NIH Collaboratory

Health Care Systems Research Collaboratory

# Collaboratory Coordinating Center

# Ethics Supplement

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Kevin Weinfurt, PhD

# Major Areas of Controversy

- Consent
- Risks and benefits
- Standard of care

# NIH Ethics Supplements

CTSA

(University of Washington & Stanford)

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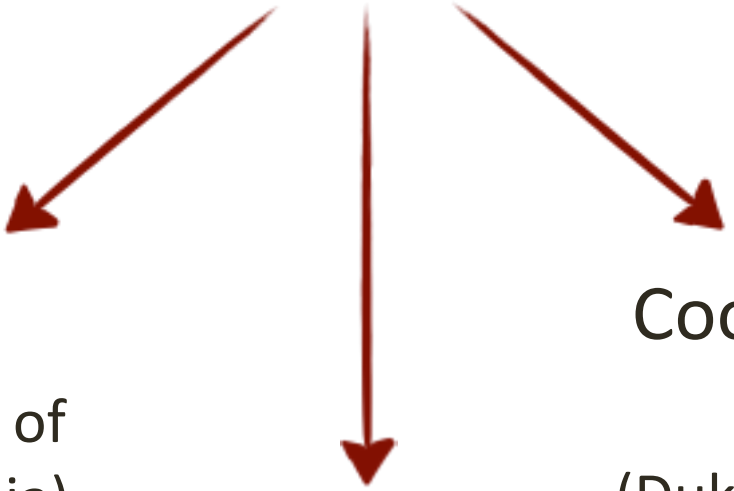


TiME

(University of Pennsylvania)

ABATE

(University of California - Irvine)

Coordinating Center

(Duke & Hopkins)

# Collaboratory Coordinating Center Ethics Supplement Team

- PI: Rob Califf
- Project leads: Jeremy Sugarman and Kevin Weinfurt
- Duke
  - Laura Beskow
  - Kate Brelsford
  - Travis Crayton
- Johns Hopkins
  - Juli Bollinger
  - Matt DeCamp
  - Rachel Dvoskin
  - Nancy Kass
  - Debra Mathews
  - Rachel Topazian

# Overarching Goal

To improve understanding of when and how different stakeholders believe research testing or comparing interventions that are each considered standard of care are acceptable and when traditional or modified approaches to consent for it should be sought.

# Project Aims

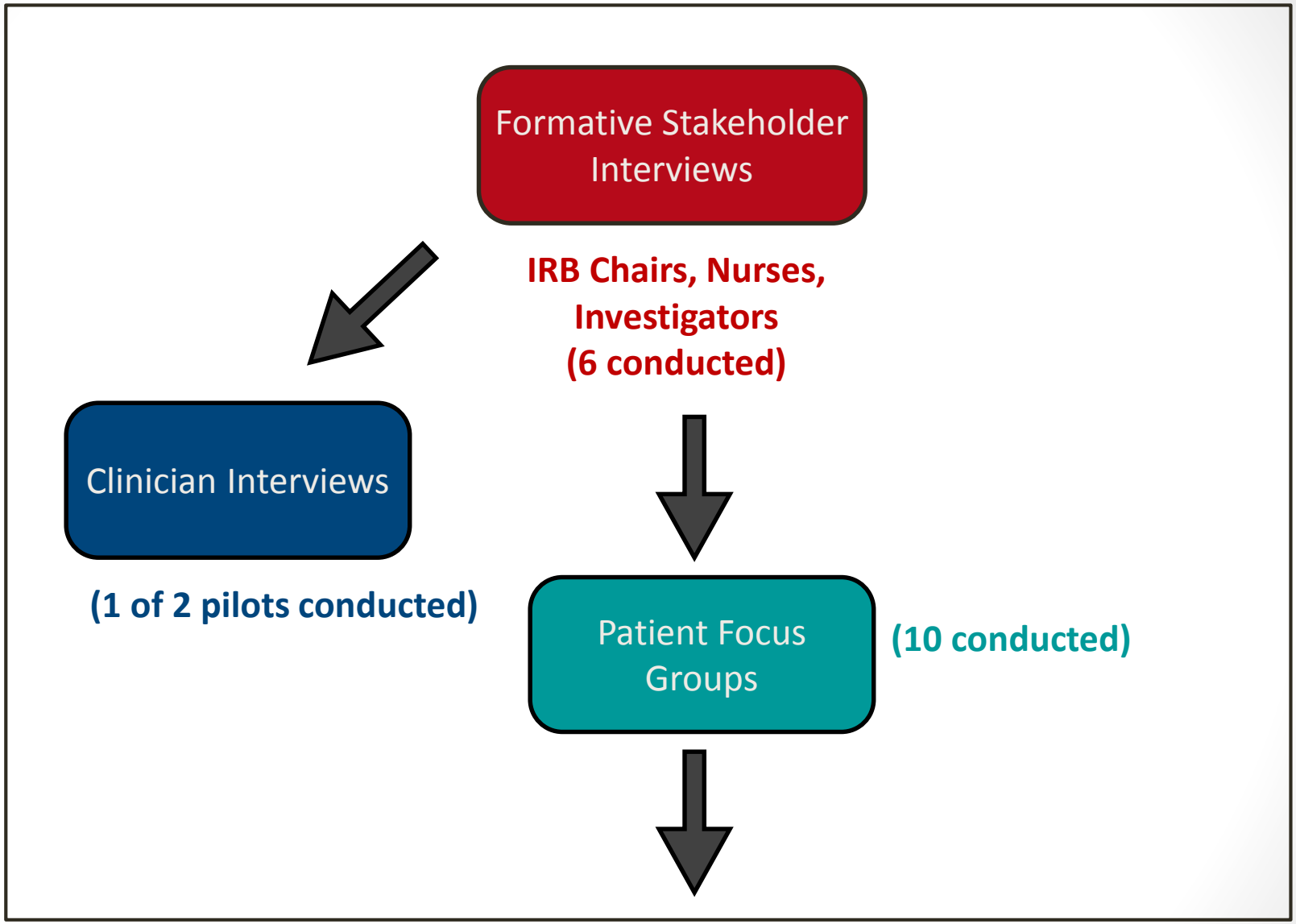
**AIM 1:** Collect rich qualitative data from patients to identify the broad range of attitudes, beliefs, and preferences concerning the need for research in usual care settings and related consent issues.

**AIM 2:** Systematically identify the factors that influence U.S. adults' beliefs concerning research and consent in different usual care situations.

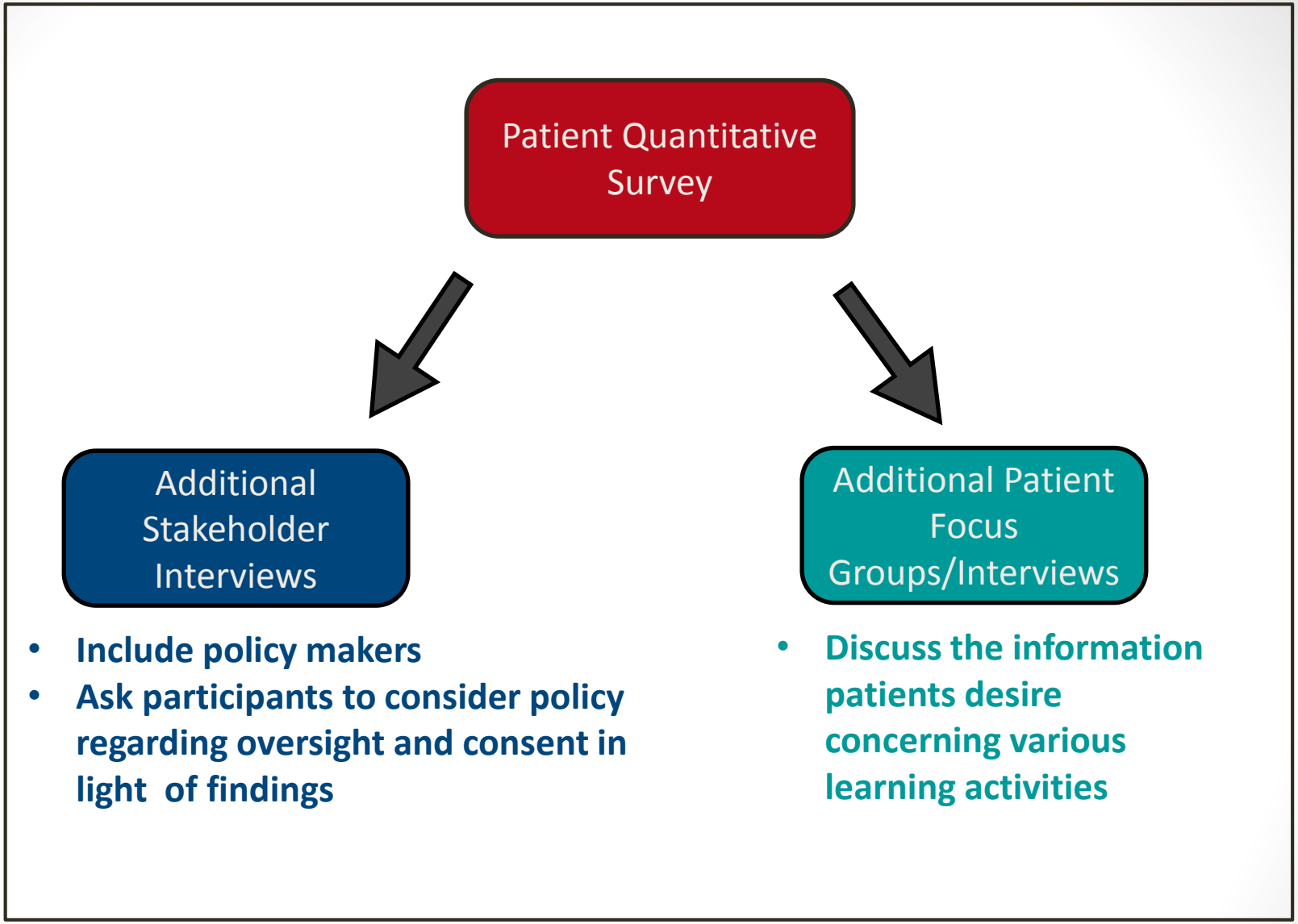
**AIM 3:** Convene a summit meeting to share emerging results and findings from related projects.

**AIM 4:** Elicit stakeholders' views concerning the appropriate models of oversight and consent for research on standard health care practices.

# Year 1


Formative Stakeholder Interviews
IRB Chairs, Nurses, Investigators (6 conducted)
Clinician Interviews
(1 of 2 pilots conducted)
Patient Focus Groups
(10 conducted)

# Year 2




We will convene a summit meeting in consultation with NIH (date TBD)

# CER Focus Groups

# Patient Focus Groups (n = 14)

- Population: general public
- Location
  - Durham, NC
  - Baltimore, MD
  - Washington, DC
  - Chicago, IL (planned)
  - San Francisco, CA (planned)

# Patient Focus Groups: Types & Domains

- Two types of groups:
  1. Comparative Effectiveness
  2. Medical Center Operations & Clinician Education/Support
- Acceptability of four methods of notification/consent:
  - General notification
  - Oral
  - Oral + information sheet
  - Express written consent

# 4 Preliminary Observations

# 1. Acceptability of “equipoise” in the abstract vs *my doctor’s uncertainty*

*. . . but I just would prefer the doctor's opinion and expertise versus just the computer just closing its eyes and saying, "Here, take one."*

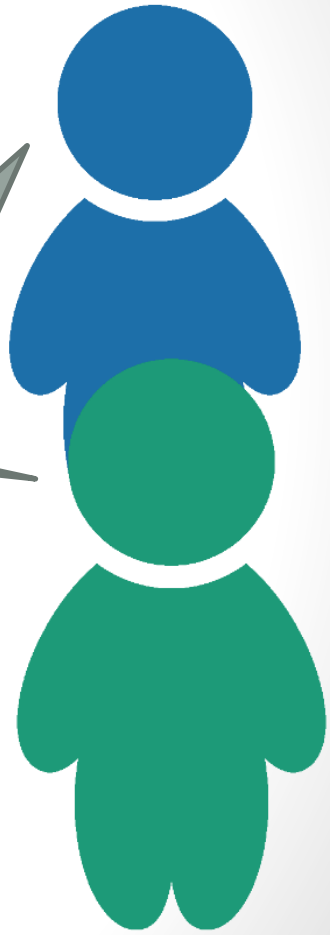
*me another doctor. Because you're supposed to know.*

# 2. Strong associations with "traditional" research interferes with understanding of CER

# 3. Some nuanced appreciation of tradeoffs associated with different notification/consent models

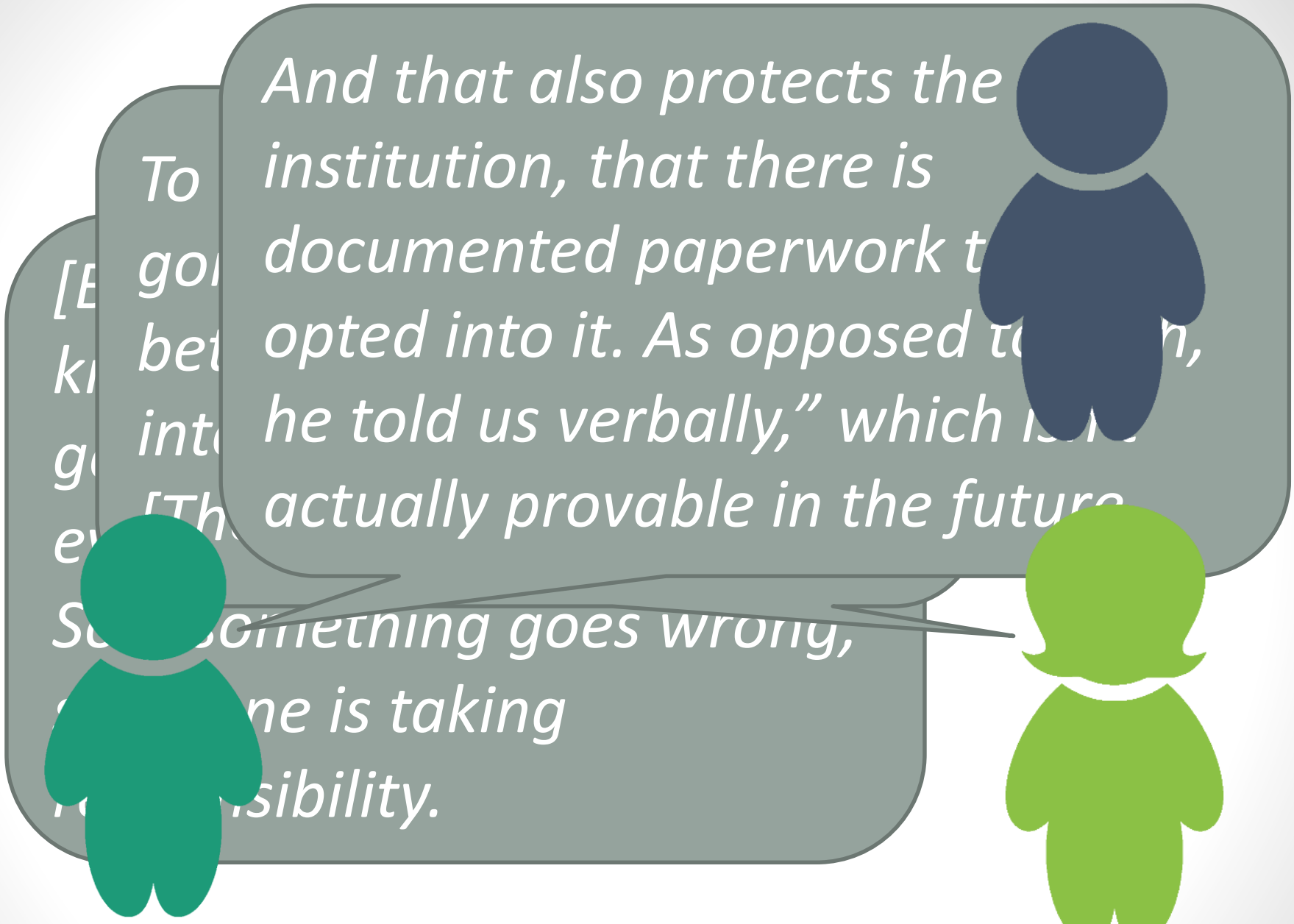
*I don't want to participate in a study to sign my life away but [. . . ] maybe a page or two that this is what this study is, are you good with it? Check yes or no.*

*Because if it is something that is simple, why would it take ten pages to describe it as opposed to the amount of space that is taken up here?*



Rethinking Clinical Trials

# 4. What does signing a consent document mean to people?

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# What would you like to ask the U.S. adult population about all of this?

# Q & A