potential research participants have the opportunity to see and hear from people with direct experience as participants in past clinical research projects at appropriate literacy levels and utilizing language that is familiar to the target audience[4]. The goal in presenting these stories is not to coerce the potential participant to agree to the study but to invite openness and encourage thoughtful review such that the decision to participate or not in a study is a fully informed one. The stories presented are intended to have an overall tone of empowerment by encouraging the participant to ask general questions about study participation.

Improving Access to Research Among Individuals from Under-represented Racial and Ethnic Minority Communities: The Strengthening Translational Research In Diverse Enrollment (STRIDE) Study

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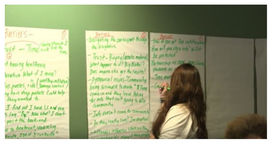
Introduction

- Under-representation in health-related research contributes to health disparities experienced by African American and Latinx communities
- This has been brought to the forefront in the context of the COVID-19 pandemic
- Barriers to research participation stem from historical injustices, are multi-faceted and include factors specific to the research process, research team members and community experiences and expectations about research participation
- Informed consent is a longitudinal process and represents an opportunity to address these barriers and potentially improve access to research by individuals from under-represented groups

Aims

- To develop, test and disseminate an integrated, literacy- and culturally-sensitive, multi-component intervention that addresses barriers to research participation during the informed consent process.

Community-Engaged Methods



- **Community Investigators(CI)** from each site were integrated as key members of the research team and contributed to intervention development, evaluation and dissemination
- **Community Engagement Studios** and **pilot testing with research team stakeholders** were used to develop an integrated eConsent and storytelling intervention
- Inclusion of CIs and other community members as "**standardized participants"** and **evaluators** in simulation-based training development and deployment

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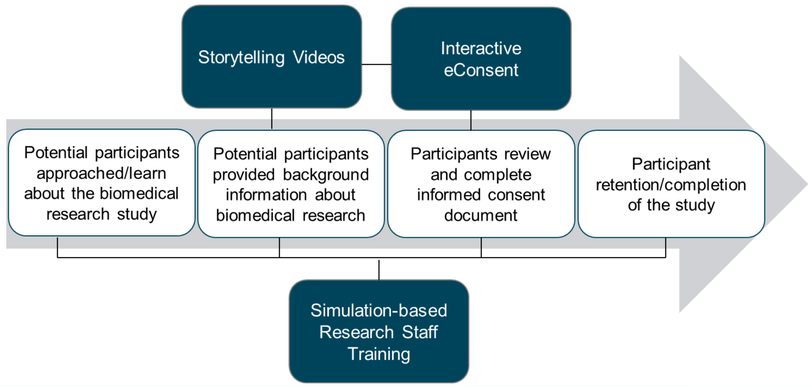
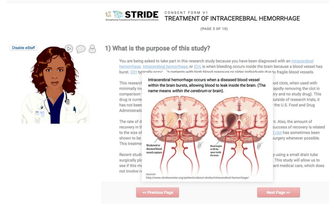
STRIDE Intervention

- The STRIDE intervention is designed to address *the process of consent,* from initial learning about a research project through study completion
- The three interventions components are designed as an integrated set of tools
- Storytelling videos and interactive eConsent are part of an integrated platform
- Simulation-based training utilizes the integrated platform



Interactive eConsent



Rationale: Interactive eConsent offers enhancements to traditional consent that provide opportunities for greater comprehension and engagement through presentation of information in literacy and culturally-sensitive manner.

Description: REDCap-based eConsent platform that can be validated for Part 11 compliance. Includes typical consent features of eConsent PLUS a series of additional , interactive features. Interactive eConsent is tailored to the specific needs of a particular study.

Tools available: REDCap modules include: Avatars that read the consent document; Videos for commonly consented research procedures (e.g., MRI, CT); Hover-over definitions with audio pronunciations for complex terms.

Storytelling

Rationale: Narrative communication via personal stories is an effective way of relaying complex information in a way that is culturally and literacy appropriate. Stories provide opportunities to see and hear from people with direct experiences as research participants in order to inform decision-making.

Description: Series of video stories that includes individuals who have participated in research or were asked to participate but declined. Stories were guided by a conceptually driven interview guide that elicits responses to domains related to research literacy. Videos can be used as an introduction to eConsent or as a stand-alone tool.

Tools available: Video library of 40 storytellers diverse with respect to race/ethnicity, gender, age and type of research study participated in; Stories categorized into the following: (1) Why should I participate in a research study?, (2) What should I know before I participate?, (3) Is it safe to participate?, and (4) Who should participate in research?; Protocols for developing new stories

Simulation-based Training

Rationale: Based on an approach utilized in medical education, simulation-based training provides research team members with hands-on learning of skills necessary to engage potential participants in a community-engaged, literacy and culturally appropriate manner.

Description: Sessions utilize interactive and experiential learning, employing community members as "standardized participants". Core content covers STRIDE rationale and structure, applied implicit bias and cultural humility exercises, simulation and deliberate practice experiences involving standardized research participant case interactions and commitment to change

Tools available: Training agenda with related slide sets; Facilitation guides; Checklists; Evaluation tools; Trigger videos; Worksheets; Training guides

Research Team Experiences

With integrated eConsent and storytelling platform pilot

- Intervention platform built for exemplar clinical trial *"plan to continue using this e-consent method in future trials"*
- 'Think-aloud' focus group with 8 (6 minority) research staff for feedback on e-consent process and storytelling *"like that the videos were not scripted; felt genuine, organic"*
- Mock consent sessions with research assistants from the exemplar trial to further refine intervention platform *"prefer a multi-modal interactive approach"* guided by the research assistant

With simulation-based training

- Training was highly valued *"Excellent, supportive learning environment. Simulation was very helpful…feedbacks were informative."*
- Training provided opportunities for self-reflection *"I learned that I say I don't assume anything, but I have to admit that often I do."*
- Training provided opportunities for skill building *"techniques to effectively engage & build rapport with patients in a research setting."*
- Training was overall well-received *"Please find a way to spread this work far and wide!"*

Evaluation

- Currently being tested in a quasi-experimental, interrupted time series design study
- The STRIDE intervention is being deployed in 3 ongoing research studies and compared to 3 studies deploying usual consent procedures
- Proportion of participants who are members of under-represented racial/ethnic minority groups will be compared
- Usage metrics are also being collected

Dissemination

- STRIDE intervention components are being made available throughout the CTSA consortium as an integrated intervention package and as stand-alone tools
- Protocols and support materials will be available
- Early dissemination activities have included use of STRIDE components (e.g., e-Consent) in COVID-19 related studies

To Learn More:
Contact Stephenie.Lemon@umassmed.edu about the STRIDE multi-component intervention.
See the poster by Lawrence et al., "A REDCap-based Model for Electronic Consent" or contact your local REDCap administrator to learn more about eConsent.

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