Healthcare Facility Access Challenges for Conducting User Research

HFES Healthcare Symposium, March 7, 2017

Moderator

Beth Loring, CHFP

Loring Human Factors, LLC

Panel Goals

- Discuss challenges in getting access to healthcare facilities to conduct research.
- Get points of view from human factors, hospital IRB, and patient safety experts.
- Discuss current state and brainstorm future approaches to allow greater access for user research.

Panelists

Mary Beth Privitera, PhD

Principal, HS-Design, U of Cincinnati

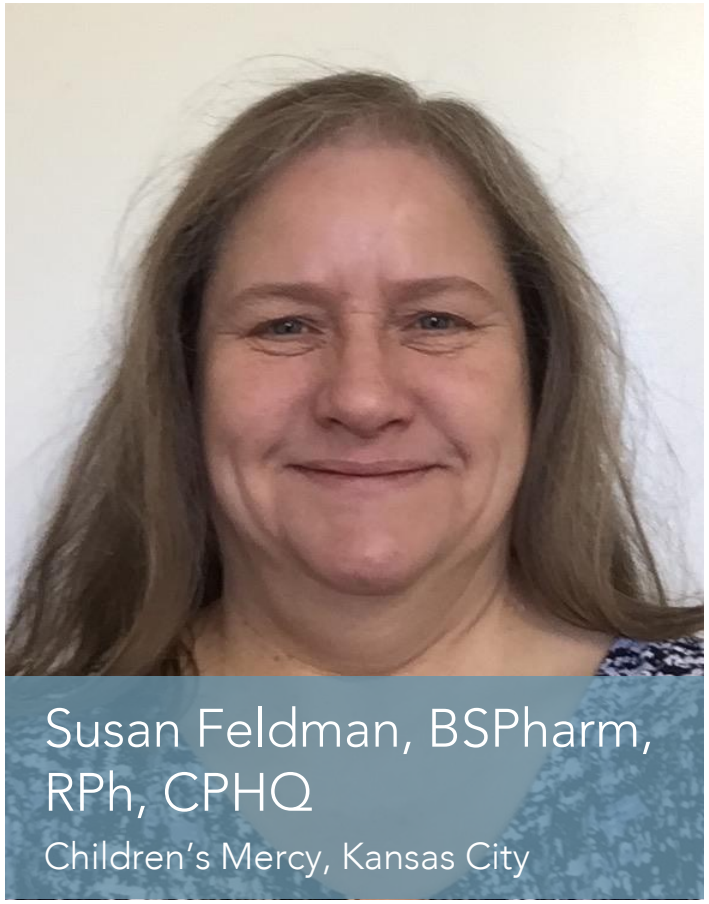
Steve Wilcox, PhD

Design Science

Ryan McDowell, MS, PMP

Children's Mercy, Kansas City

Panelists



Susan Feldman, BSPharm, RPh, CPHQ

Children's Mercy, Kansas City

Keith Karn, PhD

Human Factors in Context LLC

Panelists' Points of View

- Each panelist in turn spent a few minutes voicing his or her key thoughts and opinions.
- These included:
  - What avenues and strategies currently exist for gaining access?
  - What are the biggest barriers to gaining access? Why?
  - How can we address these issues?
  - How do we address HIPAA and patient safety concerns?
  - How can we educate stakeholders like facility managers, clinicians, IRBs, and research coordinators of the importance of this research?

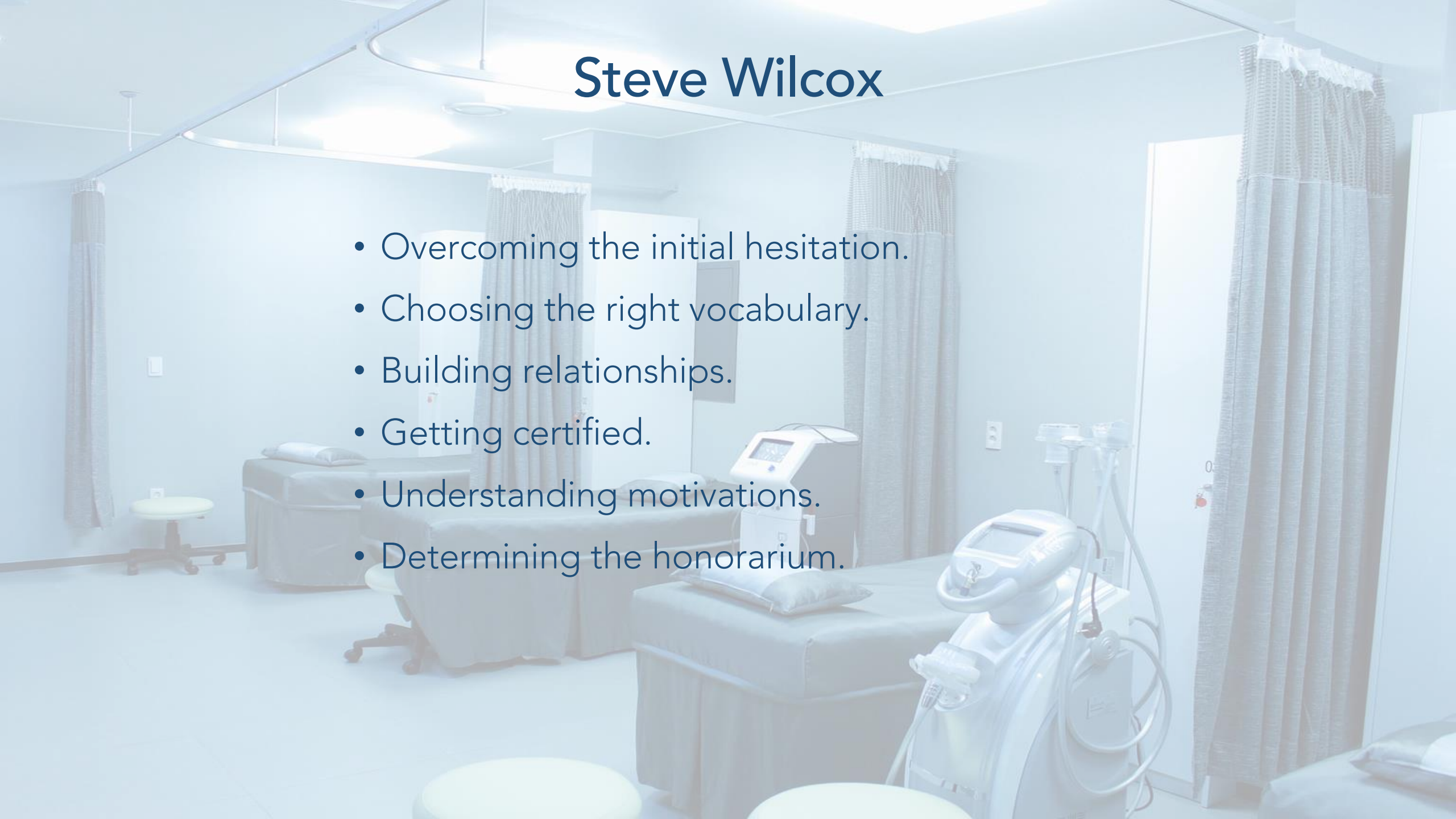
Keith Karn

- Laws intended to protect the patient can harm the patient (and society at large).
- Independent researchers have few access options.
  - Knock on the door = slam in the face.
  - "Back door access" (i.e., via networking with manufacturers' representatives and personal connections) works, but feels *sneaky*.
- Patients, HCPs, and society as a whole are missing out on the benefits user research offers.

Mary Beth Privitera

- All healthcare providers went into the practice of medicine to help people.
- Our cultural rules and expectations are not going away.
- Access & recruiting for HF studies require creative problem solving.

Steve Wilcox



- Overcoming the initial hesitation.
- Choosing the right vocabulary.
- Building relationships.
- Getting certified.
- Understanding motivations.
- Determining the honorarium.

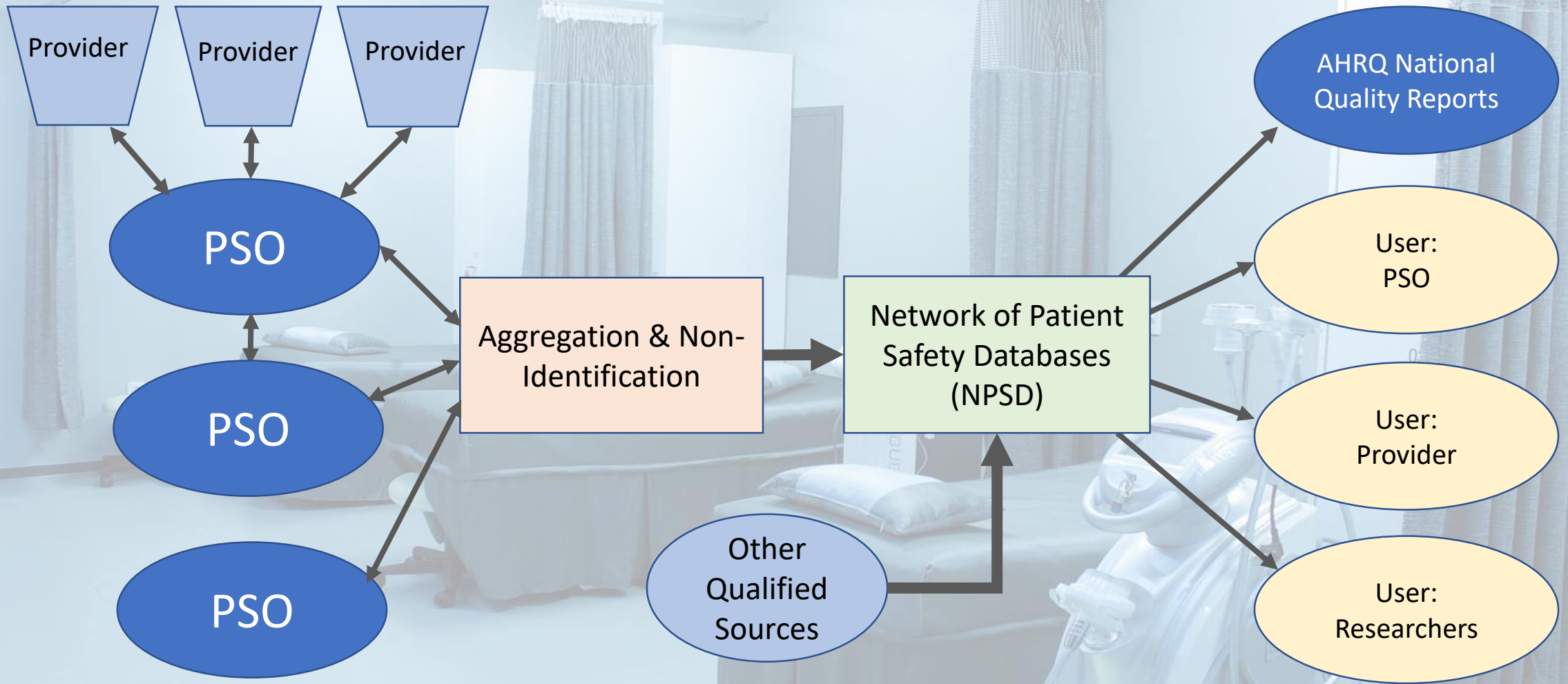
Ryan McDowell

- There is a great deal of variation across institutions on the sophistication of their IRB offices.
- In most healthcare settings, the IRB office is not even going to know what human factors research is.
- Educate yourself on the definition of human subjects research and the Office of Human Research Protections guidance on engagement in human subjects research.

Susan Feldman

- Protections in the Patient Safety Act encourage health care providers to report errors and safety concerns with intent for improvement within the organization and submission of information to PSO.
- Allows transparency internal to the organization supporting process and performance improvement work.
- Allows sharing of de-identified information among organizations participating in the PSO.
- Allows disclosure to FDA and vendors with required reporting to the FDA.
- Data submitted to PSOs intended to create a national database of errors and associated safety improvement work.

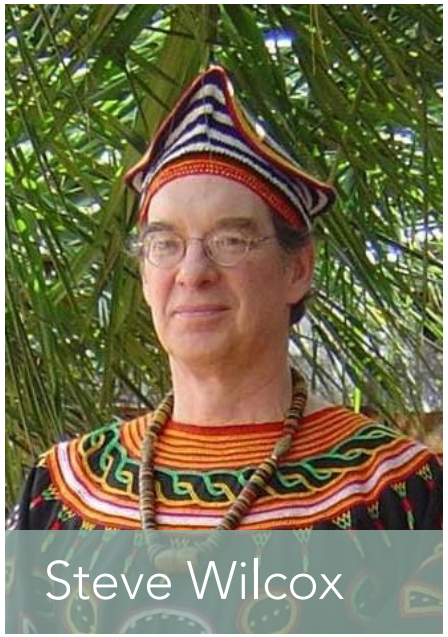
Susan Feldman



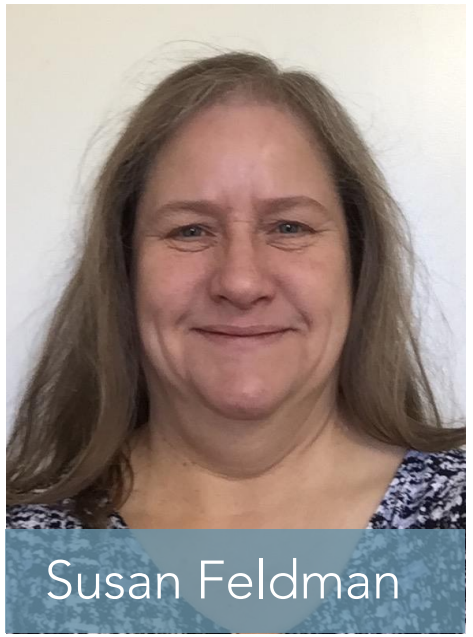
Helwig, A., Wolcott, J. (2011) Pros and Cons of Federal Reporting in Patient Safety. *Focus on Patient Safety*, 14(3), 5-6.

Questions for the Panel


Mary Beth Privitera


Steve Wilcox


Ryan McDowell


Susan Feldman


Keith Karn

Discussion Highlights

- Always go through the right channels when trying to gain access to medical facilities.
- Each facility's requirements and procedures differ, so do your homework and then call the IRB.
- Human factors practitioners should use language that hospital administrators understand.
- Do not say you are conducting research, say you're conducting a quality improvement study.
- Offer to share the data with the facility so they benefit as well (up to but not including intellectual property).

Discussion Highlights

- Plan on a minimum of eight weeks for the approval process. Double-blinded studies can take twice as long.
- Factors affecting the difficulty of approval include:
  - Whether or not the patient is awake
  - How many hospital departments will be involved
  - What types of data you are collecting
- Gaining access in Europe is generally easier than the US.
- Avoid expensive fees charged by hospitals by explaining it is not a clinical trial, and consider partnering with a faculty member as the primary investigator.

Next Steps

- Share the insights from this panel to educate other HF practitioners about best practices and what to expect when trying to gain access to medical facilities.
- Consider developing and publishing best practices for HF practitioners to follow when trying to gain access to medical facilities.
- Consider developing some templates with wording that HF practitioners can use when educating the people in the hospital about why we're there, what we're doing, and why it's important.
- Consider approaching the FDA about publishing a guidance document on the importance of conducting user research in clinical settings.

If you're interested in continuing this discussion, contact…

LORING
Human Factors

WWW.LORING-HF.COM

Beth Loring

beth@loring-hf.com

(978) 799-9359