

Grand Rounds: Rethinking Clinical Research PCORnet Building Trustworthiness in Research

September 16, 2016



Building Trustworthiness in PCORnet

*Sharon Terry, co-PI, PCORnet Coordinating Center and Chair,
PCORnet Engagement Committee*



Building Trustworthiness in PCORnet

- Hosted March 28-29 *Building Trustworthiness in PCORnet* meeting

We asked: how are we trustworthy and not trustworthy?

- Meeting objectives were to:
 - Describe the characteristics of trustworthy engagement
 - Examine successes and failures in building trustworthiness in research initiatives
 - Begin a robust dialogue around trustworthiness within PCORnet
 - Create recommendations for the networks and stakeholders that comprise PCORnet
- 166 in person attendees and 357 webcast viewers**
- More than 40 speakers and moderators** from within and outside of clinical research who fostered rich dialogue with meeting participants

Key Principles for Engagement and Building Trustworthiness

- ➊ Strive for **equity** among stakeholders
- ➋ Consider the **social determinants of health** (e.g. socioeconomic status, access to healthcare, literacy levels, culture, etc.)
- ➌ Consider the ways individuals **understand and experience** health and disease, accesses health services, and participate in research
- ➍ Be **patient/participant-driven**
- ➎ Create an environment that encourages **co-learning**

Result:

More meaningful and impactful research that matters to patients and clinicians and has the potential to accelerate the speed with which validated research findings move into clinical care.

Key Recommendations from Workshop

- **Inculcate cultural humility**
- **Recognize and engage diversity**
- **Transparency**— data, budget, privacy policy, projects
- **Design governance built around citizens**
- Train and support **community researchers** so that they can do PCOR
- **Common collaborative environment** with a wiki and sharing opportunities
 - Learn from **best practices/lessons**
- **Support dissemination** throughout research process
- Involve patients/participants more deeply in **IRB's**
- **Provide substantial \$ in project budgets** for engagement, dissemination
- **Resources for clinicians** to engage in research

What we have to LEARN





University of California
San Francisco



**THE
PRIDE
STUDY**

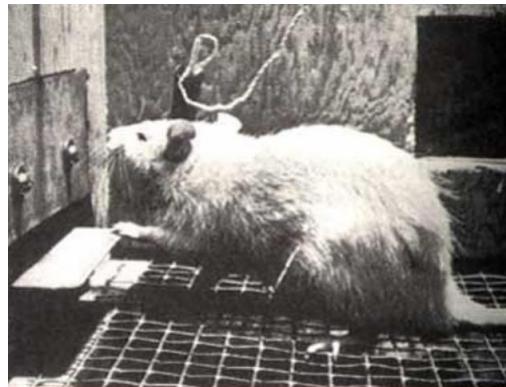
Building Trustworthiness Working with Sexual and Gender Minorities

Annesa Flentje, PhD
Assistant Professor
Mental Health Lead, The PRIDE Study
School of Nursing
UCSF



“They are only getting what they justly deserve.”

C. Everett Koop, describing the stance of Reagan’s advisers on AIDS



“At this point the patient became extremely emotional, accusing the psychologists of a complete lack of understanding of him as a person. He claimed that we ... were more interested in our experimental results than in him.”

Thorpe, Schmidt, Castell (1963) describing a research subject's response after 54 trials over 6 days of aversive conditioning pairing homoerotic images and electric shock

Building Trustworthiness

A new role as researchers

- Participant inclusion in the processes of research development
- Participants as partners
- Respect and affirmation

Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to **ask** about sexual orientation and gender identity

Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to **ask** about sexual orientation and gender identity
- Get guidance from sexual and gender minority stakeholders

Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to **ask** about sexual orientation and gender identity
- Get guidance from sexual and gender minority stakeholders
- Respond to that feedback

Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to **ask** about sexual orientation and gender identity
 - Get guidance from sexual and gender minority stakeholders
 - Respond to that feedback
-
1. What sex were you assigned at birth, on your original birth certificate?
Male
Female
 2. How do you describe yourself? (check one)
Male
Female
Transgender
Do not identify as female, male, or transgender

Building Trustworthiness: Planning

Integrating sexual and gender minorities begins with planning

- First, plan to **ask** about sexual orientation and gender identity
- Get guidance from sexual and gender minority stakeholders
- Respond to that feedback

1. What sex were you assigned at birth, on your original birth certificate?

Male

Female

2. How do you describe yourself? (check one)

Male

Female

Transgender

Do not identify as female, male, or transgender

. Do you consider yourself to be:

Heterosexual or straight;

Gay or lesbian; or

Bisexual?



Building Trustworthiness: Reporting

How we report our research is important



Building Trustworthiness: Reporting

How we report our research is important

- Sexual and gender minorities experience significant health disparities



Building Trustworthiness: Reporting

How we report our research is important

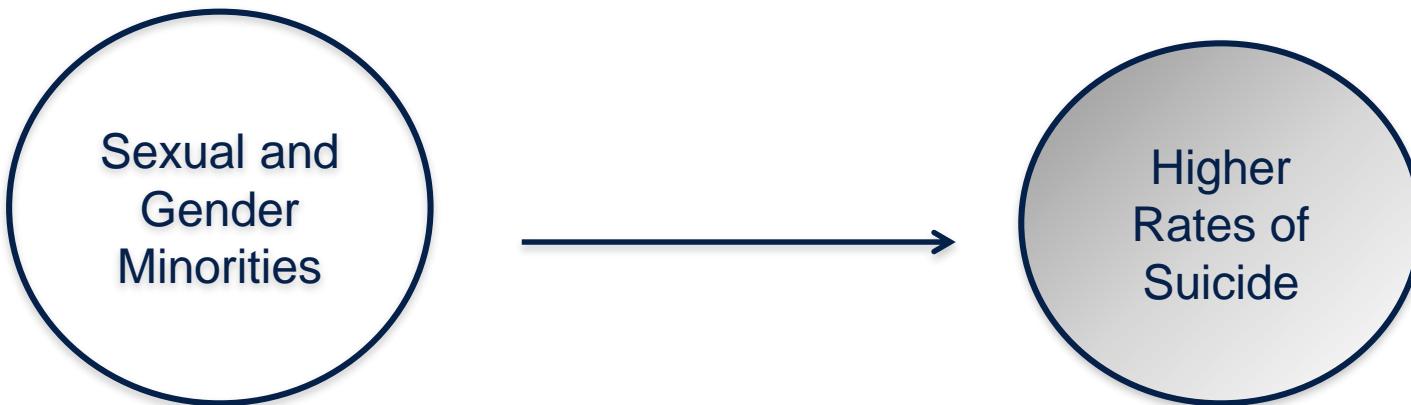
- Sexual and gender minorities experience significant health disparities



Building Trustworthiness: Reporting

How we report our research is important

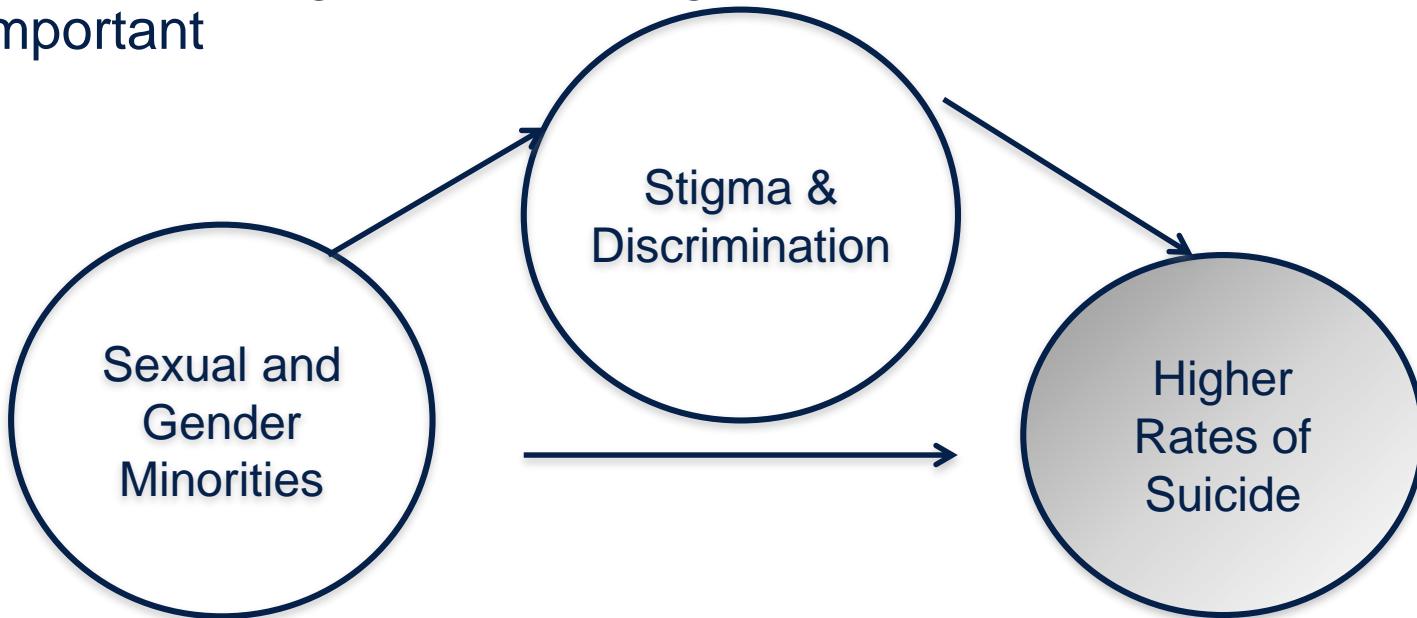
- Sexual and gender minorities experience significant health disparities
- Understanding and *explaining* the sources of these disparities is important



Building Trustworthiness: Reporting

How we report our research is important

- Sexual and gender minorities experience significant health disparities
- Understanding and *explaining* the sources of these disparities is important



Building Trustworthiness: Transparency

Be clear about your agenda and your team



Building Trustworthiness: Transparency

Be clear about your agenda and your team

- Have a link to your website which make your study goals clear



Your Story. Your Health.

Building Trustworthiness: Transparency

Be clear about your agenda and your team

- Have a link to your website which make your study goals clear
- Include bios of your team, specific to this research study

Mitchell R. Lunn, MD

CO-DIRECTOR / The PRIDE Study

PRINCIPAL INVESTIGATOR / PRIDEnet

Mitch is a long-standing advocate for sexual and gender minority (SGM) inclusion in research and higher education who lectures around the country on SGM medical education, SGM health, and SGM community engagement. He serves on the Advisory



Incorporate Feedback from Stakeholders at Every Step

- What is it like to participate in the research?
- How can the process of research be improved for the participant?
- Be prepared to adapt



Thank you!

- Annesa.flentje@ucsf.edu
- <http://www.pridestudy.org>



Building Trustworthiness in a Pediatric Chronic Illness Community

9/16/16

Jennie David | ImproveCareNow Network

- **What is trustworthiness in a pediatric chronic illness community?**
 - **What role does it play in compassionate clinical care?**
 - **What role does it play in innovative research?**
- **What do we lose without trustworthiness in this community?**

What is trustworthiness in a pediatric chronic illness community?



"Patient engagement is not a factor, it is the product of compassionate medicine that places the child at the center of an evolving developmentally and culturally-sensitive conversation. Patient engagement is what happens when the system works, when providers shake off their metaphorical white coats and enter the clinical space as equals with caregivers and children."



Facebook.com/BizarroComics

Piraro
9-2-12

BIZARROCOMICS.COM Dist. by KING Features

What role does trustworthiness play in compassionate clinical care?

“As a patient with a chronic illness, I have become well-versed at shedding my humanity and emotions and leaving them outside the clinic room, like taking off my shoes when coming home. **We are made to believe, through experience and myth, that doctors are only interested in data.** I am so practiced in this belief – or perhaps in that fear – that I can recite my diagnostic and treatment history in full, like rattling off a monologue with the medicalized Latin words becoming normalized. **Admittedly, I find tremendous comfort and status rooted in such words, they are my only signal to tell clinicians that I understand and that I am an “experienced patient.”** I try to find innocuous ways of displaying my knowledge, like a show pony, as I ask, “Was there radiographic evidence of an obstruction?” or, “My stoma hurts when the peristalsis pulls at the healed stitches.”



Flat Jennie

@Flat_Jennie

Inspired by @LivingBeyondIBD, Flat Jennie is @ImproveCareNow's traveling friend who is dedicated to downright gutsy times raising awareness about IBD.

📍 <http://c3nproject.org/pac>

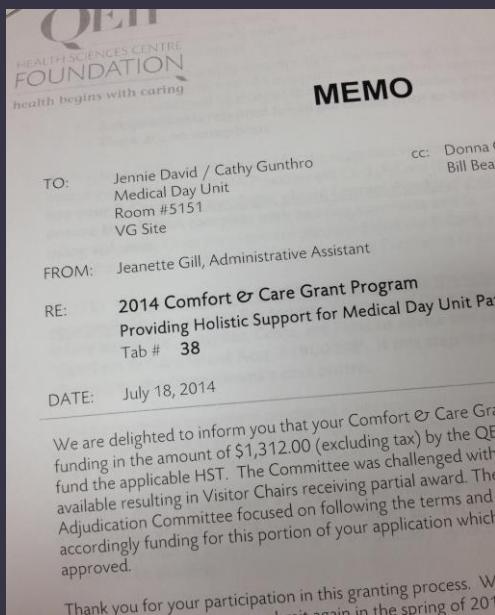
⌚ improvencarenowblog.org

📅 Joined March 2014

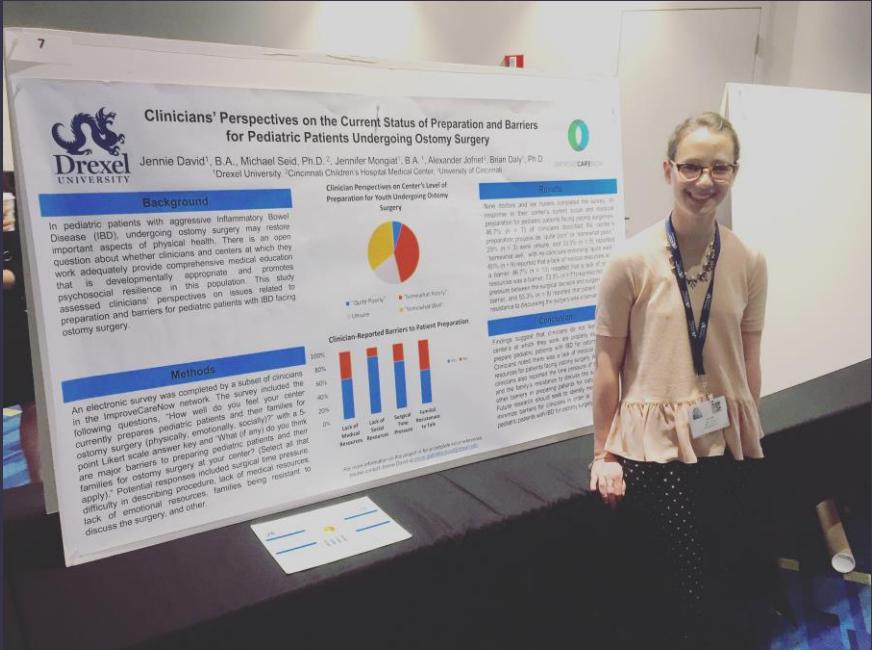
📷 142 Photos and videos



What role does trustworthiness play in innovative research?



“When we only include children as research participants and operate on a researcher’s agenda, **we miss the textures and colors that shape the veracity of our findings**. In other words, **we continue to make children’s experiences academic and sanitize children into participants.**”



What do we lose without trustworthiness in this community?



+

the ostomy toolkit

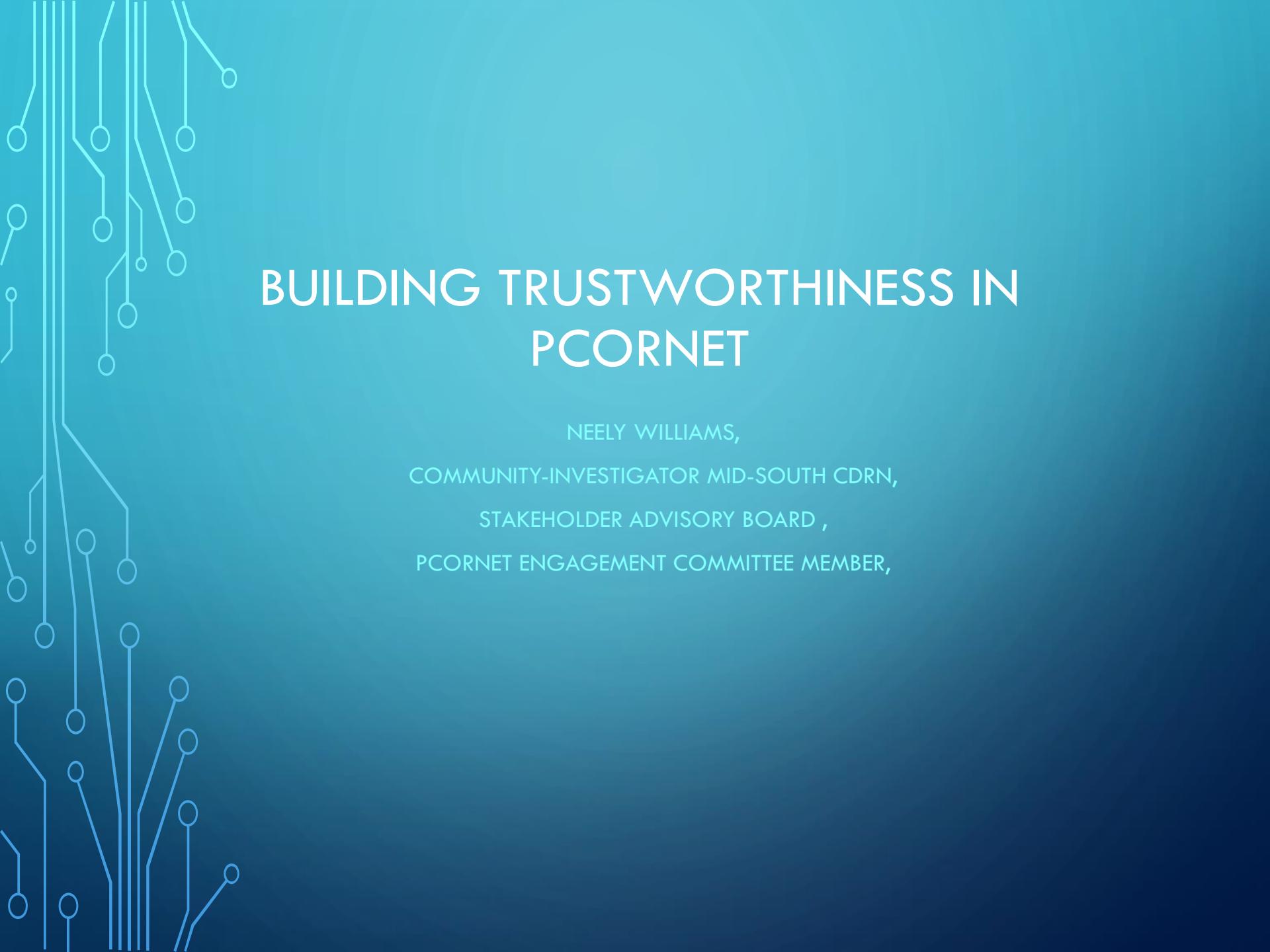


+

the ostomy toolkit: a guide to gutsy living
written and prepared by the Patient Advisory Council for the ImproveCareNow Network
for pediatric ostomates, from pediatric ostomates



“Now, instead of feeling embarrassment and discomfort at the idea of being associated with others with my illness, I feel a sense of honor and gratitude towards other patient advocates who have chosen to use their pill bottles as soap boxes in sharing stories to effect change.”



BUILDING TRUSTWORTHINESS IN PCORNET

NEELY WILLIAMS,
COMMUNITY-INVESTIGATOR MID-SOUTH CDRN,
STAKEHOLDER ADVISORY BOARD ,
PCORNET ENGAGEMENT COMMITTEE MEMBER,

RECENT ACTIVITIES TOWARD BUILDING TRUST

- Developing Messaging that enhance trust across the projects
- Hearing the voice of stakeholders throughout the research process
- Intentionally engaging patients and other stakeholders in all phases of the research

FEEDBACK FROM COMMUNITY STAKEHOLDERS

- Being transparent
 - Sharing with patients/participants how the data will be used
 - How it will benefit the patients/community
 - Researchers “going out of their way” to engage patients

IN SUMMARY:

The MS-CDRN Stakeholders:

- Trust and Engagement requires transparency, and taking the time to talk participants through the process, including discussing details about the data and how their data will be used.

Kellie Walters, MPH, CHES

Program Coordinator, Program on Health and Clinical Informatics

Project Manager, Biomedical Informatics Service

NC TraCS Institute

University of North Carolina at Chapel Hill

kmwalters@email.unc.edu

OTHER SUGGESTIONS

- Reporting results of research back to the patient partners/participants is necessary for building trust.
- Narrative data, Story telling is a primary way data is transmitted among many cultures.
- An important recent concept in building trust is the idea of Patient Reported Outcomes.

Robert Stevens (robertnstevens@comcast.net)