



# NED 2025

Networking to Enhance Development

**ITHS**

Institute of Translational Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.



# NED 2025

## A RELATIONSHIP-BASED FRAMEWORK FOR CLINICAL RESEARCH: Ethical Considerations Beyond Informed Consent

**Kate MacDuffie, PhD MA**

Associate Director of Research

Treuman Katz Center for Pediatric Bioethics & Palliative Care,

Seattle Children's Research Institute

Assistant Professor, UW SOM Department of Pediatrics

# Outline

- Research ethics: where have we been and where are we going?
- Informed consent and its challenges
- Benchmarks for ethical clinical research
- A deep-dive on respect and the importance of contextualizing research
- A framework for building trusting research relationships

# Origins of research ethics guidelines

Guidelines for ethical research are largely reactive to egregious human rights violations

- Nuremberg Trials → Nuremberg Code (1947)
- US Public Health Service syphilis study at Tuskegee → Belmont Report (1979)

# Nuremberg Code, 1st principle

“The voluntary consent of the human subject is absolutely essential.”

# The Belmont Report

“Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.”

# Research ethics today

- Not just about preventing egregious violations
- Offers guidance and tools to:
  - identify potential pitfalls
  - prevent unjustified or unnecessary harm
  - improve equitable research practices
- Elaborates upon responsibilities above the regulatory floor

# The future of research ethics

- New challenges – e.g., big data, open science, artificial intelligence
- Ethical issues arise at all stages of a study
  - Study design
  - Recruitment/consent
  - Data collection
  - Analysis
  - Dissemination
- Team science requires team ethics
  - All team members should feel empowered to identify and address ethical issues

# Questions to think about

- Have you ever faced an ethical issue in your research?
  - If so – did you bring it up? To whom? What made it easier or harder to have those conversations?
  - If not – are there ethical issues you anticipate coming up for you? Are there topics or issues you are thinking about how to incorporate?
- How do you see your role in identifying and resolving ethical issues?
  - How has your role evolved over time?

# Research ethicists here to help!

## Director

Katie Porter, JD,  
MPH



## Consultant/ Coordinator

Devan Duenas,  
MA



## Consultant

Kate MacDuffie,  
PhD, MA



## Consultant

Holly Vo, MD,  
MPH, MSc, MA



## Consultant

Elliott Weiss,  
MD, MS



## Consultant

Benjamin  
Wilfond, MD



[ITHS](#) › [Investigators](#) › [ITHS Research Services](#) › [Research Ethics Consultation Service](#)

## Research Ethics Consultation Service

The Research Ethics Consultation Service is supported by Seattle Children's Research Institute and the Institute of Translational Health Sciences (ITHS).

Our research ethics consultants offer advice to researchers, research staff, personnel involved in protection of human subjects, and research participants who have questions about any aspect of a research study. We assist when there are ethical issues that could benefit from in-depth conversation and analysis related to the development, implementation or analysis of clinical and translational research.

Research ethics consultants are all members of the Treuman Katz Center for Pediatric Bioethics and Palliative Care.

+

[Examples of Consultation Questions](#)

-

[Request a Consultation](#)

[REQUEST A CONSULTATION](#)

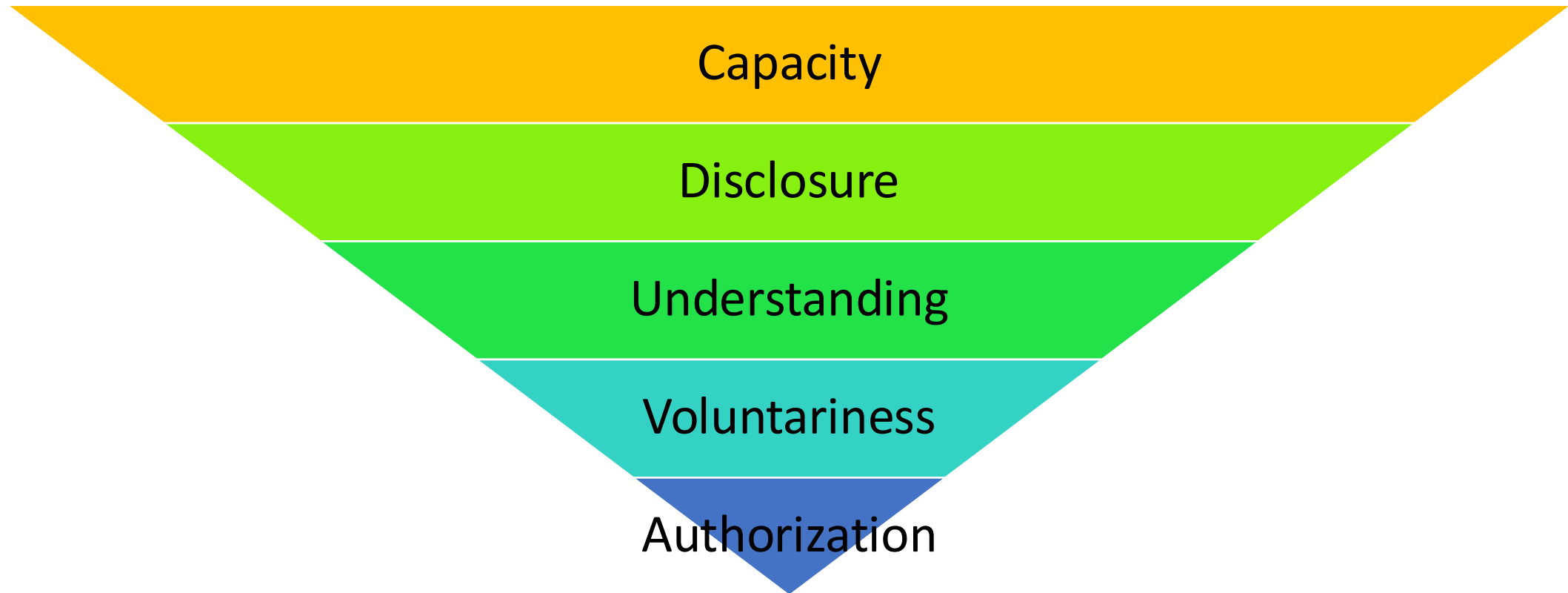


**ITHS** | Institute of **Translational** Health Sciences  
ACCELERATING RESEARCH. IMPROVING HEALTH.

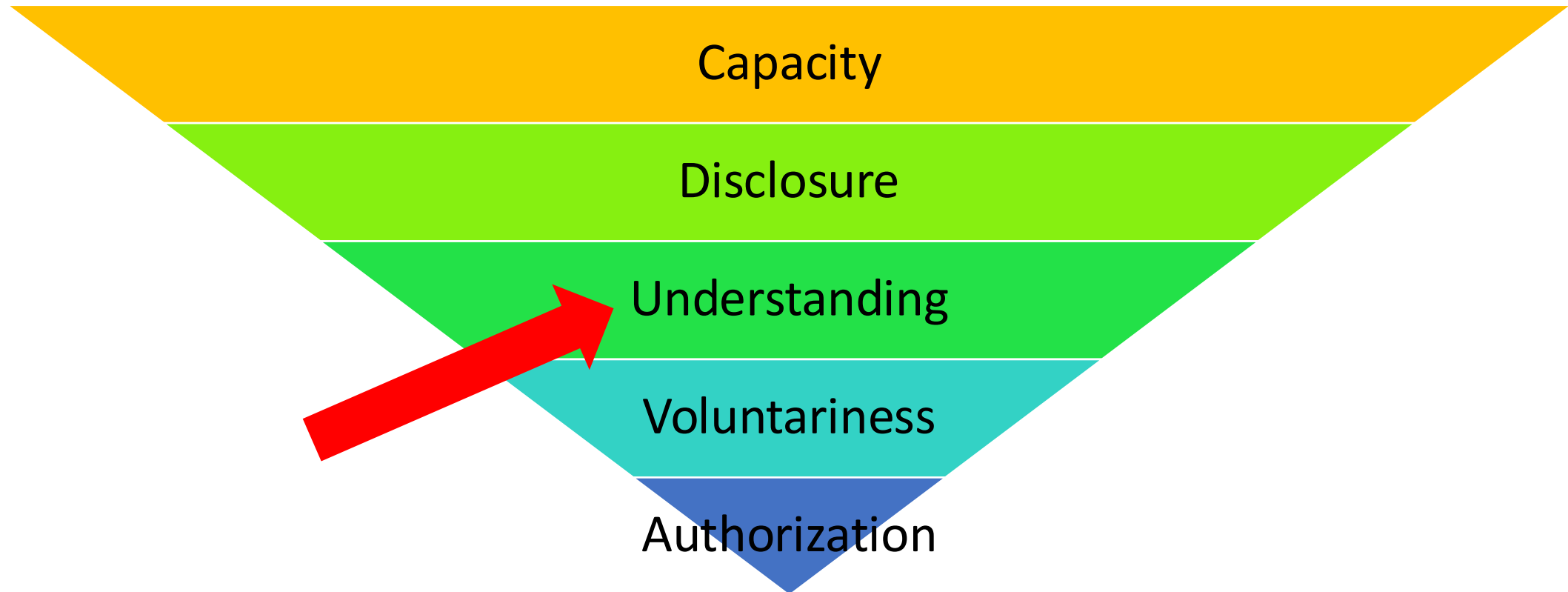


CartoonStock.com

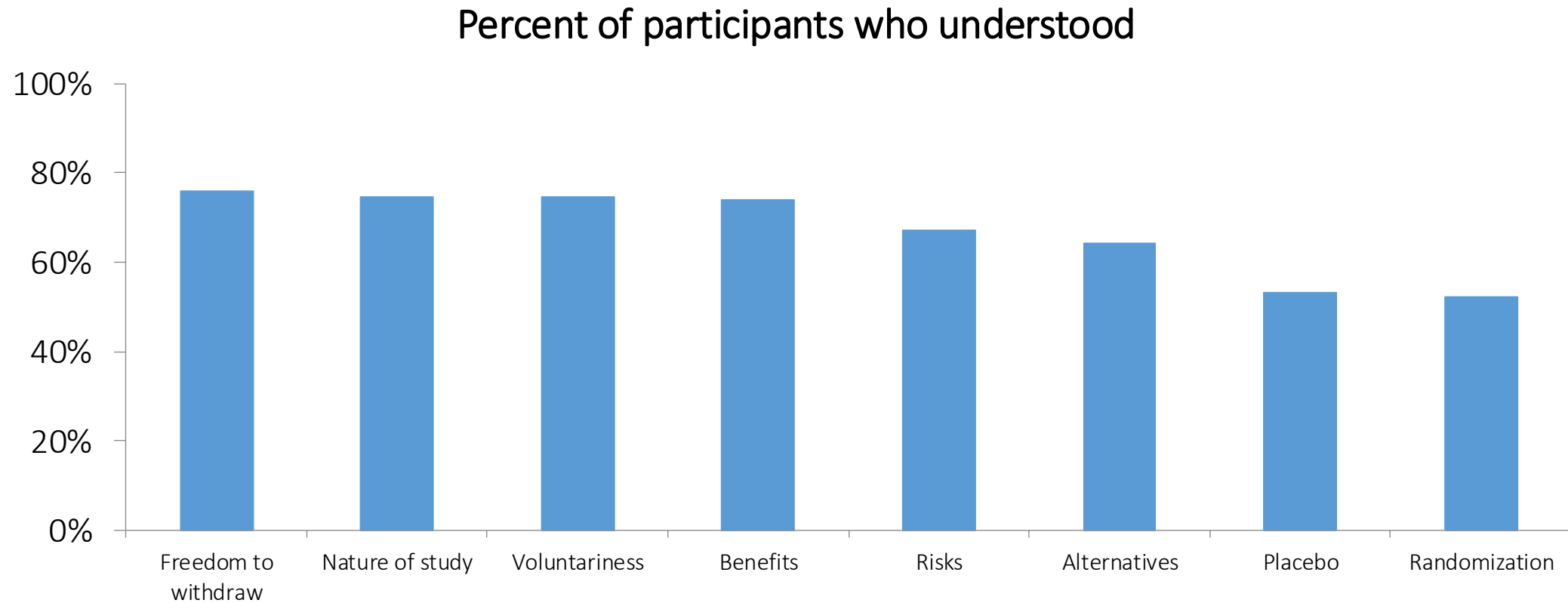
# Five elements of informed consent



# Five elements of informed consent



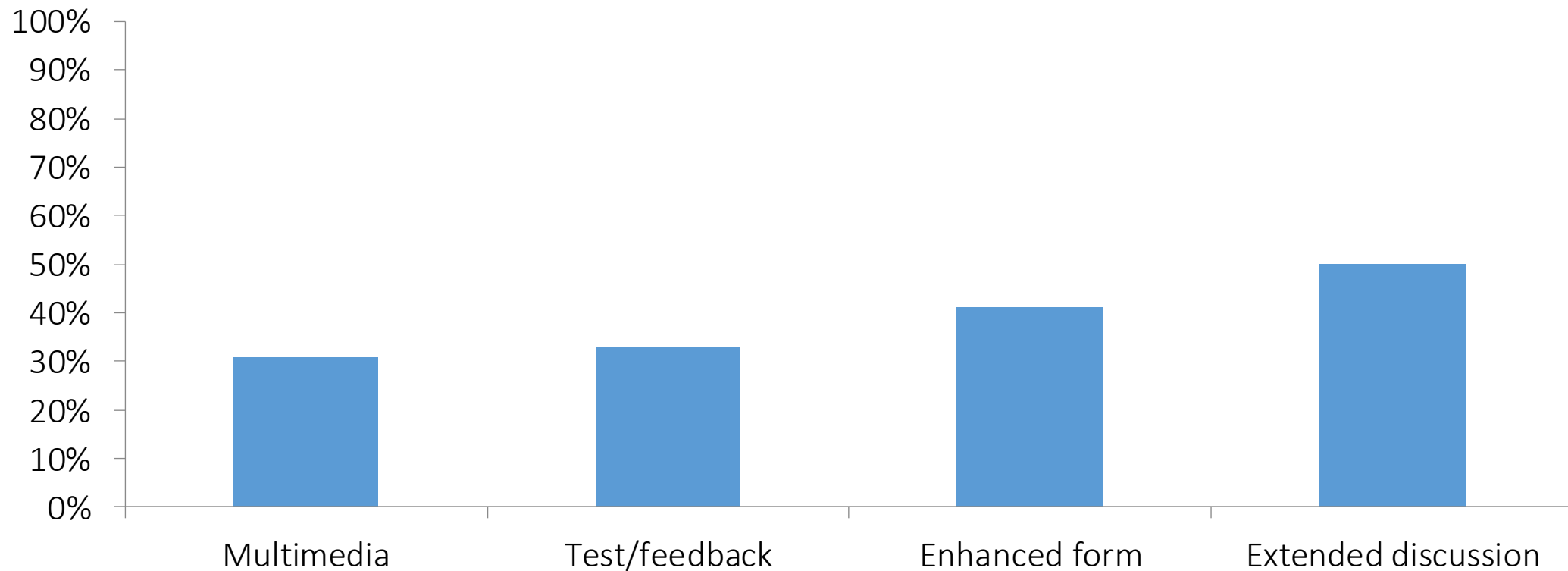
# Understanding of consent elements



Nguyen TT et al. *Bull WHO* 2015.

# Interventions to improve understanding

Percent that showed improvement in understanding



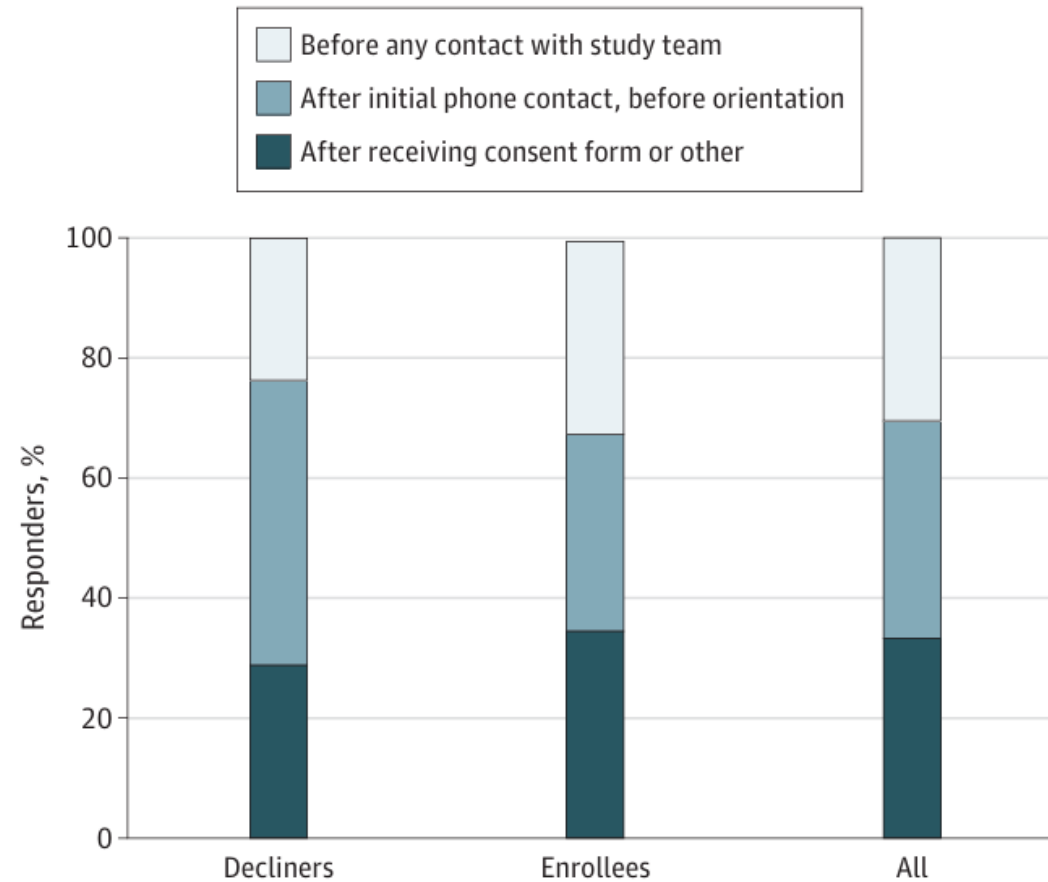
Nishimura et al. *BMC Med Ethics* 2013.

# Informed consent is hard

- Understanding is limited and hard to improve
- Discussions with study team can help
  - Do we give consenters the tools to have these discussions?
- Maybe we need to focus *earlier* in the process
  - Decisions may start with initial outreach and study team conversations

# When do people decide about research?

Figure 2. Timing of Enrollment Decision



# Contextualizing the research interaction



Health and  
health care



Finances



Society

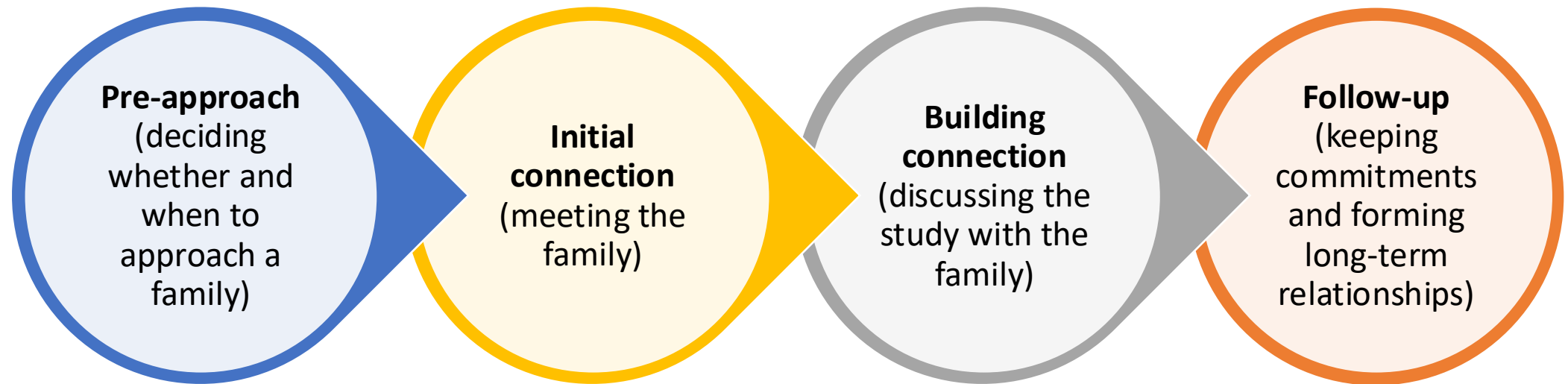


Culture



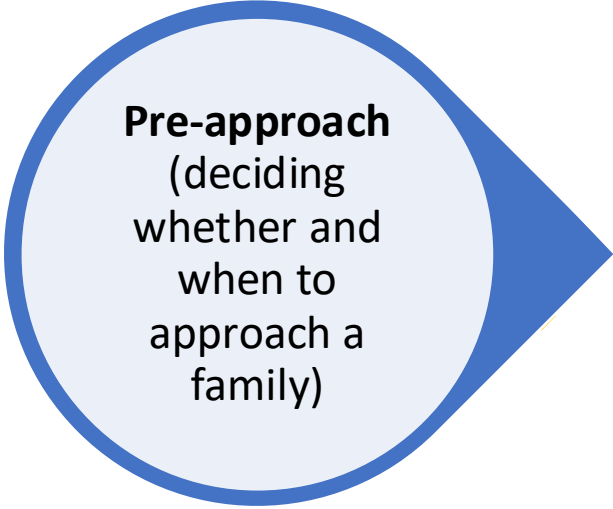
Relationships

# 4-stage relationship-building process



# 4-stage relationship-building process

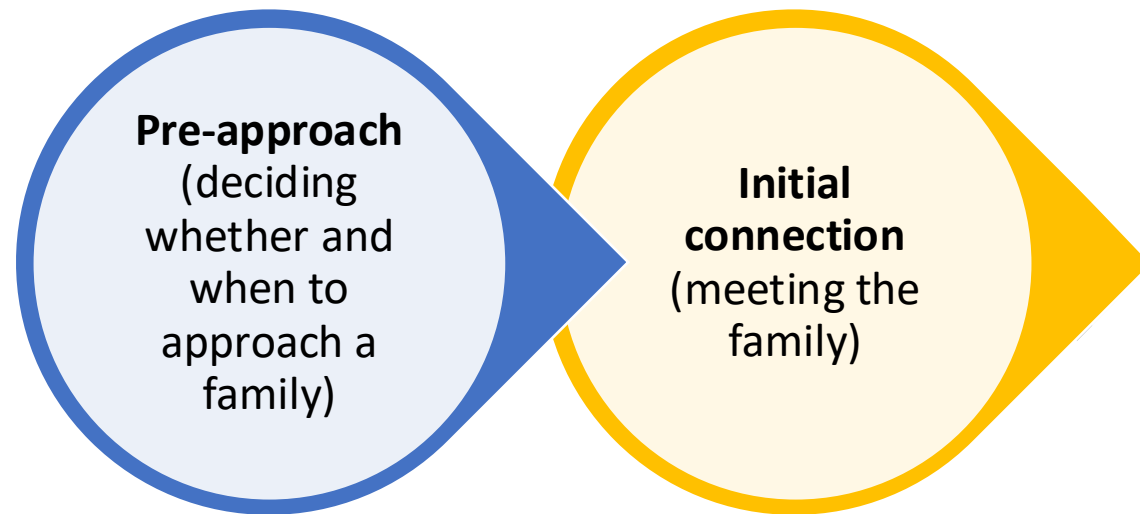
*“I will not go in, and and this will be usually the nurse or the clinical team will tell me, if a patient is getting upset, ‘cause these can be long days for parents...”*



**Pre-approach**  
(deciding  
whether and  
when to  
approach a  
family)

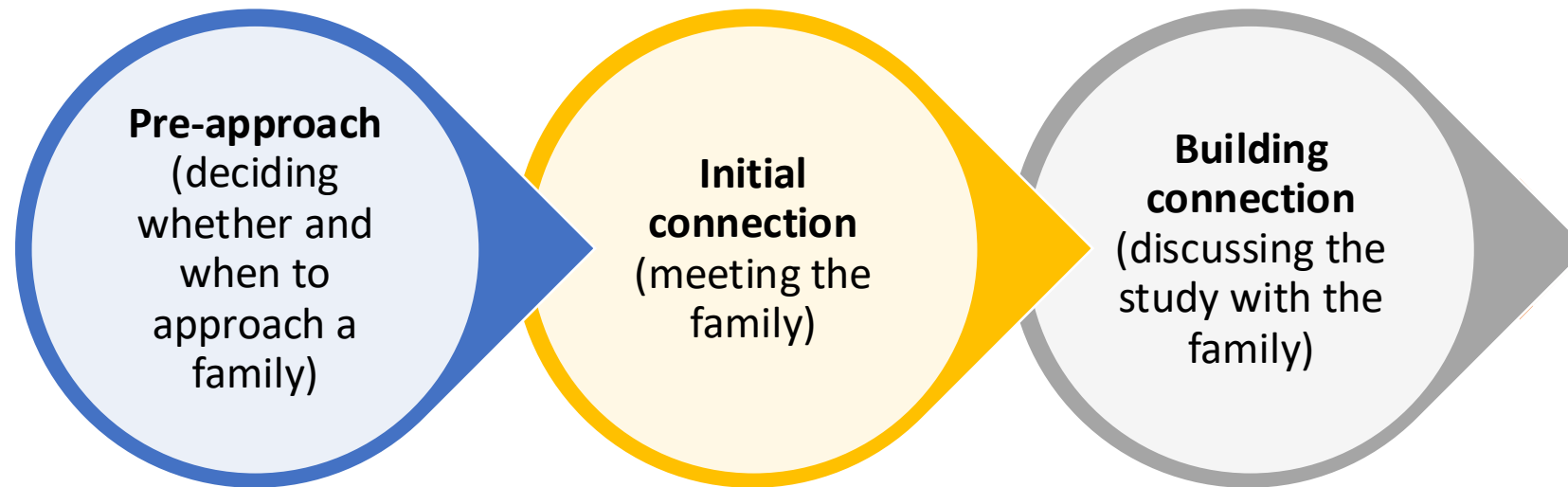
# 4-stage relationship-building process

*“I think it’s important for them to understand who you are and what you are there to do. You don’t just want to jump right into the spiel about the study. I think they first need to understand what is it really that you may need from them.”*



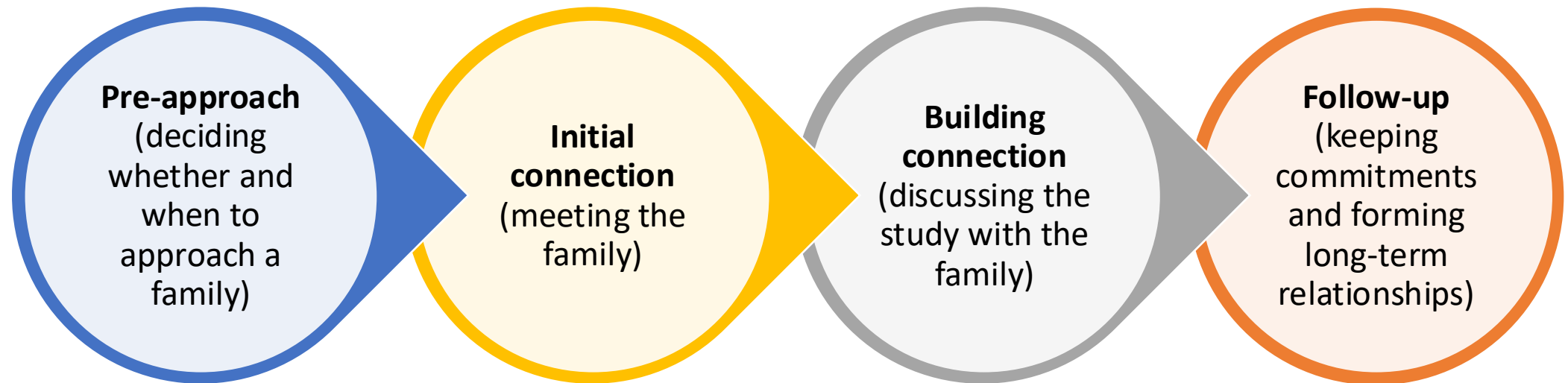
# 4-stage relationship-building process

*“I also think flexibility can be a way of showing respect. Our patients and families have different needs at different times... I’m happy to meet with a family on a weekend, or in the evening, if that works better for them, or I can schedule a pick up for study materials.”*

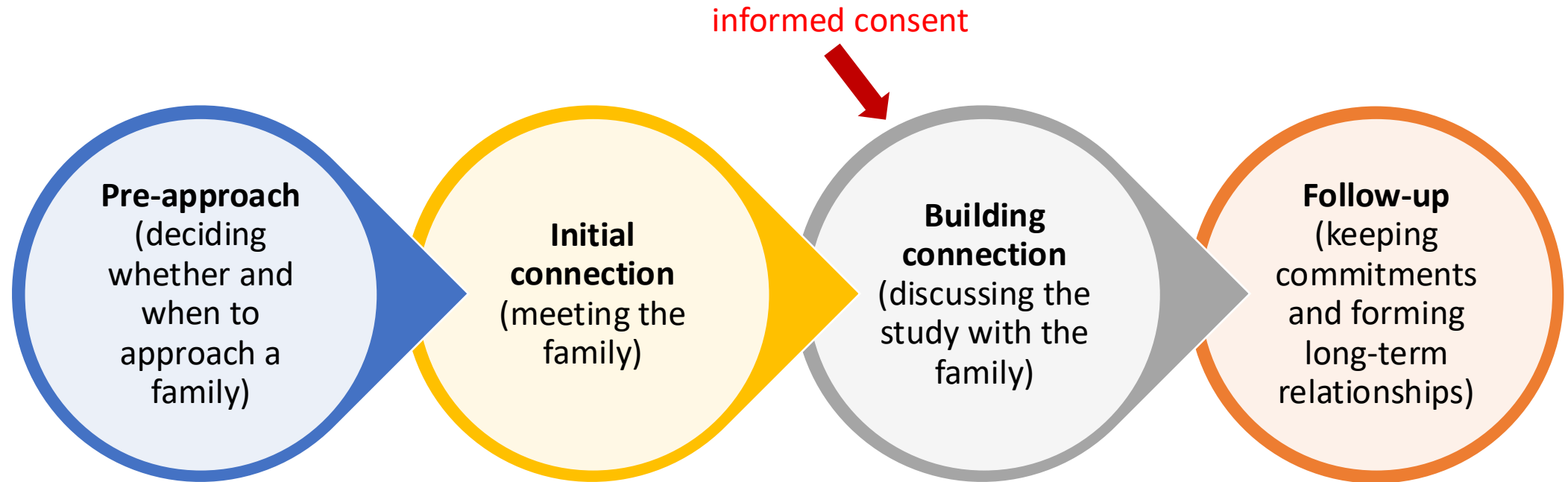


# 4-stage relationship-building process

*“We’re not the folks who have necessarily all the answers all the time, and so my approach to that is essentially letting them know, ‘You know, that is a great question. Let me go ahead and follow up with whoever is the applicable person,’ and then at that point follow up with them and let them know.”*



# 4-stage relationship-building process

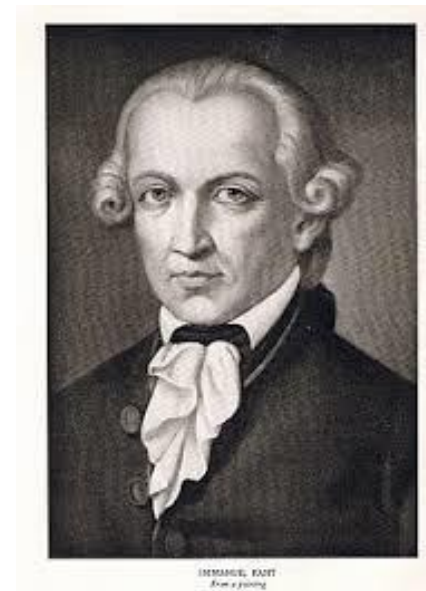


# Bite-sized philosophy lesson

**TREAT PEOPLE AS  
AN END, AND  
NEVER AS A MEANS  
TO AN END**

*Immanuel Kant*

EST. 2016 | VALOURINE



# Takeaways

- “Traditional” informed consent is important but must be viewed in context
  - As part of the study process
  - As part of the relationship building process
- Focus on building relationships with research participants before, during, and after their participation



**QUESTIONS?**