Coalition Essentials: Protecting Participants, Building Trust

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Disclaimer

This presentation is facilitated with live interaction to address any points of clarification or misconceptions.

Please note that Institutional Review Boards (IRBs) are regulated by the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services (HHS), and they hold final authority in determining policy on the necessity of an IRB protocol for research activities.

While the information provided is accurate at the time of this presentation, policies and guidelines may evolve over time.

I encourage participants to stay informed of any updates.

When in doubt about the requirement for IRB protocols, always prioritize the rights and welfare of research participants.

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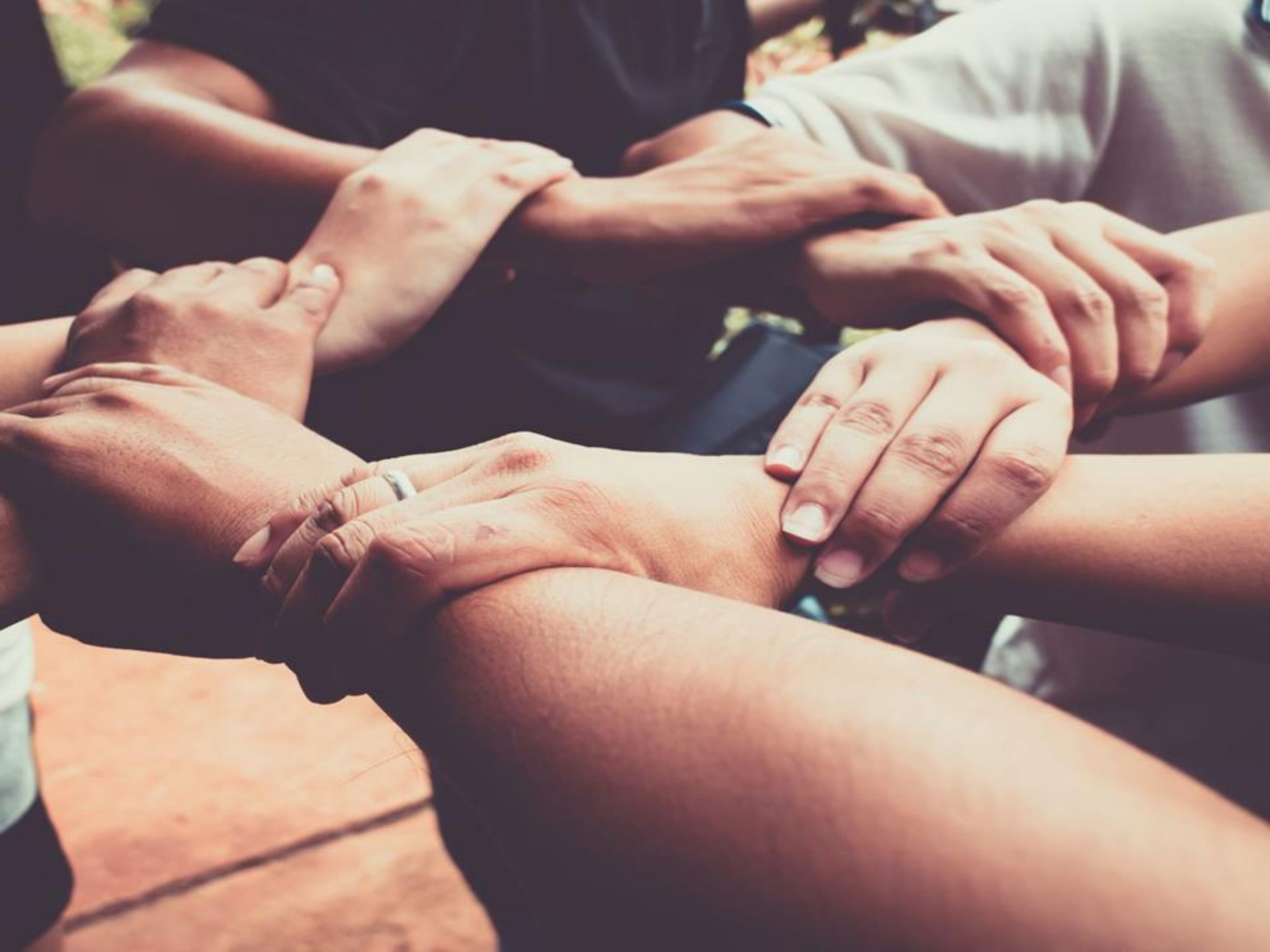

Presentation Overview

- Purpose: Clarify IRB's role in protecting research participants.
- Audience: Anyone collecting data from people.
- Key Themes:
- - IRB approval process
- - Ethical research training
- - Informed consent simplification
- - Building trust & transparency

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Why Protecting Participants Matters

- Historical context: Belmont Report, Tuskegee study → importance of ethics.

- Core principles: Respect, Beneficence, Justice.

- Trust and transparency as the foundation of credible research and evaluation.

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What is the IRB?

- Committee overseeing research ethics.

- Reviews protocols for participant protection.

- Ensures compliance with federal regulations.

- Balances risks and benefits.

IRB is your partner, not a hurdle.

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IRB Approval Process (Simplified)

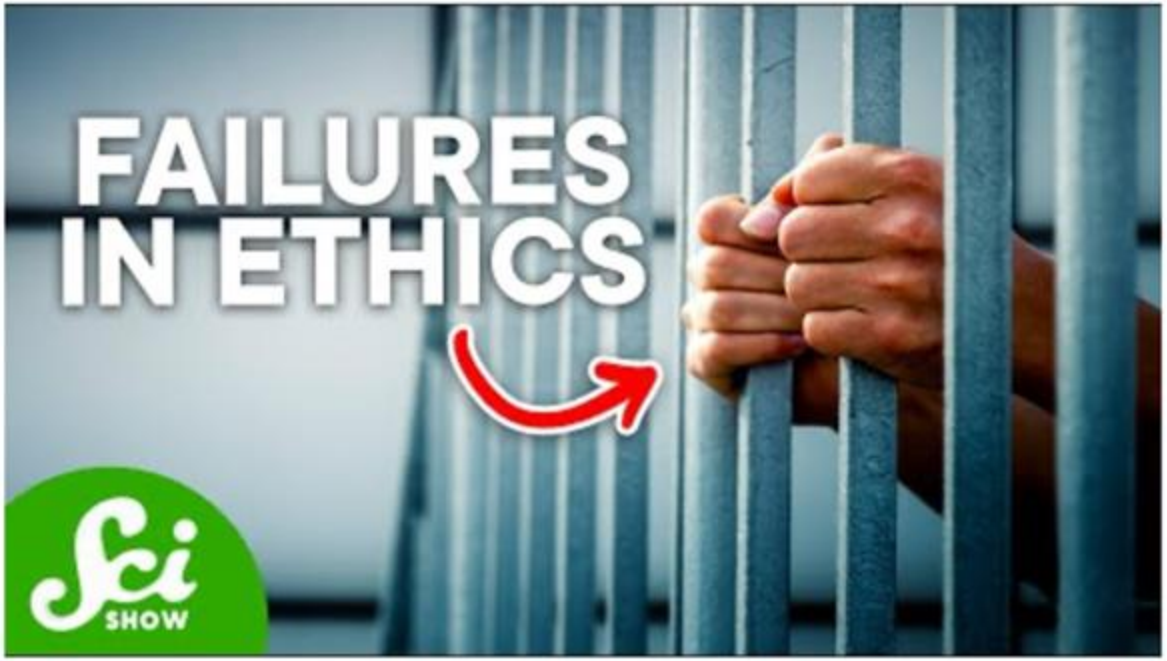
1. Prepare study protocol (objectives, design, consent forms).
2. Submit application to IRB.
3. IRB review (expedited, exempt, or full board).
4. Approval → begin research.
5. Ongoing reporting and amendments.

Objective 1

By the end of the presentation, participants will be able to explain the role of the IRB.

- Protects human participants.
- Safeguards vulnerable populations.
- Ensures informed consent and data protection.

Why do we have an IRB?



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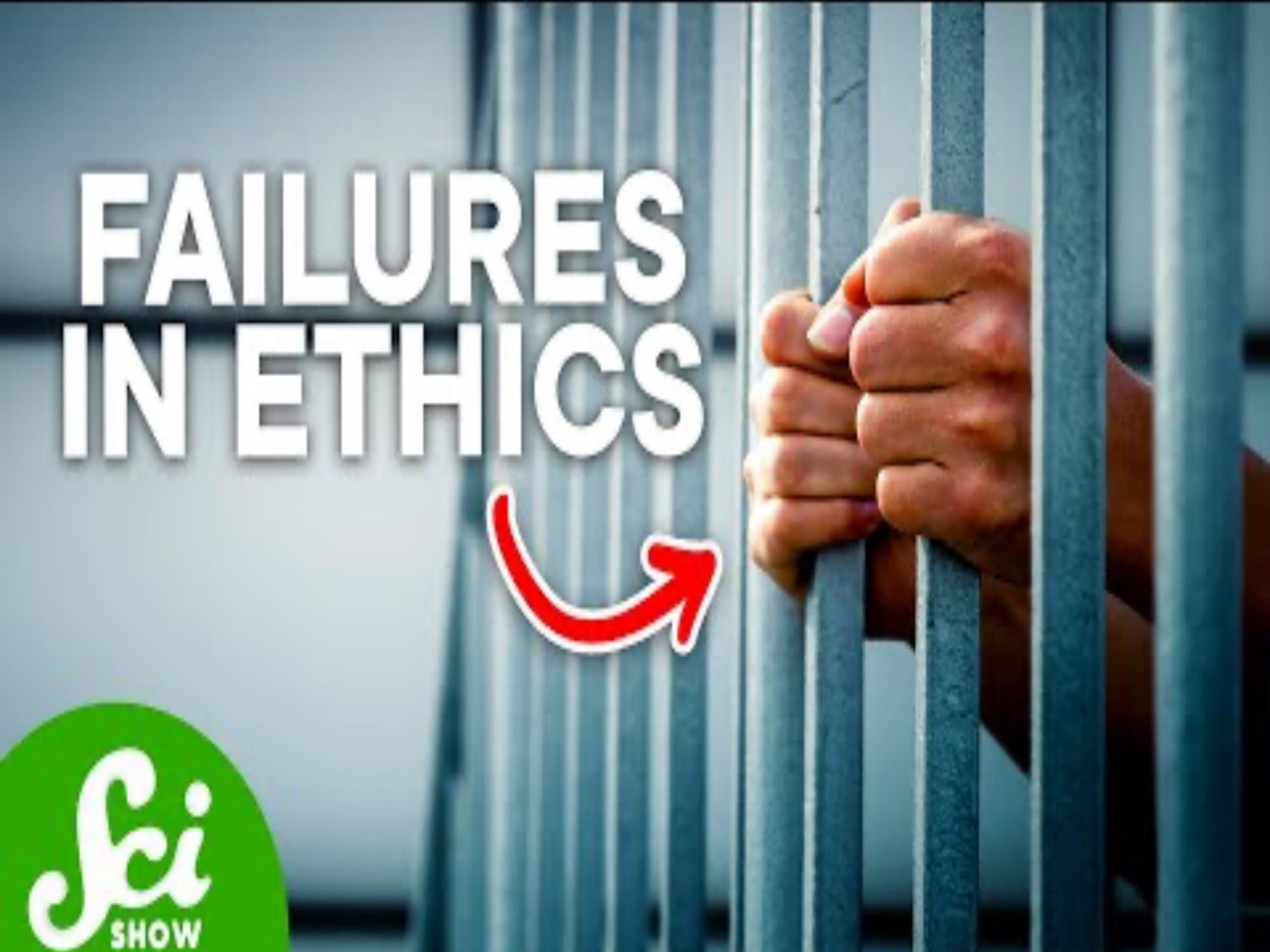
FAILURES
IN ETHICS
SHOW

TO PROTECT PEOPLE

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Ethical Research Training

- Ensures all staff understand IRB rules.

- Typical modules: human subjects protection, confidentiality, cultural sensitivity.

- Resources: NIH Protecting Human Participants training.

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Vulnerable Populations

- Children
- Prisoners (or people with limited civil freedoms)
- People with a disability
- Minorities
- Pregnant or lactating women, human fetuses, and/or neonates
- People who are disadvantaged (e.g., education level, income level)
- Patients (in or out)
- People who are illiterate
- Non-English speakers (or limited proficiency)
- People who are ill (e.g., cancer patients, drug use patients)

Protecting Participants

- Physical well-being
- Emotional well-being
- Psychological well-being
- Personal data
- Employability
- Personal reputation
- Civil or criminal liability
- Loss of confidentiality
- Dignity
- Self-respect

Shoulder Partner Discussion

- **What are examples of how research could harm a community if ethical protections aren't in place?**
- **What does "respect" for research participants look like in a community setting?**

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Informed Consent – Why It Matters

- Informed consent = respect + autonomy.
- Participants must understand the purpose, risks, benefits, and withdrawal rights.
- Must be written in plain language, not legal jargon.

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Understanding Informed Consent

Scenario:

A local organization is invited to join a research project about housing needs. Some participants speak limited English, and the consent form is long and full of technical terms.

Discussion Questions:

- What problems might this create for informed consent?
- How could researchers make sure everyone truly understands the study and their rights?
- What role could community leaders play in helping researchers communicate clearly?

Objective 2

Within one week, participants will identify three strategies to streamline consent.

- Use plain language and visuals.
- Keep forms short and focused.
- Provide opportunities for questions.
- Digital consent forms improve access and tracking.

Shoulder Partner Discussion

- **What are some ways we can make the consent process easy to understand and accessible for everyone in our community?**

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Objective 3

Outline two strategies to build trust.

- Communicate openly with participants.
- Share research outcomes with communities.
- Trust leads to better recruitment, retention, and valid data.

Building Trust and Transparency

Shoulder Partner Discussion

- **How can open communication and sharing research results help build lasting trust between you and the community?**

- **What are some practical ways you can show communities that their voices and contributions truly matter?**

Key Takeaways

- IRB ensures ethical and safe research.

- Informed consent = clarity, simplicity, transparency.

- Ethical practices build long-term trust with participants.

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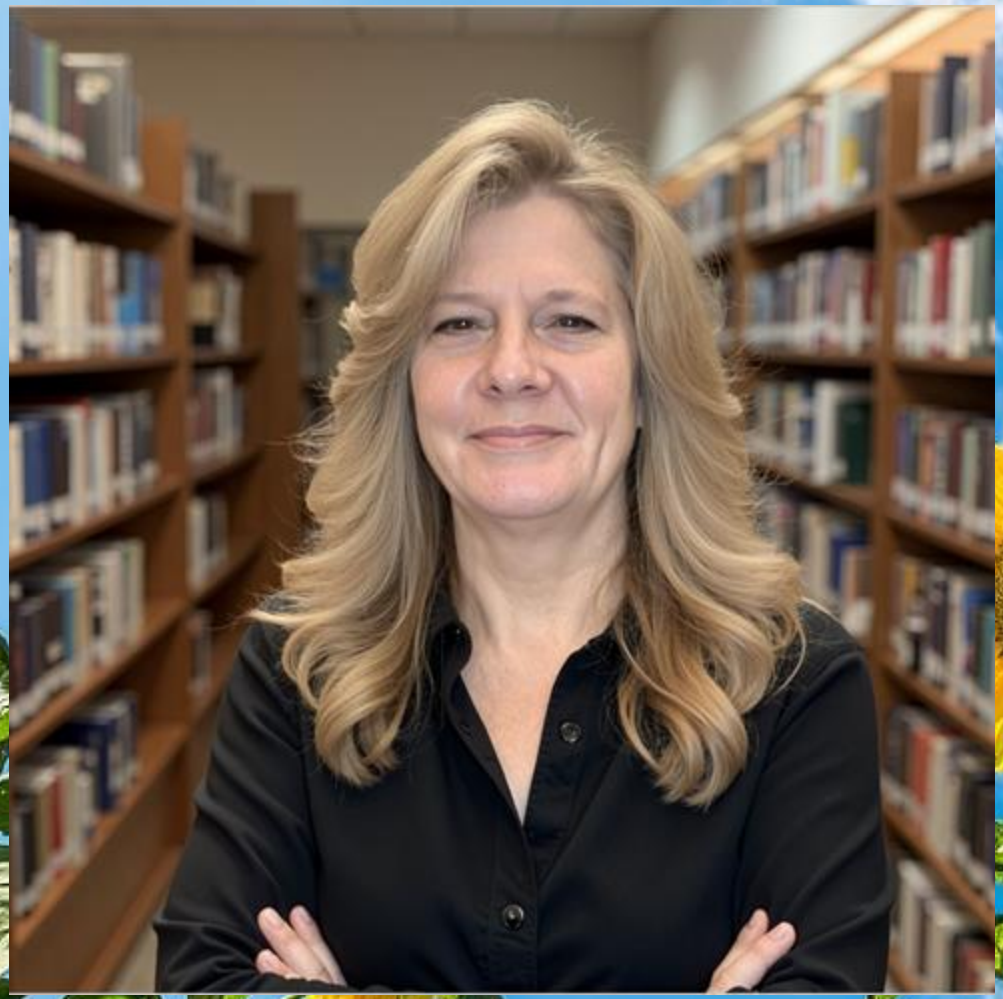

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