

STRIDE & eConsent: Moving Towards Personalized Informed Consent

12.14.17

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Vanderbilt University Medical Center

Objectives For Today

PART

1

- STRIDE Grant Overview

PART

2

- eConsent Discussion
 - Discussion of New REDCap eConsent Add-Ons
 - Questions, Feedback, Idea Generation



STRIDE

Strengthening Translational Research In Diverse Enrollment

The Goal

To improve racial and ethnic minority recruitment in clinical trials
by creating culturally relevant tools and interventions

STRIDE Specific Aims

Aim 1: **Expand 3 previously developed intervention components:** ***Storytelling*** for promotion of research literacy; ***Simulation-based training*** for improving culturally appropriate recruitment and informed consent; ***eConsent***

Aim 2: **Test effectiveness** of STRIDE multi-modal intervention to improve participation of African Americans and Latinos **in ongoing clinical trials** at each of 3 partnering CTSA hubs

Aim 3: Promote **widespread translation/dissemination** to CTSA hubs, other research institutions and community organizations

STRIDE is a Three CTSA Collaboration



- **Simulation:** training research assistants to be culturally aware when consenting participants
- **Storytelling:** participant stories to **increase understanding of** clinical trials



- **eConsent**
- **Community Studios** to provide feedback on intervention components
- **Dissemination**



- Intervention **pilot testing**
- **Integrating components** (storytelling, simulation, eConsent) **into existing clinical trials**

Community Investigators



Fred
Jenoure,
UMMS



Jackie
Simms,
VUMC



Clarice
Davis,
UAB

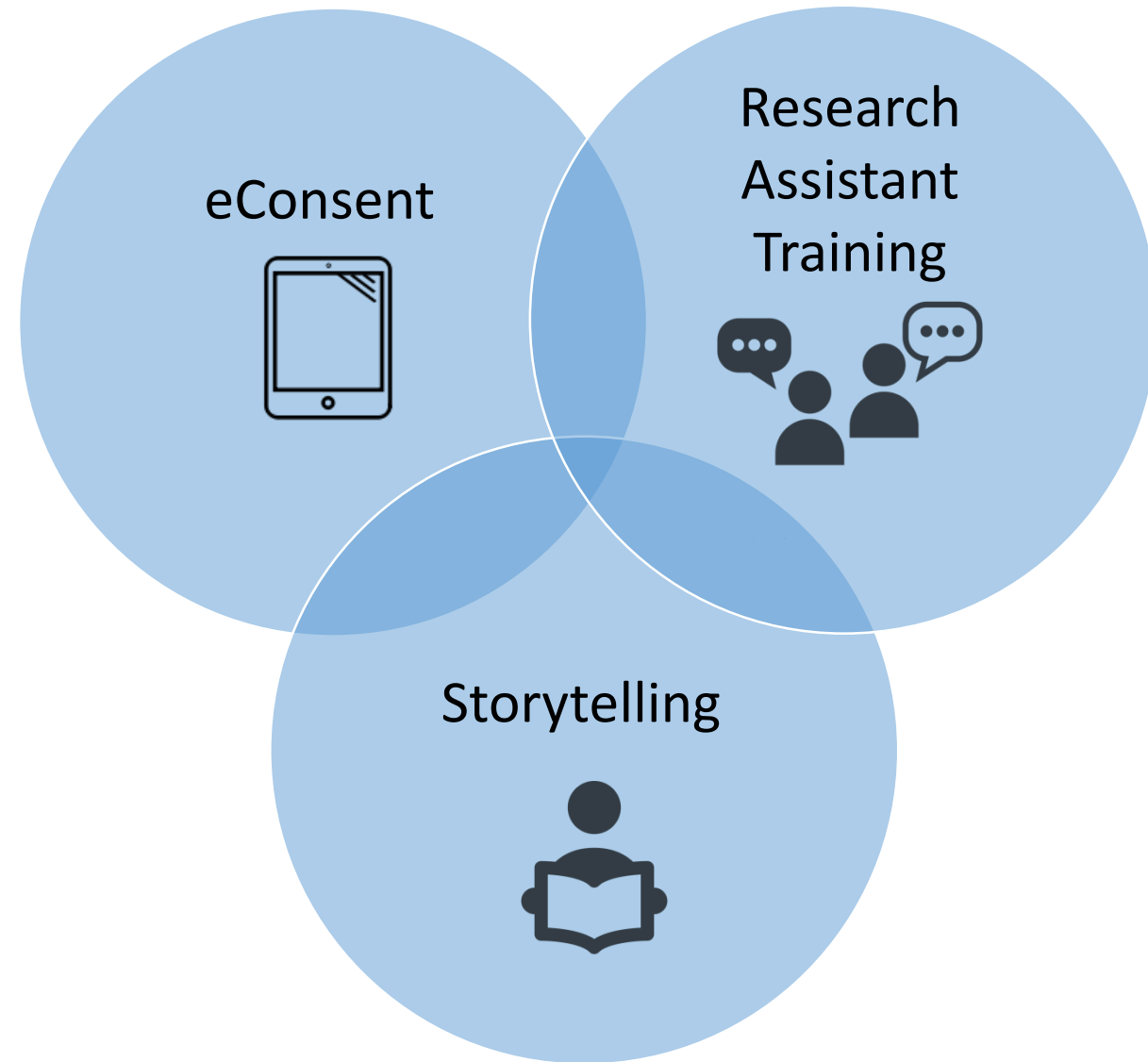
Community Engagement Studios



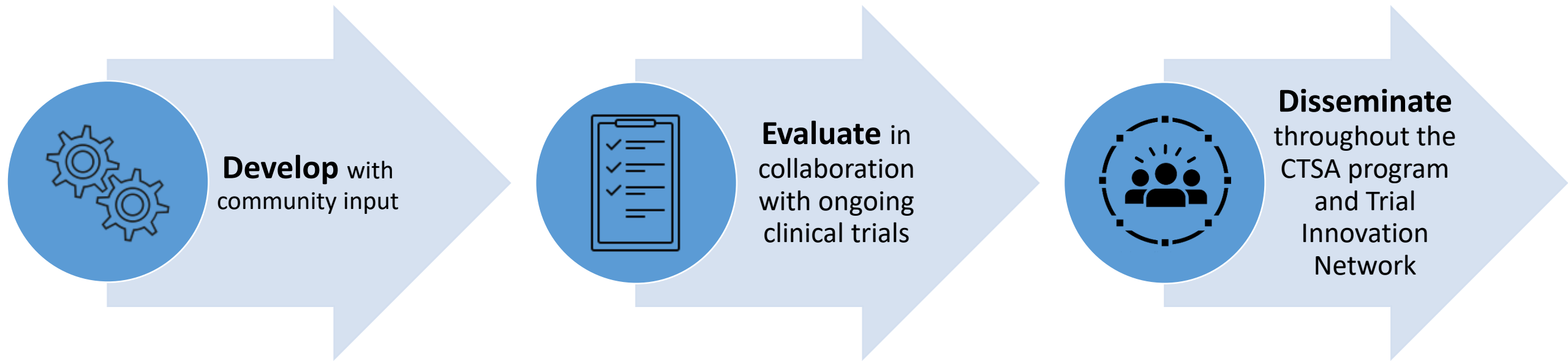
Collaboration with Community Campus Partnerships for Health (CCPH)

STRIDE Intervention Approach

- Comprehensive, multi-component approach
- Aims to provides clinical trial research teams with the training and tools for culturally adapted informed consent



STRIDE Intervention Steps

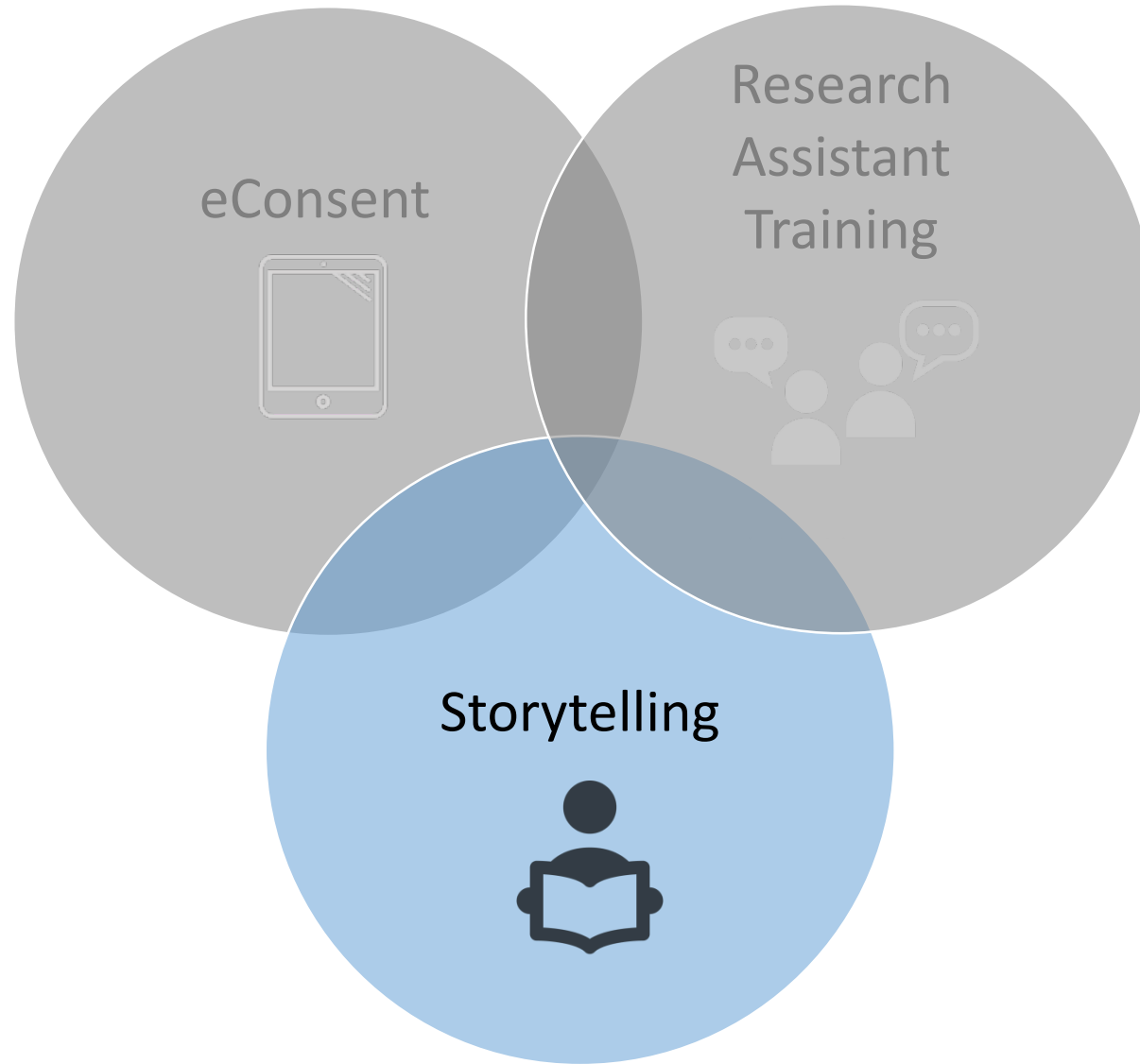




Research Assistant (RA) Training

- Simulation-based training
- Training based on previously established core competencies
- 2-day training at UMass Medical School
- Community Members serve as “acting research participants”, similar to standardized patients

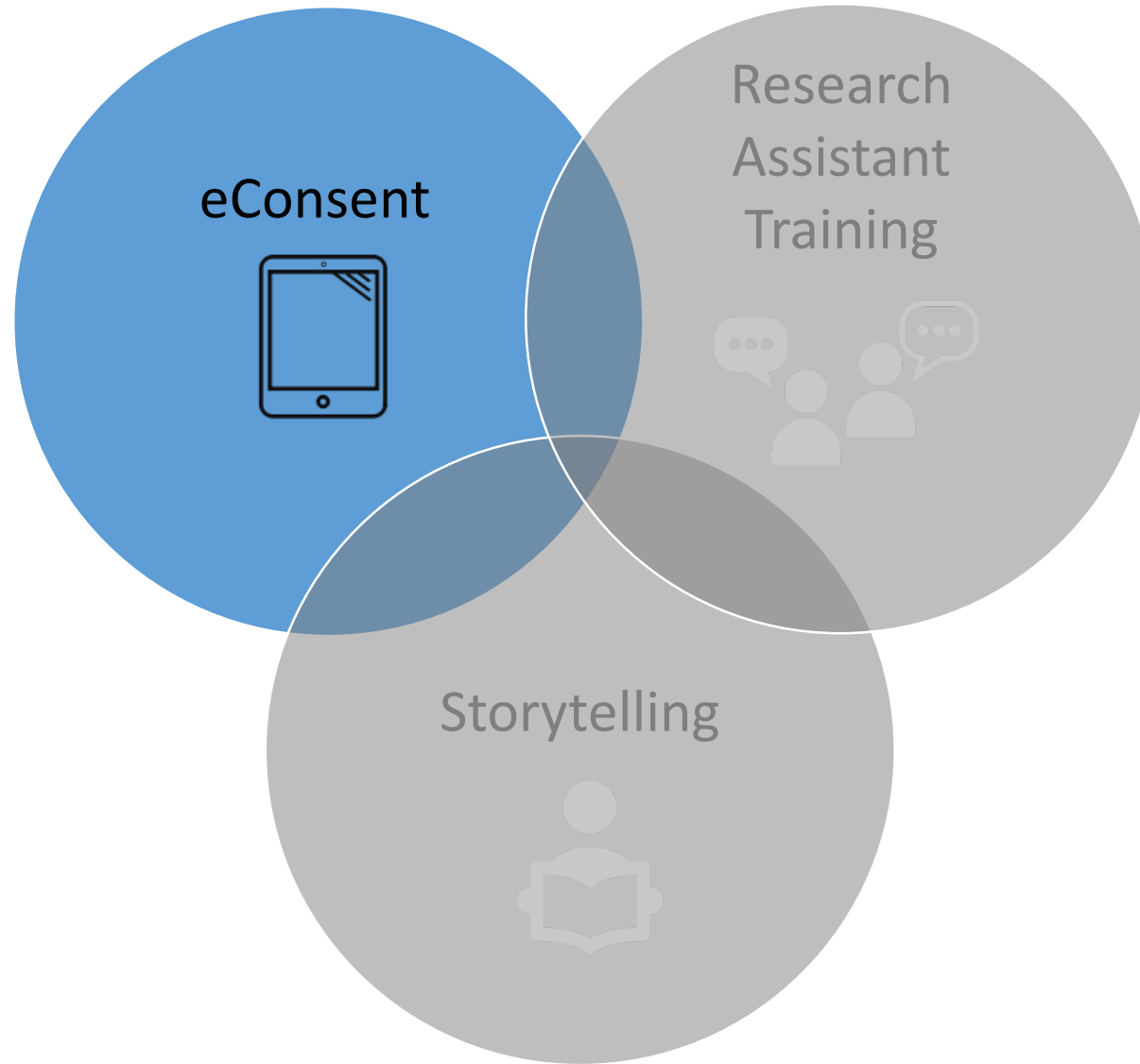




Storytelling - Stories about Participation in Clinical Research

- Short video stories
- Real participants in clinical trials
- Describe personal experiences with research
- Used as an ancillary to eConsent
 - Introduce potential participants to what research is
 - Clarify what research is during the informed consent process





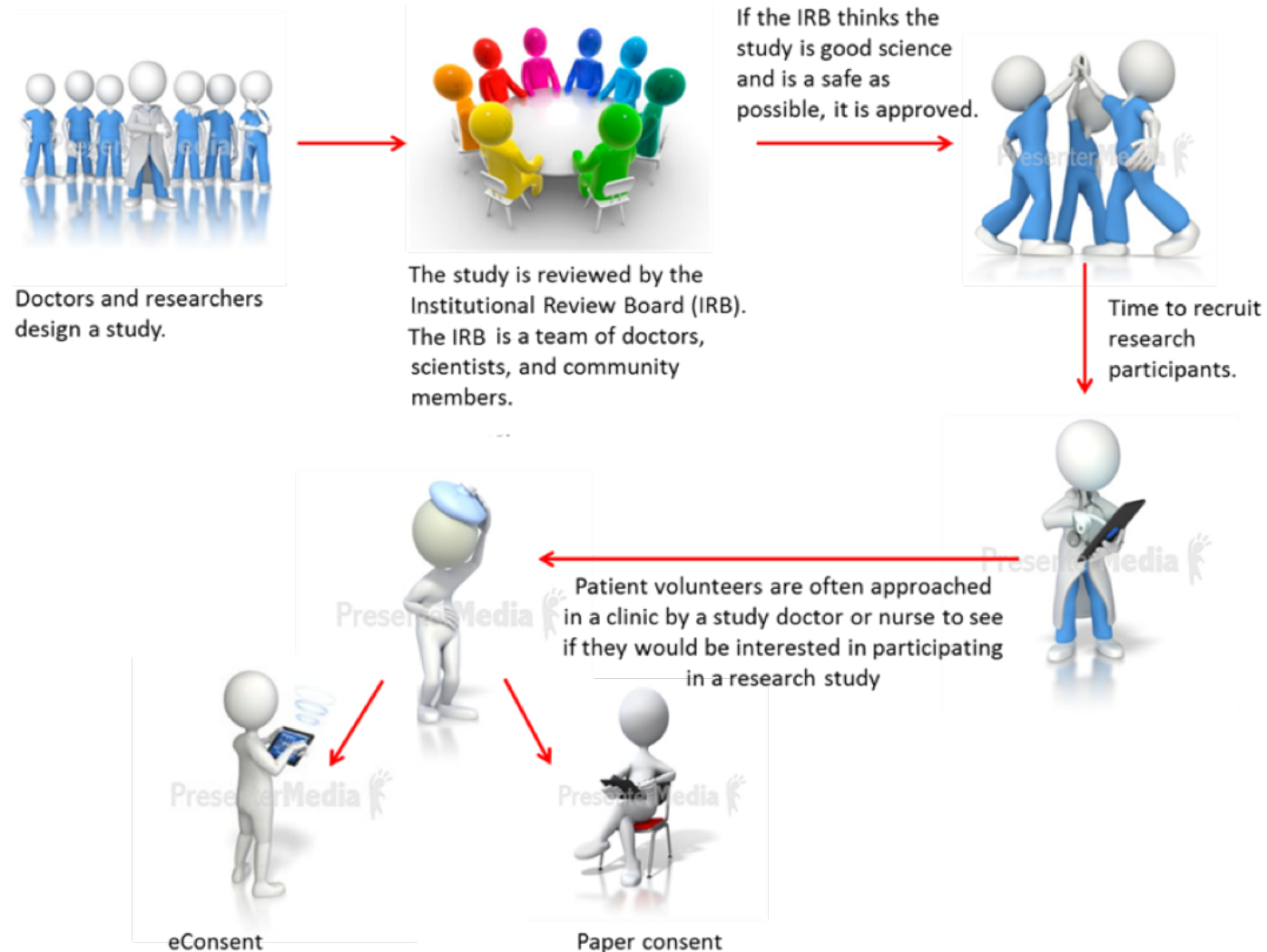
STRIDE Intervention eConsent

- Delivered using REDCap
- Covers all traditional elements of consent
- Adds new elements:

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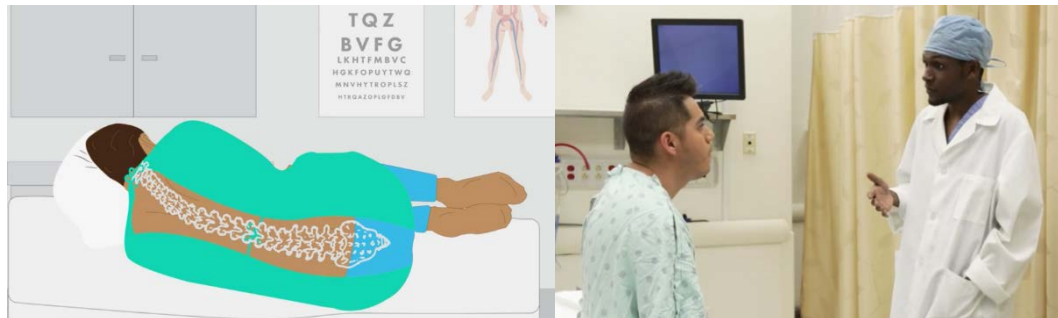
2

- Video Library
- Avatars
- Hover-over definitions
- Plan to ensure Part 11 compliance



eConsent - Video Library

- Collection of videos for 8-10 most commonly consented research procedures, available through REDCap
- IRB will review videos post production
- Videos informed by community feedback and scripts reviewed by Vanderbilt Effective Health Communication Core



Videos embedded in eConsent in-line or as a link

DL

o Dunkel, Leah

o Harris, Paul; o Lawrence, Colleen

Friday, December 1, 2017 at 3:41 PM

[Show Details](#)

This message is flagged for follow up.

Paul and Colleen,

Below, you will find links to the first 3 (4 including the CT with contrast variant) finalized STRIDE videos:

[MRI](#)

[CT with Contrast / CT](#)

[PET](#)

Please let me know if you have any questions or if there are any changes you would like me to make. Hopefully, we avoided any typos this time around.

Many thanks,
Leah



Lumbar Puncture (V1): <https://youtu.be/IDqd90abvQg>

Lumbar Puncture (V2): https://youtu.be/Lcwac1uW_Ic

Echocardiogram: <https://youtu.be/iD2Xc7s-6Jo>

5 Strategies to Boost Participation in Clinical Trials: <https://youtu.be/ZN0dzRhHD0M>

We're making life better (extended): <https://youtu.be/2wa5ic58P4s>

We're making life better (short): <https://youtu.be/YPjxUYCHirk>

Considering Clinical Trial Participation? Here's what to ask: <https://youtu.be/-XJEjERoiZI>

Importance of Clinical Trials (with CW): <https://youtu.be/90JXVjqKIIE>

There's one more in the works (Importance of Engagement) from Consuelo's interview, but we're still working to get that one uploaded. May be later this week / early next week.



Format: Abstract ▾

Send to ▾

Contemp Clin Trials. 2013 Sep;36(1):25-31. doi: 10.1016/j.cct.2013.05.011. Epub 2013 Jun 6.

Development and pilot testing of a video-assisted informed consent process.

Sonne SC¹, Andrews JO, Gentilin SM, Oppenheimer S, Obeid J, Brady K, Wolf S, Davis R, Magruder K.

Author information

Abstract

The informed consent process for research has come under scrutiny, as consent documents are increasingly long and difficult to understand. Innovations are needed to improve comprehension in order to make the consent process truly informed. We report on the development and pilot testing of video clips that could be used during the consent process to better explain research procedures to potential participants. Based on input from researchers and community partners, 15 videos of common research procedures/concepts were produced. The utility of the videos was then tested by embedding them in mock-informed consent documents that were presented via an online electronic consent system designed for delivery via iPad. Three mock consents were developed, each containing five videos. All participants (n = 61) read both a paper version and the video-assisted iPad version of the same mock consent and were randomized to which format they reviewed first. Participants were given a competency quiz that posed specific questions about the information in the consent after reviewing the first consent document to which they were exposed. Most participants (78.7%) preferred the video-assisted format compared to paper (12.9%). Nearly all (96.7%) reported that the videos improved their understanding of the procedures described in the consent document; however, the comprehension of material did not significantly differ by consent format. Results suggest videos may be helpful in providing participants with information about study procedures in a way that is easy to understand. Additional testing of video consents for complex protocols and with subjects of lower literacy is warranted.

Videos on youtube:

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

DEXA: <https://www.youtube.com/watch?v=DDFcXMmVPi8>

BIOPSY: <https://www.youtube.com/watch?v=mz4D1BcFNA4>

MRI: <https://www.youtube.com/watch?v=eogqWkx5SBA>

CAT SCAN: https://www.youtube.com/watch?v=1sjqw_SscYs

ULTRASOUND: https://www.youtube.com/watch?v=5K9R2_2XKb8

Biorepository: <https://www.youtube.com/watch?v=3cT9VFxNP3w>

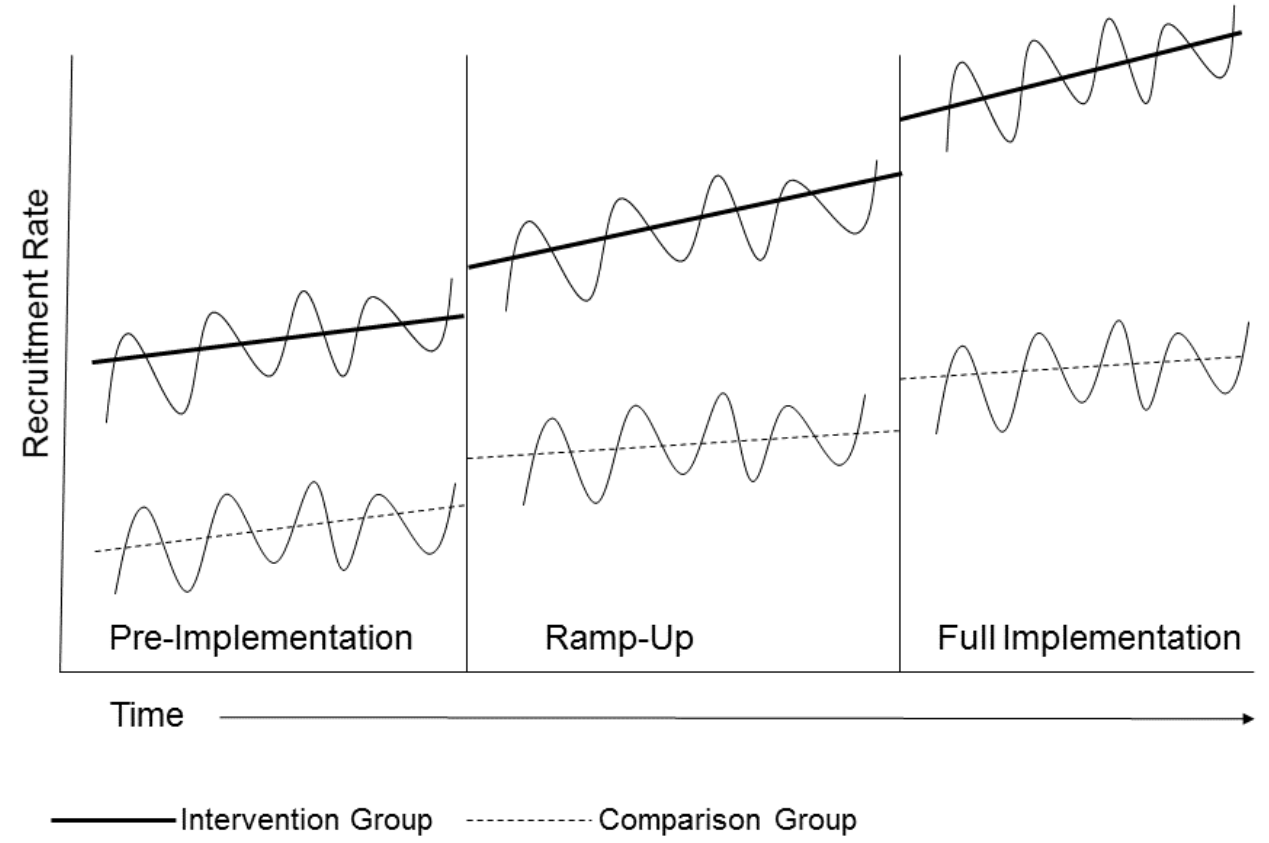
Infusion: <https://www.youtube.com/watch?v=CABcorHeE8A>



STRIDE Intervention Evaluation



- Quasi-experimental design:
 - Intervention: Integration into ongoing clinical trials at UAB, UMass and Vanderbilt (n=3 trials)
 - Comparison: Usual protocol (n=3 trials)
- Interrupted time-series design
- Assess number/rates of recruitment of under-represented minorities before and after the STRIDE intervention is introduced



STRIDE Intervention Dissemination

- Scientific publications
- REDCap consortium
- CTSA conferences and other channels
- STRIDE Toolkit



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- Call to Action - STRIDE Grant Participation

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(According to the PI – Paul Harris)

bored.

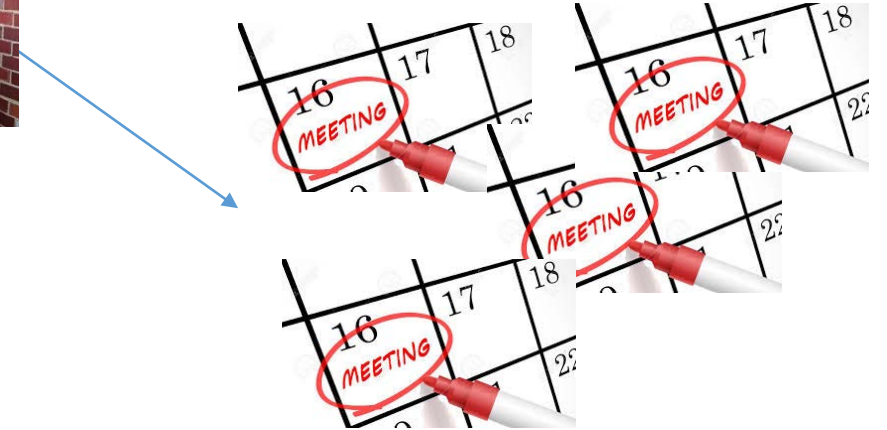


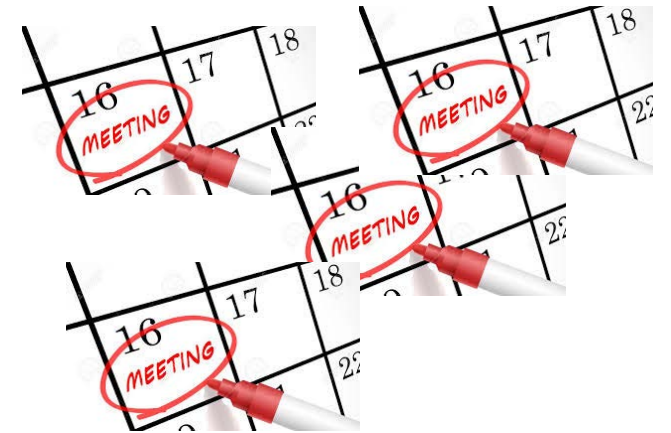
bored.



e consent





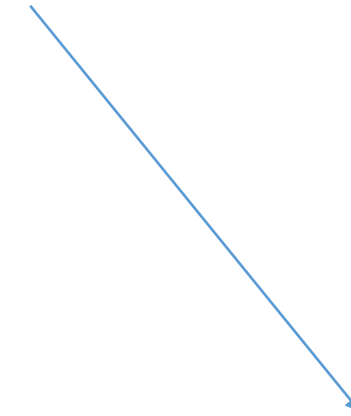


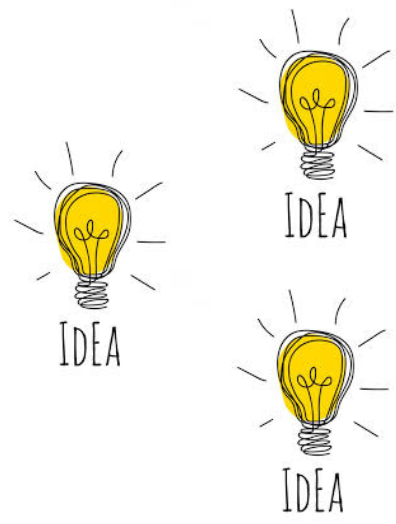
e consent



REDCap
Research Electronic Data Capture



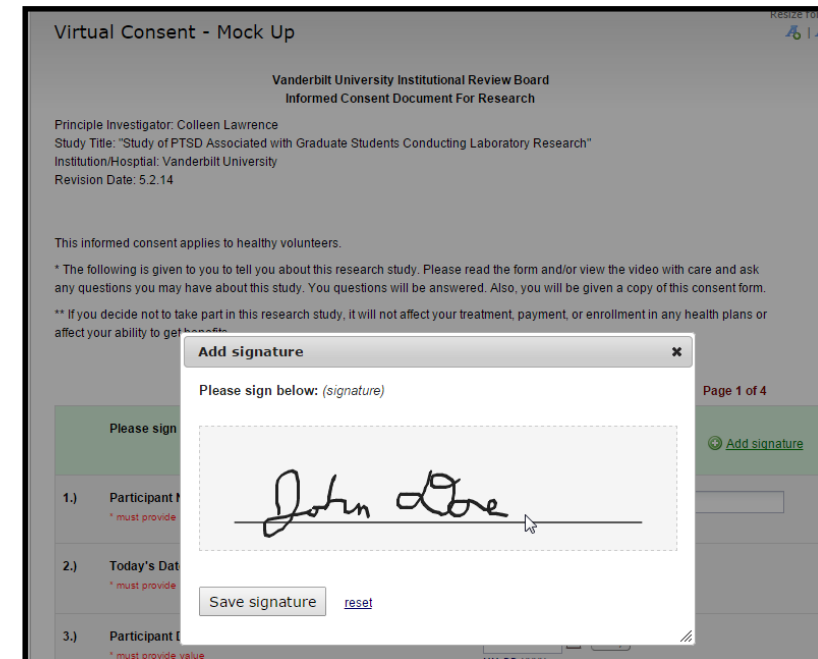
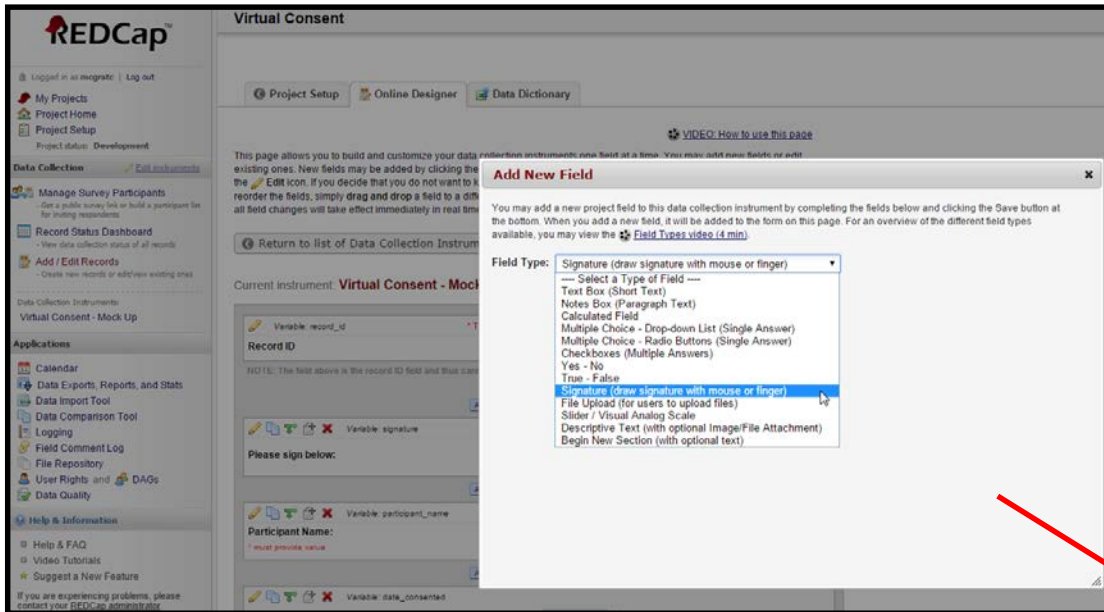




eConsent – “Signature” Process

Patients can “sign” an eConsent document by:

- Typing in their name
- Signing their name via stylus/finger
- Entering a personalized PIN number



eConsent - Avatars

- eConsent platform will use Avatars to guide participants through the consent process
- Scripted voice-over
- Avatar can respond to questions, repeat information and provide additional information



eConsent - Hover-Over Features

- Participants may hover-over keywords to see pronunciation, definitions or more information about a word
 - Gives participants ownership
- Researcher will determine keywords and information that appears



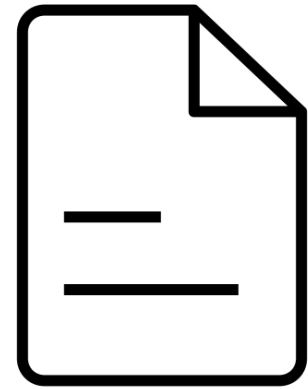
You will come in to the lab annually on National Running Day.

Each year on the first Wednesday in June, people across the United States participate in National Running Day. This day was designated as a day for runners to reaffirm their passion for running.



eConsent – Part 11 Compliance

- Virtual repository to serve as an institution-wide “lock box” for consents
- Specific meta-data elements can be used to link consents in the repository to their respective studies
- Working with Vanderbilt, UMass, UAB IRBs to ensure this repository will fulfill standards of Part 11 compliance








DEMO





(if there is time)

Participants wishing to see the entire consent document before continuing with the consent process can download and view it by clicking on the link below.

Attachment:  [VirtualConsentMockUp_VirtualCo.pdf](#) (0.05 MB)

[Branching logic exists]

    Variable: happen_time [Branching logic exists]

What will happen and how long will you be in the study?

You will be given an MRI before and after the 6 month study period. If you would like more information please watch the short informational video below.

    Variable: happen_time [Branching logic exists]

What will happen and how long will you be in the study?

You will be given an MRI before and after the 6 month study period. If you would like more information please watch the short informational video below.

MRI Scanning for Kids!



[Add Field](#) [Add Matrix of Fields](#)


Logo



1

2

Each year on the first Wednesday in June, people across the United States participate in National Running Day. This day was designated as a day for runners to reaffirm their passion for running.



ly on National Running Day.

NOW YOU'RE
TALKING.
We're listening.



For More Information About STRIDE or eConsent or Video Library

Want More
Information?

Paul Harris

paul.harris@vanderbilt.edu

Colleen Lawrence

colleen.lawrence@vumc.org

Leah Dunkel

leah.dunkel@vumc.org

For More Information About STRIDE or eConsent or Video Library

- Video links:

- STRIDE:

- https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ/videos?disable_polymer=1