Session 1

Welcome to STRIDE

Please take the STRIDE Research Assistant Pre-Intervention Questionnaire

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Session 1

Expanding Cultural Humility in Research

BLINDSPUT
Underrepresentation

Engagement and empowerment

GO STRIDE
Strengthening Translational Research In Diverse Enrollment

Goal: to increase the diversity of participants in clinical trials and help meet overall recruitment targets, without generating undue burden.

3 Key Parts:
Storytelling, eConsent, Simulation
Session 1

Share Your Training, Study, and Consent Process...

What will you do in STRIDE?

Session 1
Learn to Sim

Session 2
Explore Cultural Humility

Session 3
Sim a lot!

What will you do in STRIDE today?

Learn About Simulation

Understand eConsent & Cases

Know Checklist, Observe, and Rate Video

Get Ready for the Fishbowl

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Strengthening Translational Research in Diverse Environments
Session 1

Our goal: Conscious Competence

Unconscious Competent

Conscious Competent

Conscious Incompetent

Unconscious Incompetent

What will we do next?

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Where have you seen simulation?

Simulation Works!
Session 1

Simulation Works!

Tell me and I will forget
Show me and I may remember
Involve me and I will understand
Step back and I will act

-Kung Fu (Confucius 551-479BC)

Low/High Fidelity Simulation

Task trainers — manikins
Specific manual skills-development
emotional and process authenticity

Standardized Patients (SP)

People trained to portray a
specific clinical case with
medical accuracy and emotional
authenticity
Relational skills, history-taking,
physical examination
What will we do together?

Baseline Assessment

• Simulation methodology
• Skills development

Simulation-based Intervention

• Case based encounters with potential research participants (PRPs)
• Rating against a standard checklist

Ongoing learning

• Faculty-led feedback and debriefing
• Deliberate practice
• Cultural humility skills

What will your sim look like?

• Complete a baseline interview with an SP
• Use simulated eConsent form (iPad)

Let’s do Sim #1!
Welcome Back!

Self-assessment:
• How did that feel?
• What went well?
• What do you think you might have done differently?
• What questions do you have about the process?

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Effective research communication requires...

KNOWLEDGE
• Patient knows and understands research goal and process
• Patient freely chooses to join, or not, based on risks and benefits (INFORMED CONSENT)

BEHAVIORS
• Show respect
• Assess understanding
• Show empathy
Session 1

**eConsent Key Components**

- Storytelling videos
- Hover over capability
- Pop-ups or links to URLs
- Explanatory/procedural videos
- e-signatures (box to agree to consent, signature, certification of accuracy)
- eStaff

**Your Discussion with the Patient**

**Compare eConsent & Paper Consent**

**Same**
- Study information
- Patient may want more or less assistance

**Different**
- Technology issues
- Embedded information
- Confirmatory requirement
- Storytelling, Hover, Videos, URL links
- adaptable
Session 1

How might this impact your interaction?

- Patient can be more independent
  - it might take more time
- Need to assess patient’s comfort with technology
- How to remain engaged with the patient

Still All About Communication

<table>
<thead>
<tr>
<th>Respect</th>
<th>No Respect</th>
</tr>
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<tbody>
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<td>Empathy</td>
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Show Respect, Show Empathy

- “May I...?”
- “Thank you...”
- “Help me understand more about...”
- “Tell me more...”
- “What might help you...?”
- “Is this a good time to talk...?”
Session 1

Assess Understanding

Empathy
"Learning more about you will help me give you better information about the study. May I ask you some questions?"
"I am sorry to hear that. Do you feel comfortable continuing to talk with me?"
"Help me understand more about your familiarity with..."
"Tell me more about that concern. What might help?"

Respect

Our Trials

Case A
Can yoga help patients with type 2 diabetes?
12 wks with 12 mos follow up; no stipend; low risk

Case B
Can remote blood pressure monitoring help new moms with hypertension?
2 weeks; no stipend; low risk; phone consent

Case C
Can a new injection device help patients with glaucoma?
6 weeks; stipend; higher risk (injection & sample)

Let’s consider some challenges...

• Patient does not want to reveal that s/he does not understand the technology. How do you probe this with empathy?
• Patient is concerned about time, how do you respect their needs?
• How can you determine if the patient wants you to stay with them/give privacy?
• What if the patient needs help interpreting the interactive resources (if asks medical questions)?
Session 1

Assess Understanding (Technology): Q-A-R

RA: “There is a lot of helpful information about the study in the eConsent. Are you familiar with using tablets?”

Patient: “Well, a little bit.”

RA: “OK. At this point we have a few options… would you prefer that I…”

Respond, Based on What You Heard and Saw

“Thank you for telling me about your experience using tablets and websites. I don’t think you will have any trouble with the eConsent software, but if you do I will be here to help.

Thank you for sharing your concerns about participating in research. Your concerns are valid. May I tell you about some of the ways you are protected?”

Show Respect: Time

Empathy

Respect

“Thank you for…”
The eConsent form can take 5-20 minutes to complete depending on how many of the features you explore. You can use as many of the interactive features as you think would be helpful, and you don’t have to complete it today… Do you have any concerns about the time?

With regards to the eConsent, some people prefer I stay here with them to answer questions, and others ask that I step away so they can review it privately. What is your preference? (If you choose the latter I will return in 5 minutes to answer any of your questions)
What about those medical questions?

That is an excellent question — (share information you have/confirm understanding)

That is an excellent question, and I don’t know the answer, however while you are looking at the next portion of the eConsent, if it is ok with you I will step out and see what I can learn from …

What will you do in STRIDE today?

Learn About Simulation
Understand eConsent & Cases
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Get Ready for the Fishbowl
Learning from Sim: the Full Checklist

What wasn’t observed/scored?
- Comfort using English
- Explaining the process of consent (email, paper, eConsent)
- Explaining how they will interact during the consent
- Decision to/not participate won’t impact care
- Elicit personal perspective/feelings about participating
- Assess understanding (teach back, summary, questions)
- Use of technology

Assess Understanding:
Patient comfort with the language you are using
- Accent
- Non-verbal cues
- Questions
- Ask directly:
  - We ask all of our patients what language they prefer to speak.
  - Some of the patients I talk with prefer to hear this information in another language. I speak only English, but have interpreters available to help me. Would you like me to call an interpreter ...
  - It is important that I explain this study to you clearly...
And Now?

Preparation for Other Challenges

- What have you encountered? Do you anticipate?
- How about dealing with emotion?
- Managing consent by phone?
- How can you assess patient preferences?
  - verbal, non-verbal cues
- What can you do if you recognize a bias in yourself as you are talking with a patient?
  - walk in shoes, counter-stereotyping, recognize the context (stress, fear, anxiety, time urgency)

What worked well for you?

- Starting with open-ended questions
- Learning about the patient
- Listening as the patient tells story
- Teach-back
- What questions do you have for me?
- Summarizing
Session 1

Our Trials

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Respect - Understanding - Empathy
Content +

What will we do next?

- Learn About Simulation
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The Fishbowl

STRIDE

Strengthening Translational Research In Diverse Enrollment
Goals of Feedback
Ensuring that the learner improves, while at the same time maintaining his/her self-respect.

“Be gentle. Not subtle.”

Characteristics of Effective Feedback
- Conversation
- Self-Assessment
- + and opportunities
- Non-judgmental
- Specific, observed behavior
- Limited
- Ends with a plan

What Feedback?

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Strengthening Translational Research in Diverse Environments
Session 1

Fishbowl Debriefing Will Include...

- Facilitator
  - Order, Support & Learning
- Learner RA
  - Self-Assessment & Deliberate Practice
- Patient SP
  - Permission: How it felt
- CI(s)
  - Permission: Cultural Content

May Also Include...

- Observer(s)
- Learner RA
  - Self-Assessment & Deliberate Practice
- Patient SP
  - Permission: How it felt
- CI(s)
  - Permission: Cultural Content

Debriefing and Deliberate Practice

- Facilitator
- Learner RA
  - I struggled to assess understanding.
- Let’s try it now.
- “The risks seem OK.”
- Patient SP
  - Permission: How it felt
- CI(s)
  - Permission: Cultural Content

- Observer(s)
- Observer RA
  - Permission: Checklist Content
- Observer SP
  - Permission: Checklist Content

STRIDE

Striving to Enhance Research in Diverse Environments
Session 1

More Cycles

Fishbowl Debriefing

Session 1 Key Points
- Simulation can expand knowledge and improve behavior
- STRIDE seeks to increase the diversity of participants in clinical trials
- People of color may mistrust medical staff and researchers
- Current research protects human subjects (i.e. Informed Consent)
- Checklists help raters focus on relevant behaviors
- STRIDE uses “yes/no” to score if specific behaviors occurred:
  - Greet, Inform, Close
  - Show Respect, Assess Understanding, Show Empathy
- STRIDE raters use “1-5” to score how effective behaviors were:
  - Establish rapport
  - Respond to emotion
  - Establish rapport similarly
  - CI raters share nuanced insight about regional effectiveness with RAs
  - STRIDE raters use “yes/no” to score if specific behaviors occurred:
    - Greet, Inform, Close
    - Show Respect, Assess Understanding, Show Empathy
  - STRIDE raters use “1-5” to score how effective behaviors were:
    - Establish rapport
    - Respond to emotion
- Feedback in the Fishbowl:
  - Safe for the learner (non-judgmental language and permission seeking)
  - Breaks brief targeted practice of a specific skill or word choice
  - RAs use a checklist to complete a process and build a relationship
- Empathetic communication saves time, increases patient understanding
- RAs can improve communication skills via deliberate practice to:
  - Describe respect
  - Assess understanding
  - Show empathy
Session 1

**Coming Soon: “Sim-formed” Consent**

- eConsent
- Cultural Humility / Sensitivity
- Informed Consent

**STRIDE**

- Session 1: Learn to Sim
- Session 2: Understanding Implicit Bias
- Session 3: Sim a lot!

**Citations**

Session 1

- Knowles, M the Adult Learner, 1984
- McLaughlin et al, Simulation in Graduate Medical Education… Acad Em Med 2008, 15(11): 1117-1129
- Morgan et al, Simulation technology...Anesthesiology 2002 Jan; 96(1): 10-6.