

Session 1

**WELCOME to**  **STRIDE**  
Strengthening Translational Research In Diverse Enrollment

Please take the [STRIDE Research Assistant Pre-Intervention Questionnaire](#)



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Knowledge that will change your world

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*Session 1:*  
**Research Assistants Learn to Sim**

UMMS developers:  
Annie Delaney-Magee  
Melissa Fischer  
Fred Jenoure



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# Session 1

Expanding Cultural Humility in Research

BLIND SPOT  
HIDDEN BIASES of GOOD PEOPLE  
MAHZARIN R. BANAJI  
ANTHONY G. GREENWALD

Engagement and empowerment

Underrepresentation

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<https://strideproject.org/>

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

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3 Key Parts:  
Storytelling, eConsent, Simulation

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Storytelling  
eConsent  
Simulation

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



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What will you do in STRIDE?



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What will you do in STRIDE today?



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# Session 1

**Our goal: Conscious Competence**

Unconscious Competent

Conscious Competent

Conscious Incompetent

Unconscious Incompetent

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**What will we do next?**

Learn About Simulation

Understand eConsent & Cases

Know Checklist, Observe & Rate Video

Get Ready for the Fishbowl

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**Where have you seen simulation?**

Simulation Works!

**STRIDE** <https://www.youtube.com/watch?v=DyO2k5TqYf4&list=PLyouth.be&P32> University of Massachusetts Medical School umassmed.edu

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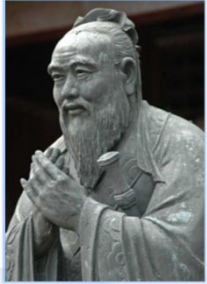
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**Simulation Works!**

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 Fuzi (Confucius 551-479BC)



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**Low/High Fidelity Simulation**

Task trainers → manikins

Specific manual skills-development  
emotional and process authenticity



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**Standardized Patients (SP)**

People trained to portray a specific clinical case with medical accuracy and emotional authenticity

Relational skills, history-taking, physical examination



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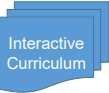
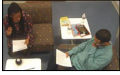

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### What will we do together?

<b>Baseline Assessment</b>  <ul style="list-style-type: none"><li>• Simulation methodology</li><li>• Skills development</li></ul>	<b>Simulation-based Intervention</b>  <ul style="list-style-type: none"><li>• Case based encounters with potential research participants (PRPs)</li><li>• Rating against a standard checklist</li></ul>	<b>Ongoing learning</b>  <ul style="list-style-type: none"><li>• Faculty-led feedback and debriefing</li><li>• Deliberate practice</li><li>• Cultural humility skills</li></ul>
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### What will your sim look like?

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



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*Let's do Sim #1!*



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**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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**What will we do next?**





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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**

**Content +**

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### 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



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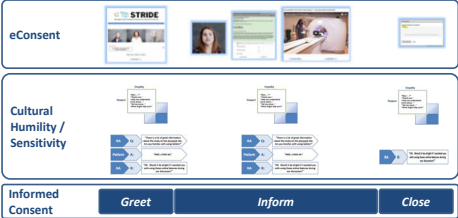
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### Your Discussion with the Patient



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### Compare eConsent & Paper Consent

Same	Different
<ul style="list-style-type: none"><li>• Study information</li><li>• Patient may want more or less assistance</li></ul>	<ul style="list-style-type: none"><li>• Technology issues</li><li>• Embedded information</li><li>• Confirmatory requirement</li><li>• Storytelling, Hover, Videos, URL links</li><li>• adaptable</li></ul>



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### 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



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### Still All About Communication

	Empathy	No Empathy
Respect		
No Respect		



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### Show Respect, Show Empathy

	Empathy	No Empathy
Respect	<p>"May I...?" "Thank you." "Help me understand more about..." "Tell me more..." "What might help you?" "Is this a good time to talk?"</p>	
No Respect		



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### Assess Understanding

Empathy


Respect

"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?"



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### Our Trials

Case A	Case B	Case C
Can yoga help patients with type 2 diabetes?	Can remote blood pressure monitoring help new moms with hypertension?	Can a new injection device help patients with glaucoma?
		
12 wks with 12 mos follow up; no stipend; low risk	2 weeks; no stipend; low risk; phone consent	6 weeks; stipend; higher risk (injection & sample);



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### 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)?



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### Assess Understanding (Technology): Q-A-R

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

Patient: A: "Well, a little bit."

RA: R: "OK. At this point we have a few options...would you prefer that I ..."

Patient empowerment

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### Respond, Based on What You Heard and Saw

Empathy

Respect

"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?"

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### Show Respect: Time

Empathy

Respect

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**Show Respect: Time**

Empathy

Respect

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?



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**Show Respect / Show Empathy:  
Preserve Autonomy - Give Support**

Empathy

Respect



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**Show Respect / Show Empathy:  
Preserve Autonomy - Give Support**

Empathy

Respect

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)



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### What about those medical questions?

Empathy

Respect

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### What about those medical questions?

Empathy

Respect

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 ...

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### What will you do in STRIDE today?

Learn About Simulation

Understand eConsent & Cases

Know Checklist, Observe & Rate Video

Get Ready for the Fishbowl

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What do you see?

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Focus on *GREET*

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Learning from Sim: the Full Checklist

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## Session 1

**Learning from Sim: the Full Checklist**



<https://www.youtube.com/watch?v=72722564>



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**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



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**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...



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And Now?



<https://umassmed.edu/477345321>

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**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)

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**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



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### Our Trials

<b>Case A</b> Can yoga help patients with type 2 diabetes?	<b>Case B</b> Can remote blood pressure monitoring help new moms with hypertension?	<b>Case C</b> Can a new injection device help patients with glaucoma?
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*Respect - Understanding - Empathy*  
**Content +**

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### What will we do next?

Learn About Simulation

Understand eConsent & Cases

Know Checklist, Observe & Rate Video

Get Ready for the Fishbowl

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### The Fishbowl



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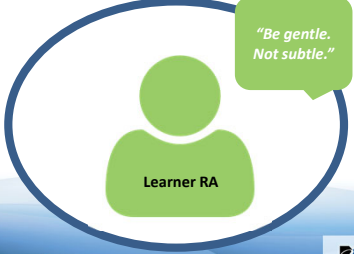
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### Goals of Feedback

Ensuring that the learner improves, while at the same time maintaining his/her self-respect.



“Be gentle.  
Not subtle.”

Learner RA



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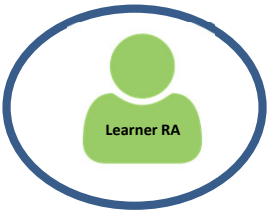
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### Characteristics of Effective Feedback



“Be gentle.  
Not subtle.”

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



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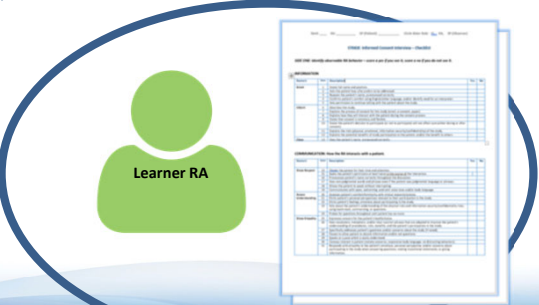
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### What Feedback?



Learner RA



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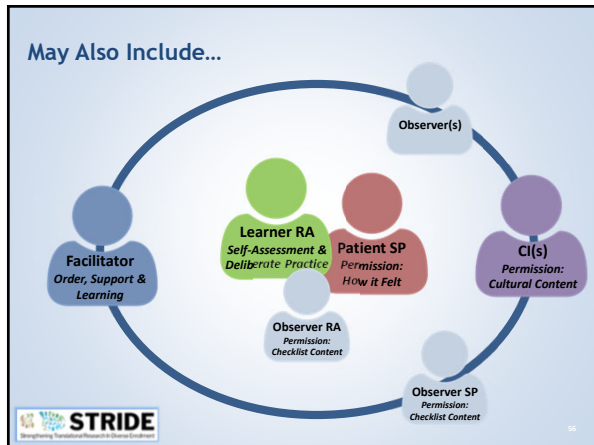
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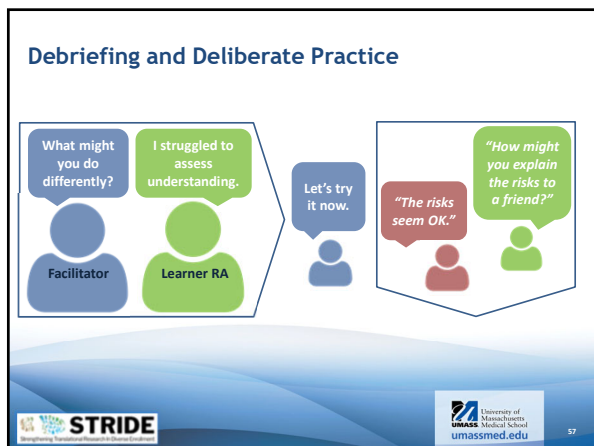
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### More Cycles

Facilitator Patient SP Learner RA

Let's try it now.

Facilitator CI Learner RA

Let's try it now.

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### Fishbowl Debriefing

Facilitator Learner RA

Let's try it now.

Facilitator Patient SP Learner RA

Let's try it now.

Facilitator CI Learner RA

Let's try it now.

Facilitator Others Learner RA

Let's try it now.

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### 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 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

- Raters strive to score learners similarly
- CI raters share nuanced insight about regional effectiveness with RAs
- Scoring enables feedback
- Effective feedback relies on direct observation, self-assessment and is:
  - Limited and prioritized (by time and learner performance)
  - Gentle, not subtle
- Feedback in the Fishbowl
  - Safe for the learner (non-judgmental language and permission-seeking)
  - Promotes brief targeted practice of a specific skill or word choice
- RAs have a hard job: complete a process and build a relationship
- Empathetic communication saves time, increases patient understanding
- RAs can improve communication skills via deliberate practice to:
  - Show respect
  - Assess understanding
  - Show empathy

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# Session 1

### Coming Soon: "Sim-formed" Consent

eConsent

Cultural Humility / Sensitivity

Informed Consent

Greet Inform Close

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Strengthening Translational Research In Diverse Enrollment

Session 1  
Learn to Sim

Session 2  
Understanding  
Implicit Bias

Session 3  
Sim a lot!

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