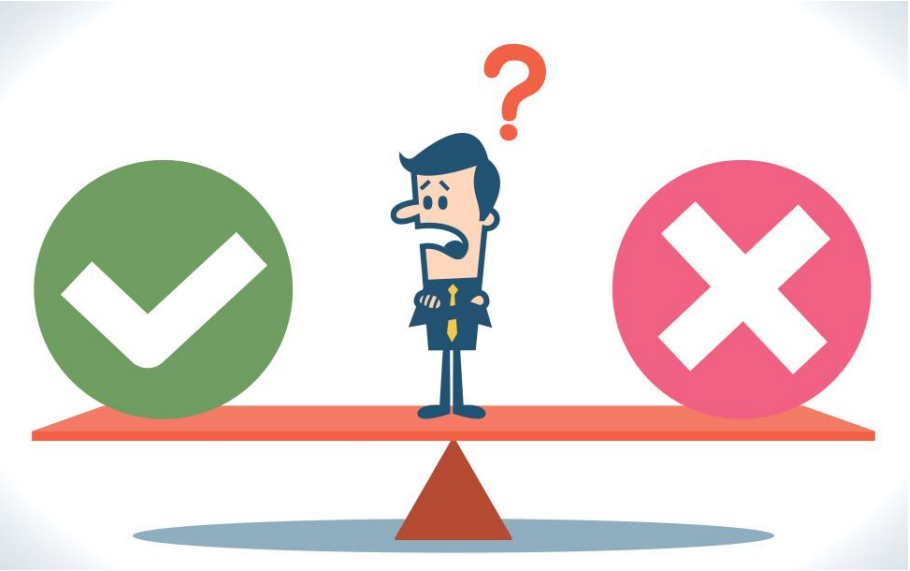
ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Favorable risk/benefit ratio

Does the research minimize risks and maximize benefits?

If benefits > risks to individual, proceed

If risks > benefits to individual, societal benefit must justify net risk



ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Independent review

Has the study been reviewed by an independent body?

Minimizes impact of potential conflicts of interest

Assures society that research is ethically appropriate

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Informed consent

Has the participant made an informed decision about whether to take part?

Some research can be ethical without all elements of consent

Serves multiple functions: control, transparency, trust, values concordance

Respect for participants and communities

Is the research team treating participants with respect throughout the study?

Obligations may include:

- Confidentiality
- Right to withdraw
- Compensation for injury
- Sharing results

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

What does respect mean to participants?

- Personal study team interactions
- Study communication processes
- Inclusion
- Consent and authorization

"For me, it comes down to how they treat me. They don't treat me like a patient. They don't treat me like a number. They treat me like a person."

Personal study team interactions

"Having the research staff person check in and really make sure that I was understanding everything … just having that awareness of nonverbal cues that might indicate that I'm not sure about things or don't really want to participate."

"They take their time with people, at least in my case; that they've always treated me well. They speak to me in my language, which is Spanish, and for that I thank them very much."

Conclusions

- "Traditional" informed consent and IRB review are important, but not sufficient – and imperfectly realized
- Eight benchmarks can help systematically identify issues that need attention – but balancing is often necessary
- Research staff have a critical role in embodying respect for persons

Case study

You are a study coordinator recruiting and consenting parents via Zoom for a study about childhood vaccines. You are talking with a single mom who says she wants to join the study but is very distracted by multiple young children during the call and doesn't seem to be paying full attention, but she says her wifi is bad so she may not be able to connect later. You are not sure if you should consider her to have given informed consent, if you should try again later, or if you should mark her as unavailable on your list.

What benchmarks are at play?

Case study

You are a research nurse working with a PI to design the protocol for a Phase III RCT for a new COVID-19 treatment. You are discussing whether the study should ask participants to collect daily nasal swabs for 30 days versus less frequent swabbing. Doing more swabs would provide more data, but it might be burdensome for participants and people might return invalid samples or even quit the study if the process is too onerous.

What benchmarks are at play?


Questions?
stephanie.kraft@seattlechildrens.org
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.


Introduction to Clinical Research
Boot Camp 2020
SEE YOU TOMORROW!
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.