Save the Date!

ACCORDS & CCTSI Community Engagement Forum

January 28, 2026

12:00-1:00pm MT

Receive advice and guidance on your research project from experienced community members and academics

CCTSI/ACCORDS Community Engagement Consultations

Email Kaylee: Kaylee.Gordon@cuanschutz.edu for more information or to request a consult.

https://www.cuanschutz.edu/cctsi/community/programs

Stay updated by joining our mailing list:
https://ucdenverdata.formstack.com/forms/pact_mailing

CCTSI Community Engagement Pilot Grants

Next RFA Posted November 2025

Email Kaylee: Kaylee.Gordon@cuanschutz.edu for more information.

CE-Pilots: https://cctsi.cuanschutz.edu/funding/cepilot

ICYMI:
watch previous Community Engagement Forums

https://medschool.cuanschutz.edu/accords/educational-offerings/archive/seminar-series-(2025---2026)

What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a ‘one-stop shop’ for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally

ACCORDS Upcoming Events – mark your calendars!

November	• November 4 & 6 – Introduction to Qualitative Research Workshop
December	• December 8 – ACCORDS Highlights
January	• January 12 – ACCORDS Grand Rounds, Bethany Rose-Daubman, MD • January 15 – D&I Science Graduate Certificate application launch • January 28 – ACCORDS/CCTSI Community Engagement Forum
March	• March 9 – ACCORDS Highlights
April	• April 8 & 9 – ACCORDS D&I Science for Researchers Workshop
May 20-21, 2026	Colorado Pragmatic Research in Health Conference *Pragmatic Outcomes Research: Methods, Tools, and Technology for Rapidly Changing Contexts*

Ethical Data Practice: From Storage to Sovereignty - Introduction

Alison Lakin, RN, LLB, LLM, PhD

Associate Vice Chancellor
Regulatory Compliance

October 22, 2025

Denver | Anschutz

GOALS

Topics

- Key Regulatory Definitions
- What is the impact of all these regulations?
- How do you **still** do meaningful community engaged research?

Why is there inconsistency in approach to research?

Challenges:

- Each research project is different
- Interpretation of regulations can vary
- Regulations change/technology changes
- The regulations are general in nature so need to be applied to the specifics
- Researchers and Community Partners can have varying experience in research
- Researchers and Community Partners may have similar but different goals or priorities

Definitions

What is an Institutional Review Board

An Institutional Review Board

- An independent committee consisting of scientists, non-scientists and community members
- Required for any institution receiving federal funds for research involving participants
- It strives to protect the rights, safety and welfare of individuals participating in research protocols
- Ensures compliance with ethical standards and regulations before and during studies

What does the term ‘Engaged in Research’ mean?

‘Engaged in Research’ is a regulatory term to define:

Institutions or individuals that are required to follow certain regulations because of the nature of their role in a research protocol. You are engaged if you:

1. Obtain data about participants through **intervention** or **interaction** with them,
2. Obtain **identifiable** private information about the participants or
3. **Obtain** informed consent from potential participants for research.

What is left?

Active roles in a research study that do not trigger these regulations include:

- Recruitment activities
- Use of space
- Involvement in research design
- Conduct activities that are not for research
- Analysis of **de-identified or** potentially **coded** data
- Review of aggregate data results
- Assisting with the writing of a research paper or sharing the results

Why does it matter?

If you are considered to be engaged then:

The institution must register a FWA or Federalwide Assurance which means that they certify that they agree to:

- Follow the research regulations that apply and are subject to IRB oversight
- All individuals conducting these activities must be trained on the regulations and follow them
- All individuals must follow the protocol and consent as written and cannot deviate
- The activities may be audited for compliance

It may make sense especially in a long-term partnership

Data Descriptors associate with HIPAA

HIPAA
COMPLIANCE
Health Insurance Portability
and Accountability Act

Regulations: **Privacy, Security and Breach Notification**

Only applies to hospitals and clinics or health billing – “**covered entities**”

Protected Health Information: Name, address plus health information

Limited Data Set – includes dates, birth dates and zip codes (HIPAA still apply)

Coded: A link to maintain a connection between identifiable and de-identified data (HIPAA may still apply depending who has code)

De-identified: Personal information has been removed (not subject to HIPAA)

It is not all about HIPAA:

Other important data types to consider:

Aggregate Data – summary data

Personal Data – Any information linked to a specific individual

Sensitive Data – Any information that may increase risk to the data owner

Data Ownership v Data Stewardship v Data Governance

Data Ownership	Data Stewardship	Data Governance
Participant – provides limited rights to research institutions under consent / authorization **Federally funded** – research data owned by institution funded **Industry funded** – research data owned by industry sponsor	Hands on role that ensures that the data governance policies are implemented and followed	Provides the framework that guides data management practices across the collaboration and ensures compliance with applicable regulations

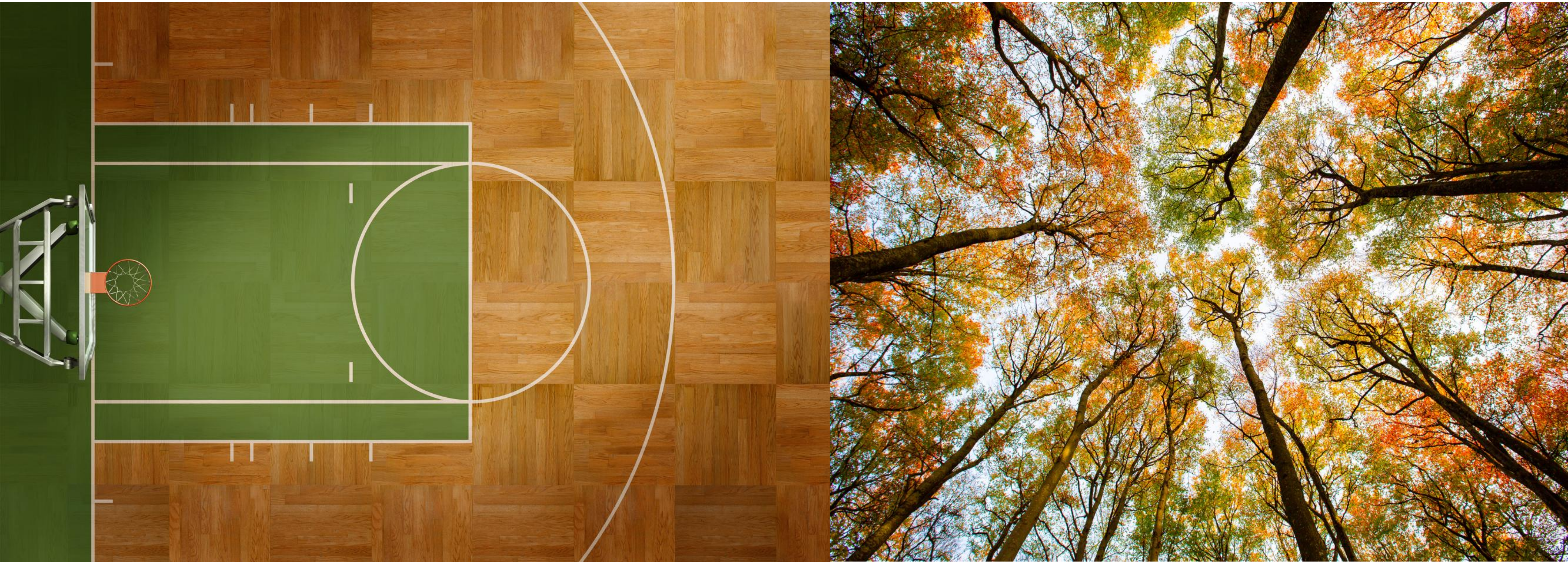
What is the impact of all these regulations?

Perpetual Halloween – FEAR!!!!

Research is complicated

- Further limited by time and money
- Know the data set to be collected and the specific regulations that apply
- Communicate with all partners about expectations - be creative and thoughtful to develop a strategic approach
- Bring in expertise as needed to navigate

Regulations are the floor not the ceiling



Lots of flexibility to do what is 'right'

Before **grant submission** or **IRB review** bring in community partners early to consider the research project from different perspectives:

- There are other risks and benefits that may be important for the specific research project – so be clear on the data collection
- Plan and design the study to answer the research question but also be feasible to operationalize. This involves collaboration and compromise.
- Plan data storage, access and dissemination early – understand priorities

Don't use IRB approval as an excuse – protocols can always be amended

How do you still do research that engages meaningfully with the community?

The importance of Planning

- Plan early and budget thoughtfully so can meet all obligations
- Partnership and Trust – ensure agreed data security and data access plan
- Realistic study design and timeline – ensure consent/authorization lists key parties who may see data
- Understand the priorities of all key parties –ensure data collection meets the needs
- Clear and continuous communication as data challenges develop
- Data governance
- Dissemination plan
- Long term data storage

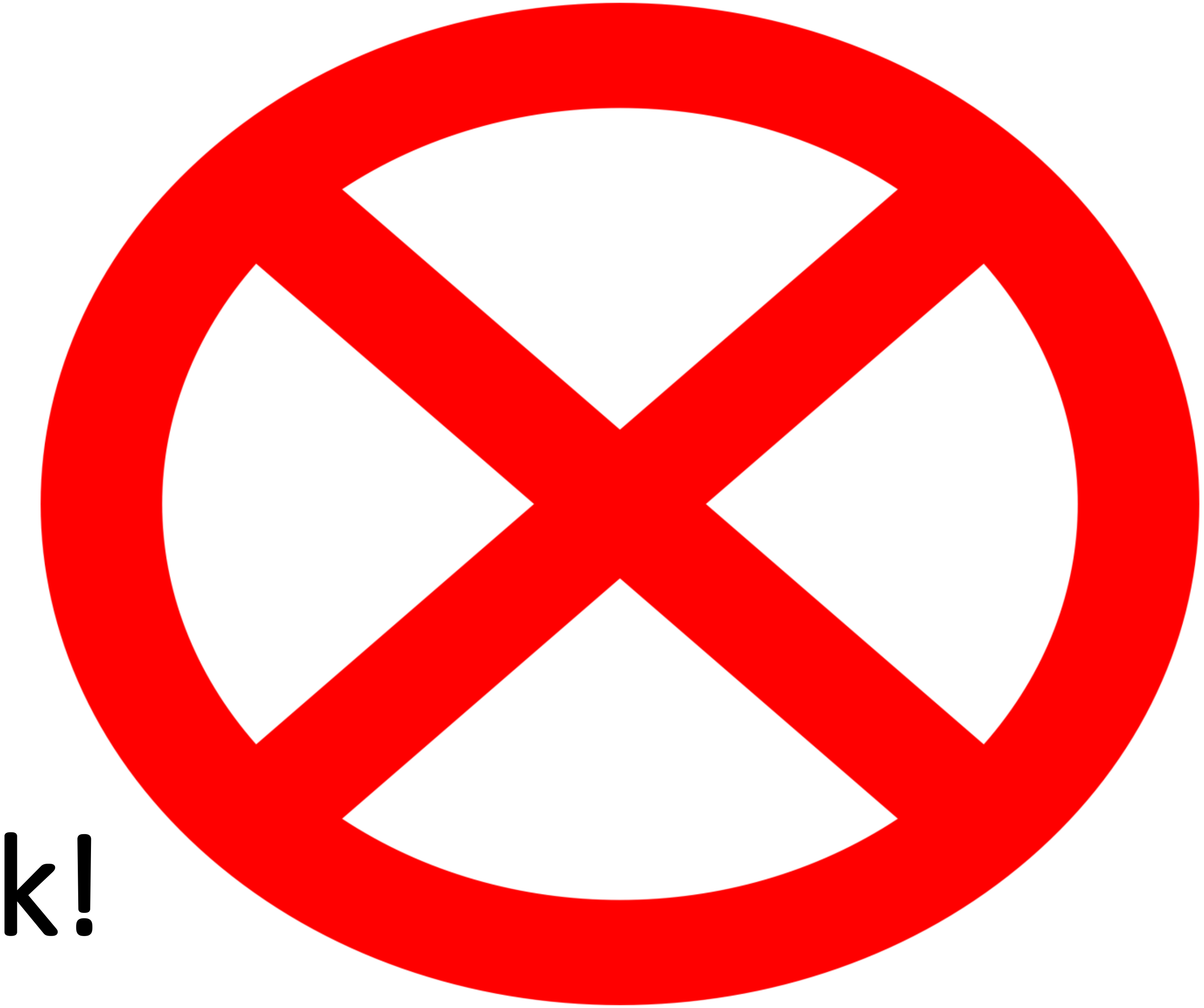
Dissemination of Results

- Individual health related results provided to each participant
- Unexpected health related results for individual participant
- Study results dissemination to the academic community
- Study results to the participants involved in the study
- Study results to the local community impacted by the research results
- Study results to the public in general

Don’t allow the regulatory framework to be a barrier

There is usually a feasible solution

Just Ask!



THANK YOU

research.cuanschutz.edu

CO-CEAL Community Paper

Zachary Giano; Don Nease; Charlene Ortiz; Susan Moore

CO-CEAL Community Paper

- Main Goal: Submit and publish a manuscript with CO-CEAL Results
  - In conjunction with CO-CEAL Community partners
    - Data collectors, community liaisons, CU academic partners, etc…

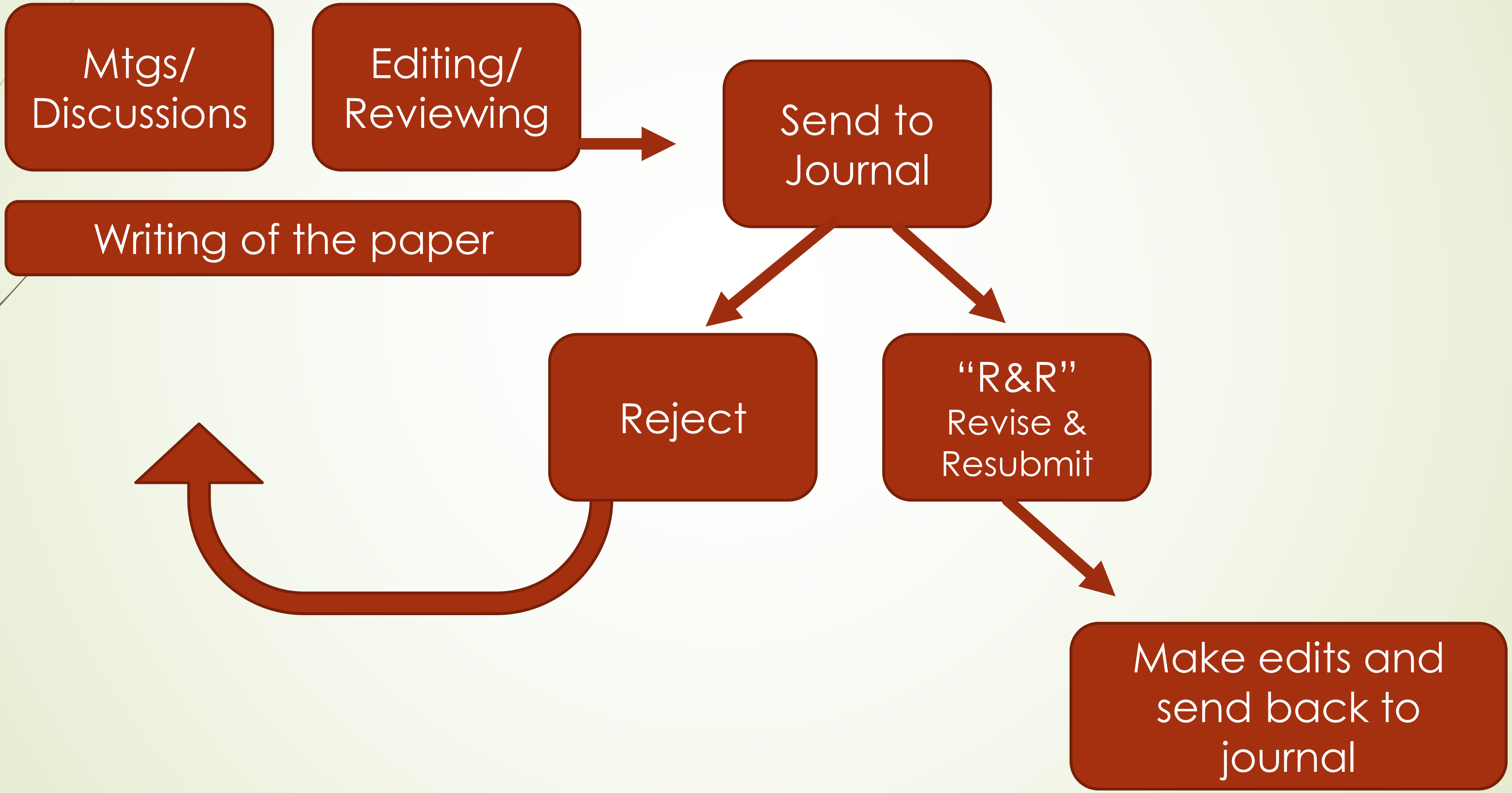
Model:

Evaluation Team Runs Analyses

Approval by internal CO-CEAL Team

Initial e-mail with video explanation

Example from video:



Mtgs/ Discussions

Editing/ Reviewing

Writing of the paper

Send to Journal

Reject

"R&R" Revise & Resubmit

Make edits and send back to journal

Example from video:

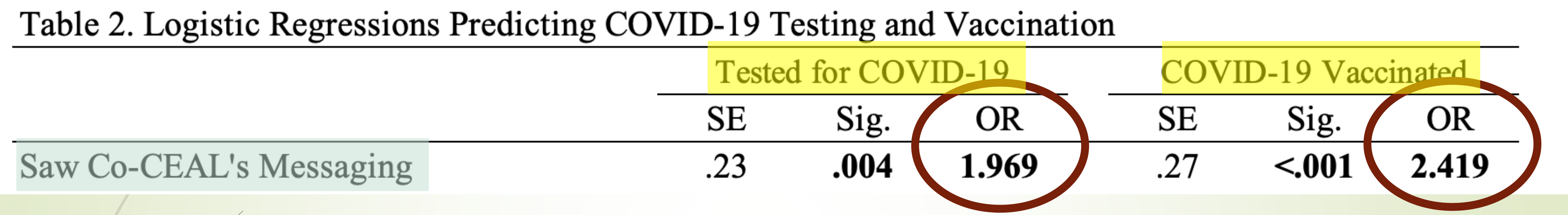
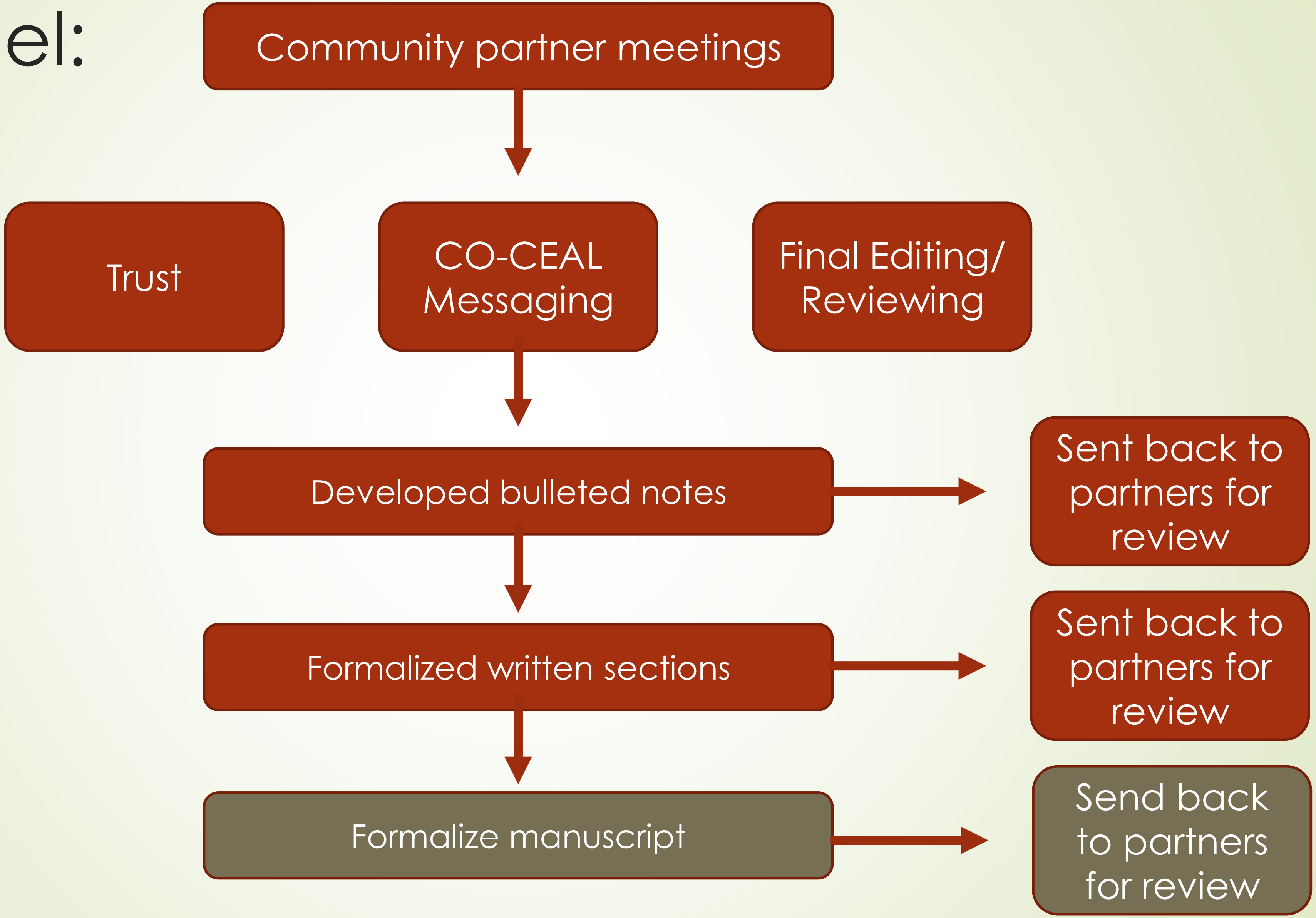


Table 2. Logistic Regressions Predicting COVID-19 Testing and Vaccination

	Tested for COVID-19			COVID-19 Vaccinated		
	SE	Sig.	OR	SE	Sig.	OR
Saw Co-CEAL's Messaging	.23	**.004**	**1.969**	.27	**<.001**	**2.419**

- Those who saw Co-CEAL’s messaging were almost twice as likely to get tested for COVID-19
- Those who saw Co-CEAL’s messaging were almost 2.5x as likely to get vaccinated for COVID-19

Model:



Community partner meetings

Trust

CO-CEAL Messaging

Final Editing/ Reviewing

Developed bulleted notes

Sent back to partners for review

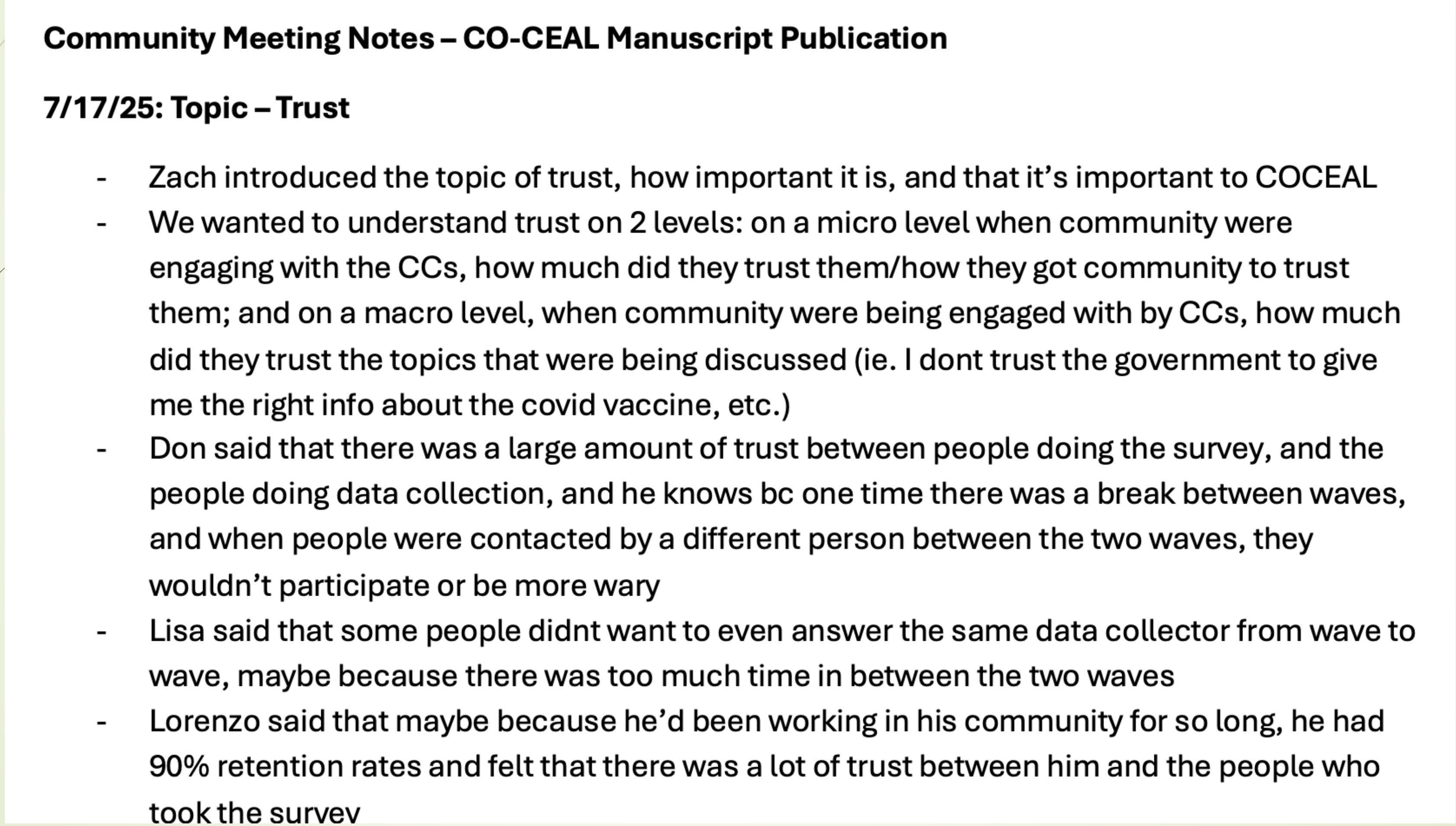
Formalized written sections

Sent back to partners for review

Formalize manuscript

Send back to partners for review

Example: Meeting notes

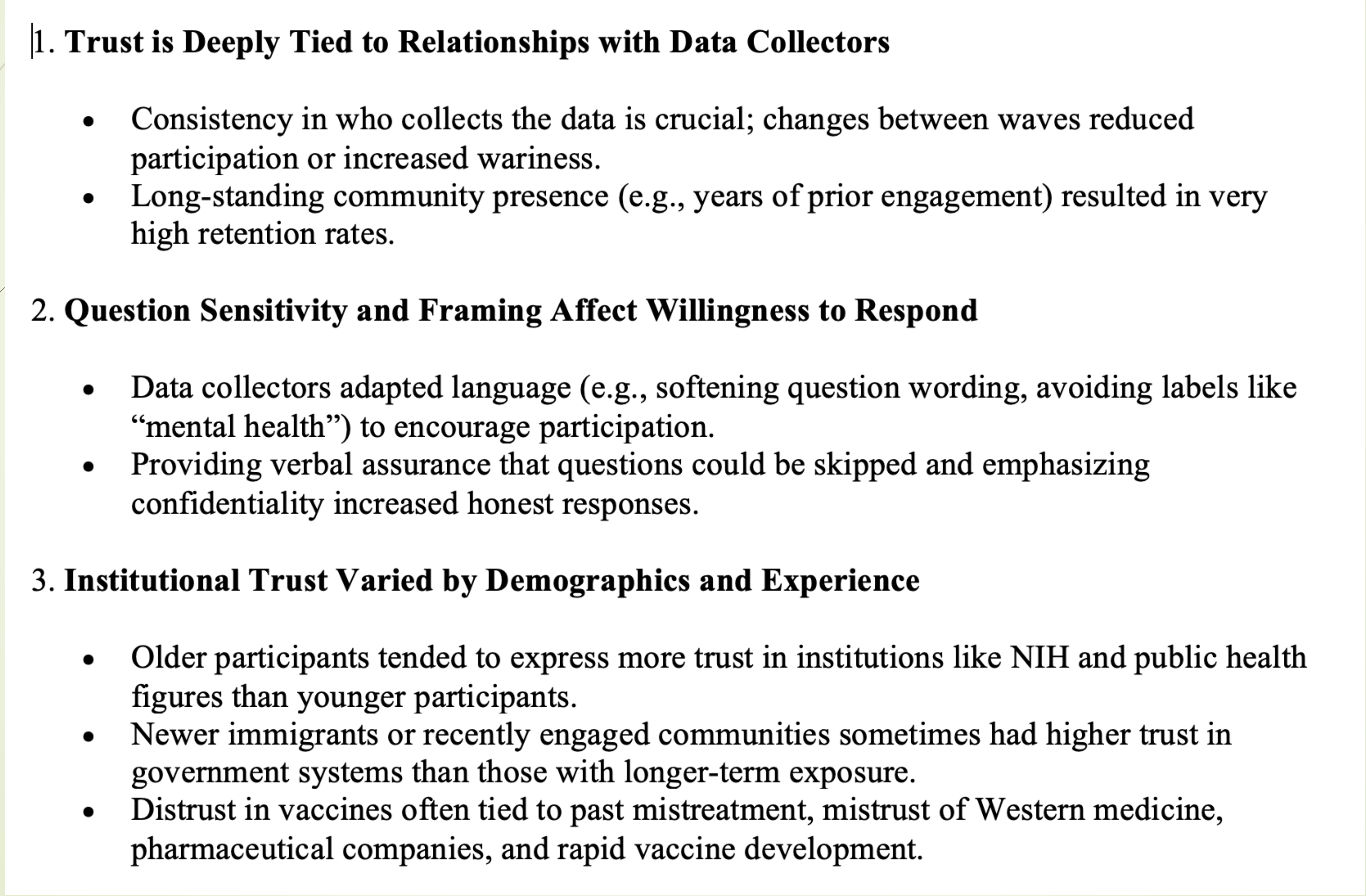


Community Meeting Notes – CO-CEAL Manuscript Publication

7/17/25: Topic – Trust

- Zach introduced the topic of trust, how important it is, and that it’s important to COCEAL
- We wanted to understand trust on 2 levels: on a micro level when community were engaging with the CCs, how much did they trust them/how they got community to trust them; and on a macro level, when community were being engaged with by CCs, how much did they trust the topics that were being discussed (ie. I dont trust the government to give me the right info about the covid vaccine, etc.)
- Don said that there was a large amount of trust between people doing the survey, and the people doing data collection, and he knows bc one time there was a break between waves, and when people were contacted by a different person between the two waves, they wouldn’t participate or be more wary
- Lisa said that some people didnt want to even answer the same data collector from wave to wave, maybe because there was too much time in between the two waves
- Lorenzo said that maybe because he’d been working in his community for so long, he had 90% retention rates and felt that there was a lot of trust between him and the people who took the survey

Example: Bulleted Points



1. **Trust is Deeply Tied to Relationships with Data Collectors**

   - Consistency in who collects the data is crucial; changes between waves reduced participation or increased wariness.
   - Long-standing community presence (e.g., years of prior engagement) resulted in very high retention rates.

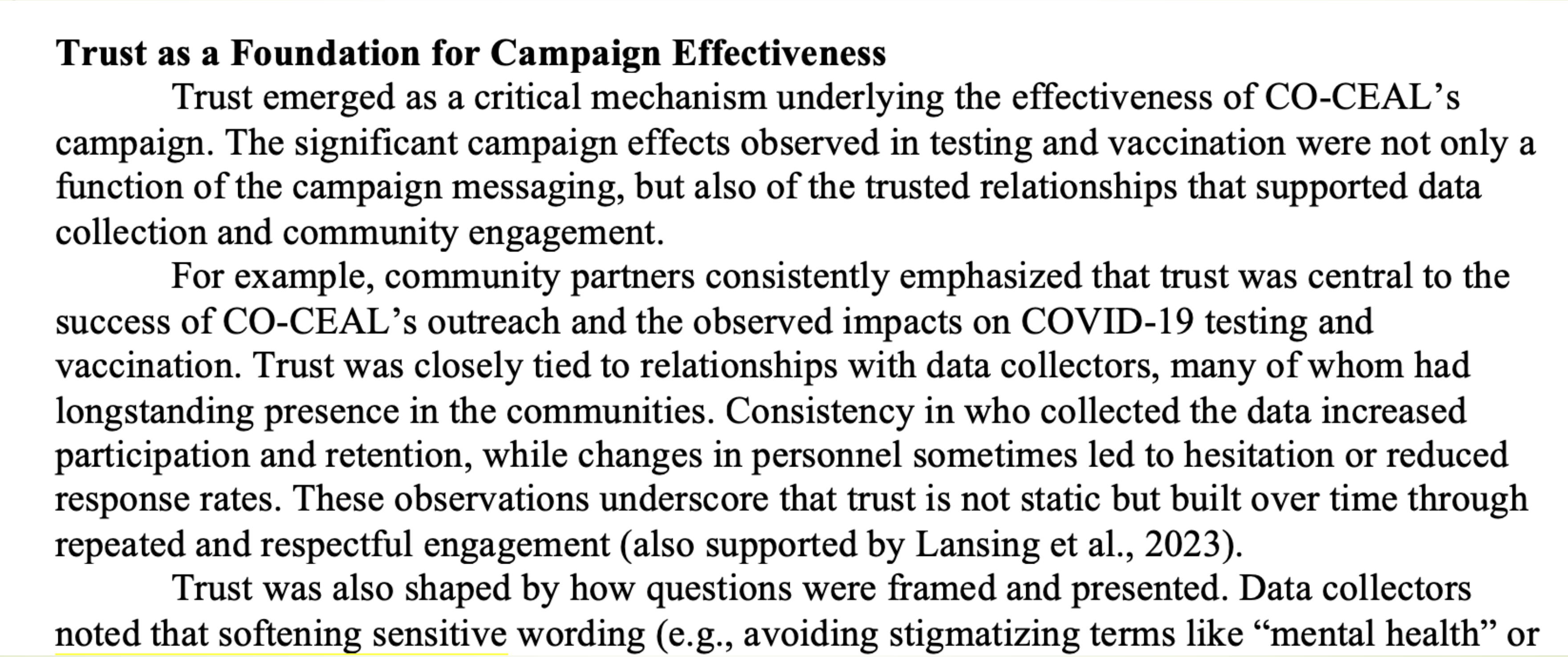
2. **Question Sensitivity and Framing Affect Willingness to Respond**

   - Data collectors adapted language (e.g., softening question wording, avoiding labels like "mental health") to encourage participation.
   - Providing verbal assurance that questions could be skipped and emphasizing confidentiality increased honest responses.

3. **Institutional Trust Varied by Demographics and Experience**

   - Older participants tended to express more trust in institutions like NIH and public health figures than younger participants.
   - Newer immigrants or recently engaged communities sometimes had higher trust in government systems than those with longer-term exposure.
   - Distrust in vaccines often tied to past mistreatment, mistrust of Western medicine, pharmaceutical companies, and rapid vaccine development.

Example: Manuscript section



Trust as a Foundation for Campaign Effectiveness

Trust emerged as a critical mechanism underlying the effectiveness of CO-CEAL's campaign. The significant campaign effects observed in testing and vaccination were not only a function of the campaign messaging, but also of the trusted relationships that supported data collection and community engagement.

For example, community partners consistently emphasized that trust was central to the success of CO-CEAL's outreach and the observed impacts on COVID-19 testing and vaccination. Trust was closely tied to relationships with data collectors, many of whom had longstanding presence in the communities. Consistency in who collected the data increased participation and retention, while changes in personnel sometimes led to hesitation or reduced response rates. These observations underscore that trust is not static but built over time through repeated and respectful engagement (also supported by Lansing et al., 2023).

Trust was also shaped by how questions were framed and presented. Data collectors noted that softening sensitive wording (e.g., avoiding stigmatizing terms like "mental health" or

CO-CEAL Community Paper

- Challenges
  - Process is MUCH slower
  - Follow up with community partners
  - Synthesizing a lot of ideas
- Benefits
  - Community engagement
  - Better, more well-rounded paper
  - Beneficial for readership

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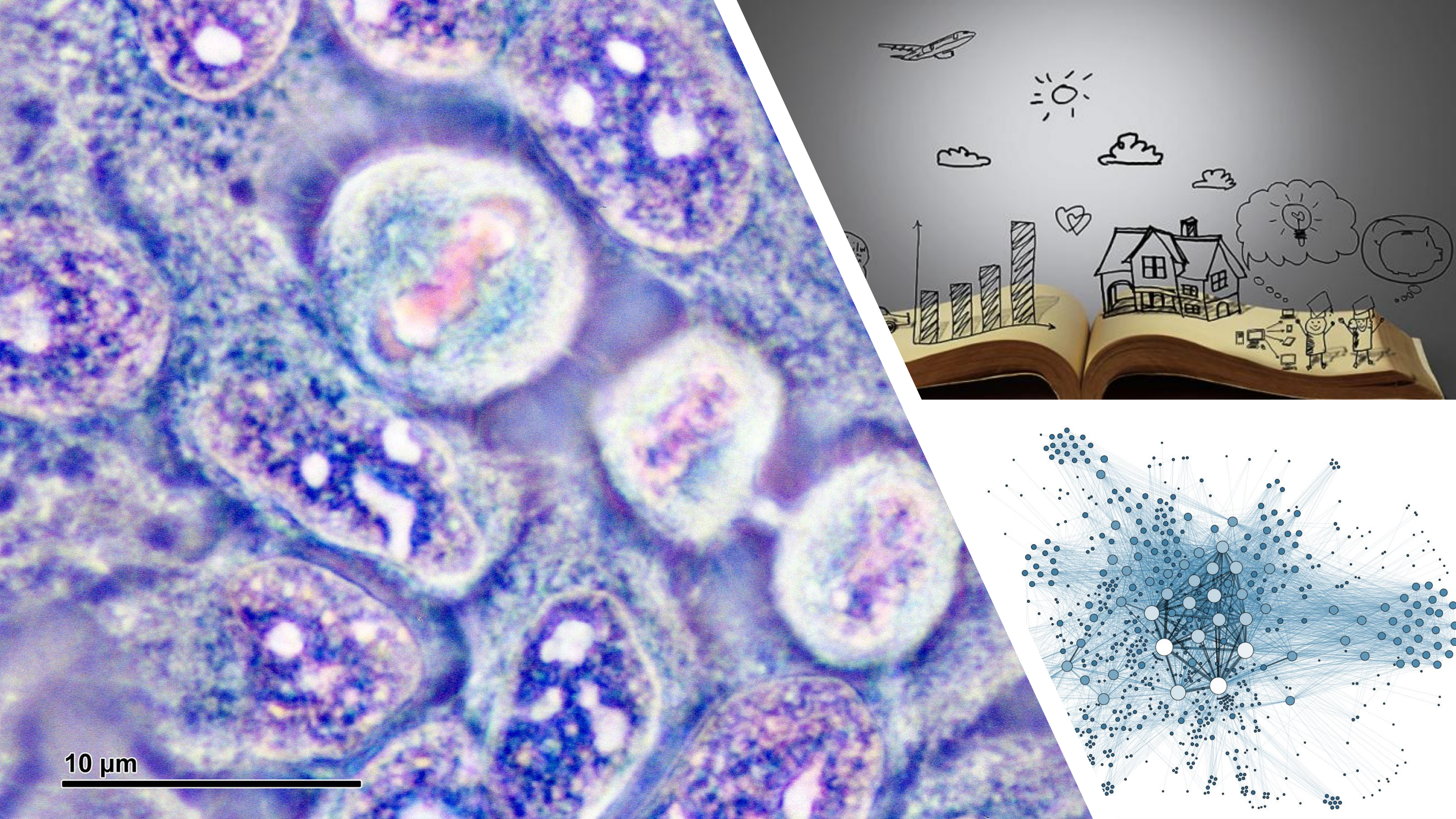
Whose Data?

Why is it important?

CCTSI/ACCORDS Community Engagement Forum, October 22, 2025

Charlene Barrientos Ortiz, Community Research Liaison

Colorado Clinical and Translational
Sciences Institute (CCTSI)
UNIVERSITY OF COLORADO DENVER | **ANSCHUTZ MEDICAL CAMPUS**


10 µm

Data is more than charts and figures

Who owns the data?

Research participant ***consent*** *– what are folks agreeing to?*

Federal and Industry funded – institution funded, industry sponsored.

****Funders may require data to be publicly available.***

FOR ENGAGEMENT TO SUCCEED…

5. Partnering with the community is necessary to create change and improve health.

… "***current approaches to translational research explicitly recognize that community engagement significantly enhances the potential for research to lead to improved health by improving participation in the research, its implementation, and dissemination of its findings.***"

Principles of Community Engagement (2nd Edition) | Community Stress Resource Center | ATSDR

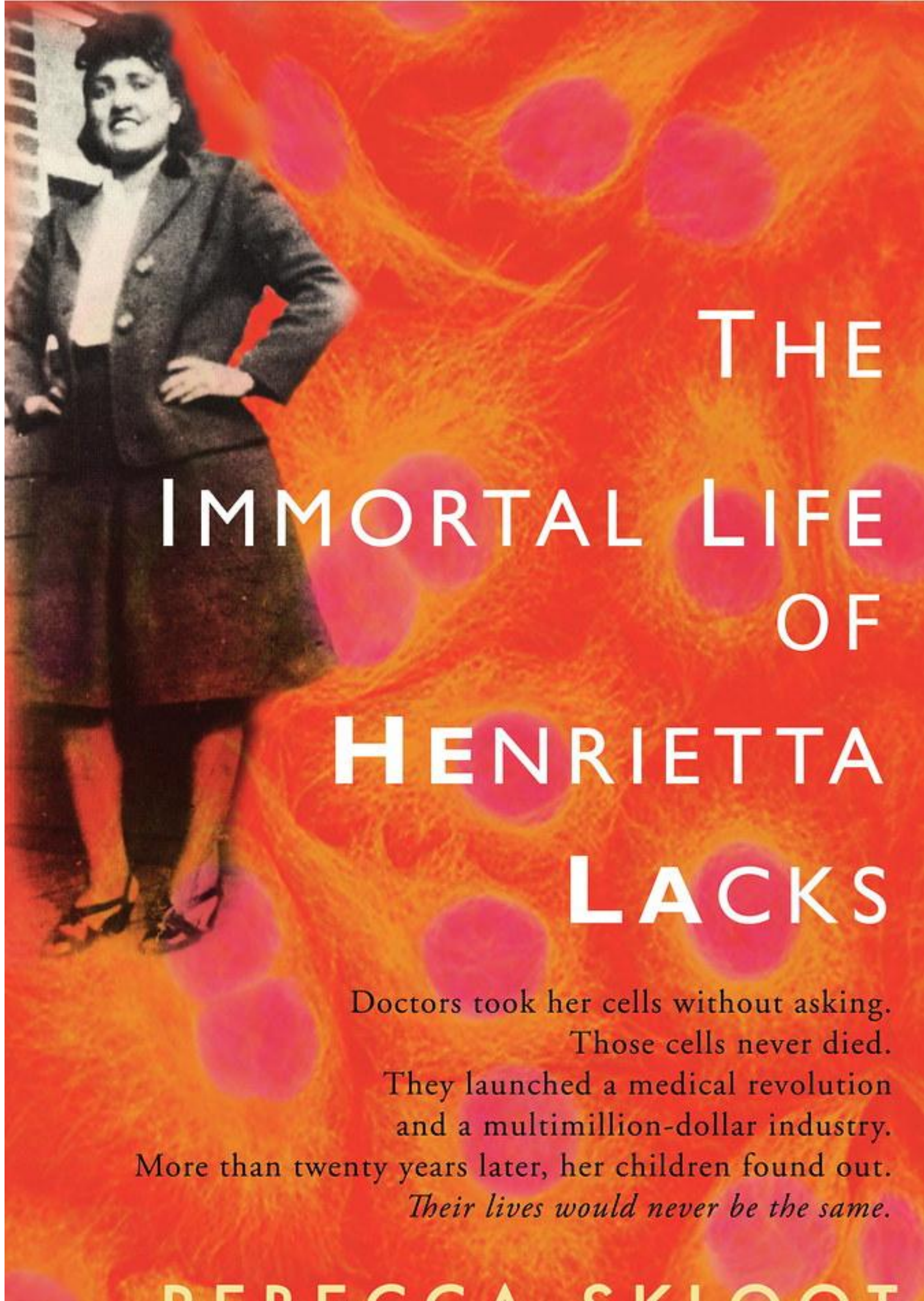
Storage, Accessing and Messaging

- There is agreement - we do want data to be kept confidential and safe.
- Access – **who has access and for how long?**
  - **Gatekeeping vs Roadblocks**
- There is agreement – share and dissemination the findings.
  - Expectation on the academic side to publish – manuscripts, conferences, presentations.
- Community also wants to know **and why not,** its part of their story…**who decides when, how and who will share.**

Protocols, Agreements and Action!

- Research protocols.
- Agreements.
- ***Actions make a difference*** – *if in the background,* what is said or not said, what is shared or not shared can have very long-lasting implications to academia and communities alike.
- Data – interpretation of data, message and messenger.

Ethical, engaging, respectful partnerships can be long-lasting.



Recommendations

Organizers

- Have an in-person roundtable discussion.

Research and Community Partners

- Folks can be generous; everyone should be paid for their expertise and work.
- Interpreting data is part of the dissemination process.
- Talk about dissemination at the beginning of the project and keep talking.
- Share back data back in various formats and messengers.
- When disseminating findings, it is a story.   Whose story you are telling?
- The Immortal Life of **He**nrietta **La**cks (HELA cells)