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‘Big Win for Health Equity’

TRI Advances Plain-Language Computer-Guided Consent Forms

Members of TRI’s Informed Consent Navigator team include (front, l-r) Mathias Brochhausen, Ph.D., Nicki Spencer, M.H.A., Alison Caballero, MPH, CHES, and Jonathan Bona, Ph.D.; (back row) Justin Whorton, Sarah Fountain, MPH, CPH, CHES, Jennifer Gan-Kemp, MBA, CRS, and Aaron Kemp, MBA. ***Photo by Bryan Clifton***

A new software tool developed by the Translational Research Institute (TRI) will help researchers quickly create consent documents in plain language for their prospective study volunteers.

Called the Informed Consent Navigator, the web-based tool breaks new ground with its ability to guide researchers through the creation of plain-language informed consent forms (eighth-grade reading level or below). *The Journal of Clinical and Translational Science* published the TRI team’s

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Dear Colleagues,

Seven years ago, TRI supported the UAMS Center for Health Literacy’s development of a plain-language informed consent template for researchers that improved readability from 10th grade-plus to 6th to 8th-grade levels.

While the innovative plain-language template proved effective, we wanted to speed the document-creation process and eliminate opportunities for researchers to make mistakes.

In this issue of *The TRIbune*, I am excited to highlight the Informed Consent Navigator, a significant development that will help researchers more easily produce plain-language consents. Thanks to a strong interdisciplinary team, this novel project has delivered in a software tool that guides researchers through the creation of plain-language consent forms. As far as we know, UAMS is the only institution with a computer-powered consent platform that includes such robust plain-language features.

We anticipate that by automating the process for researchers, utilization of the plain-language template will increase significantly at UAMS and other institutions. The *Journal of Clinical and Translational Science* published our work in December, drawing immediate interest from several research institutions across the United States.

This project aligns with our CTSA goal to ensure that research opportunities are broadly accessible and understandable to many groups in Arkansas. I greatly appreciate the research team’s commitment to making the Informed Consent Navigator a reality.

Sincerely,

Laura James, M.D.
Director, TRI
Associate Vice Chancellor for Clinical and Translational Research, UAMS

Big Win for Health Equity (continued from page 1)

work in December, drawing immediate interest from several research institutions across the United States.

"This is a big win for health equity and a big achievement for UAMS," said co-author Mathias Brochhausen, Ph.D., a professor in the College of Medicine Department of Biomedical Informatics.

Interdisciplinary Research

Led by first-author Jonathan Bona, Ph.D., the project involved interdisciplinary researchers including biomedical informaticists, software developers, research ethicists, and experts in community engagement, health literacy, health education, plain-language writing, clinical trials and informed consent. The team was assembled and supported by TRI Director Laura James, M.D., a co-author.

"This project truly played to UAMS' strengths and is a testament to multidisciplinary team science and the vital support of TRI," Brochhausen said.

Ensuring Readability

Consent forms are often long, detailed, and introduce new concepts, said co-author Alison Caballero, MPH, CHES, director of the Center for Health Literacy. The forms can be a barrier to conducting research, especially with populations underrepresented in research and with limited health literacy.

While other institutions across the U.S. have been working on similar automated consent processes, UAMS appears to be first with its automated plain-language consents.

"We were able to get further than any other group with our tool's added health equity benefits," Brochhausen said.

The Informed Consent Navigator builds on years of work by a collaborative team including the UAMS Center for Health Literacy, which created a plain-language consent form template and made it available to all researchers. Now part of the navigator, the text is automatically populated in the informed consent form based on the user's answers to questions presented by the navigator.

Where researchers must write original text about their specific studies, the navigator provides instructional text, content examples and real-time feedback with readability scores and suggestions to improve readability.

The navigator also uses survey logic that helps tailor what researchers see as they are guided through the process, reducing the difficulty and eliminating errors often made when using print-based templates.

"The goal for this is not just to make it easier for researchers to build forms, but to do so in a way that checks and encourages — and in some cases enforces — that the forms are readable," Bona said.

Next Steps

The team's immediate plans are to pilot the Informed Consent Navigator at UAMS and other institutions. Longer term, the team will establish an electronic consenting platform (e-consent). It will also work toward artificial intelligence-powered management of consents to expand the navigator's functionality.

Bona said the team ultimately hopes to see the navigator deployed at research institutions across the U.S. and beyond with the ability to query the network's data.

Community Feedback Improves Consent Tool

Before introducing its novel plain-language, computer-guided Informed Consent Navigator, TRI assembled two Community Review Boards (CRBs) to assess its readability.

The CRB reviews complemented the work of the project's plain-language experts at the UAMS Center for Health Literacy, who developed the text for the navigator.

CRBs are typically one-time meetings of community members to provide feedback on a researcher's project, including aims, goals and promotional materials.

For the navigator project, TRI's Community Engagement team put together one CRB with five community members who had never participated in research, and the other, with nine members, included former research participants and volunteers who have served on other TRI community boards.

Also unique, was a health literacy assessment of the CRB members, administered by Nicki Spencer, M.H.A., senior program manager for the TRI Community Engagement program, after training from the UAMS Center for Health Literacy.

"We always benefit from community feedback, and the screenings confirmed that we were including a variety of health literacy levels in those reviews," said Alison Caballero, MPH, CHES, director of the Center for Health Literacy.

After reviewing the nine-page consent form, the CRB members largely agreed the language was readable, but they expressed concern that the form was too long and redundant in places. They also suggested using images to aid comprehension of the text.

"The CRBs did a fantastic job of identifying needed improvements, and we are very grateful for their work," said Jon athan Bona, Ph.D., who led the navigator's software development.

CTSA Post 'Invaluable' for TRI Director

TRI Director Laura James, M.D., recently concluded a year's national service as the co-chair for the Clinical and Translational Science Awards (CTSA) Steering Committee.

Her committee membership continues through Dec. 31, 2023, although her role shifted this year to supporting the new 2023 co-chair, Duane Mitchell, M.D., Ph.D., principal investigator for the University of Florida CTSA.

"The experience has been invaluable," said James, UAMS associate vice chancellor of Clinical and Translational Research, and the first to represent Arkansas on the Steering Committee.

She shared co-chair duties with Michael Kurilla, M.D., Ph.D., who oversees the CTSA Program as director of the Division of Clinical Innovation at the NIH National Center for Advancing Translational Sciences (NCATS).

As one of 10 CTSA principal investigators (PIs) on the committee, James said the experience was rich with relationship building and information and idea sharing among her peers and NCATS leadership.

"I learned a lot listening to their unique perspectives and hearing about their successful approaches," she said. "It has benefited me as a CTSA leader, and it benefits our CTSA at UAMS."

UAMS is one of about 60 CTSAs across the U.S., and one of the few representing a rural southern state.

"Our CTSA offers the unique perspective of a rural state with tremendous health disparities," James said. "At TRI, we have multiple nationally recognized programs that are providing research solutions to address the health care needs of populations underrepresented in research and that are likely to experience health disparities.

"The great promise of clinical and translational research is that the findings are relatable to individuals here in Arkansas. Faculty and staff members at TRI have worked to ensure that our research is meaningful to Arkansans."

TRI Study of the Month

UAMS Principal Investigator: Deanne L. King, M.D., Ph.D., assistant professor and director of Clinical Research, College of Medicine Department of Otolaryngology – Head & Neck Surgery

Summary: A phase 3 multi-center trial, it will evaluate the safety and efficacy of a new drug candidate for Meniere's disease.

Significance: There are few treatment options available for Meniere's disease, a common inner ear disease whose symptoms include hearing loss, dizziness/vertigo and tinnitus. The anti-inflammatory drug candidate has shown promise as a treatment in smaller studies.

TRI Services: Medicare coverage analysis, study budget development, regulatory and nurse/clinical coordinator support, administration of Clinical Trial Management System, and post-award financial management.

Sponsor: Sound Pharmaceuticals Inc.

Deanne King, M.D., Ph.D., (left) meets with TRI's Kennetha Newman, the study's lead research coordinator.

UAMS | Translational Research Institute

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Join Us April 4 for TRI Research Day

All are invited to TRI Research Day

Tuesday, April 4, from 10 a.m. to 4 p.m.

at Heifer International headquarters in Little Rock.

Our keynote speaker is Duane Mitchell, M.D., Ph.D., professor of neurosurgery and director of the University of Florida Clinical Translational Science Institute (CTSI). He is also assistant vice president for Research and associate dean for Clinical and Translational Sciences at the UF College of Medicine.

The event will showcase TRI-supported research with oral presentations from select TRI-supported investigators. A poster session (with prizes!) will include an array of TRI-supported projects across its range of funding and training programs.

Please mark your calendars.

Use the QR code to register.

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