

THE TRIBUNE

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Mission: Not Impossible

UAMS, Collaborators Working on Solution to National Research Problem



Meredith Zozus, Ph.D., front right, with her team (l-r): Ph.D. students Kat Donovan and Michael Rutherford, and Fan Yu, M.S. Not pictured, Anita Walden, M.S.

A UAMS study team and its collaborators at Duke and Vanderbilt universities may be on the cusp of fixing a major research problem that some view as unsolvable.

The three Clinical and Translational Science Awards Program (CTSA) institutions have designed a possible solution to a complex data and workflow problem that affects all federally funded multisite clinical studies in the U.S. Their work is supported by a \$1,878,612 supplemental award to the Duke CTSA from the NIH National Center for Advancing Translational Sciences (NCATS).

Ten years ago, the idea of a single Institutional Review Board (IRB) system for federally funded multisite research was a dream. The dream became a federal mandate in 2018.

Establishing a workflow to quickly convert the traditional local IRB review framework to a single IRB system requires experts who think like engineers.

Meredith Zozus, Ph.D., is the UAMS site principal investigator for the single IRB project and co-investigator for the UAMS CTSA. Her early training was in engineering, and she has more than 20 years of experience in research standards development.

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Dear Colleagues,

In this TRIBune we're celebrating recent successes with national implications for clinical and translational research and local implications for grooming future researchers.

First, Dr. Meredith Zozus is co-leading an NCATS-funded effort to remove workflow barriers for federally funded multisite studies, which now must use a single IRB. Zozus and her CTSA collaborators are building the electronic workflow and standards that further operationalize the single IRB model, a new federal mandate, and provide communications and tracking with local IRBs. While the complexity of this task is huge, the impact of their work will be a big win for clinical and translational research in the U.S.

Earlier this spring, TRI's Community Scientist Academy (CSA) hosted its first class of high school

students – an idea suggested by their teacher and academy graduate Cynthia Booker.

Teaching high school students about research? Why not? The Little Rock School District Excel Program teaches students about medical sciences. At the CSA graduation, the students' excitement about research inspired the audience. These eager students acknowledged that their original career interests aligned with traditional health care fields, not research. One graduate stated, "I thought research meant googling!" The academy dispelled those notions, and it suggests that we can plant the seeds for future research careers earlier than we had envisioned.

Sincerely,

Laura James, M.D.
Director, TRI

Associate Vice Chancellor for Clinical and Translational Research, UAMS

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“This is a huge opportunity,” said Zozus, a critical member of TRI’s informatics team and an associate professor in the Department of Biomedical Informatics, College of Medicine. “It’s a national problem, and we’re honored to be a part of the team working to fix it.”

Critical issues to resolve include:

- Ensuring that unique local issues are addressed when local IRB authority has been ceded to a central IRB.
- Maintaining local institutional oversight; use of IRB submission information to trigger and manage internal processes; and maintaining accountability of researchers.
- Sharing documents automatically between electronic IRB systems.
- Developing and demonstrating software that enables such sharing.
- Developing standards for document templates.

UAMS’ Kay Shuttleworth, Ph.D., experiences these issues daily as the IRB/regulatory administrator in the Data Coordinating and Operations Center for the IDeA States Pediatric Clinical Trials Network (ISPCTN). Making the single IRB model work means working closely with up to 31 research sites per ISPCTN study. Each study location has its own requirements, requiring her to create custom document templates so that each site can enter their local content.

It adds up to hundreds of documents to keep track of via email, Shuttleworth said. “It’s a challenge.”

She is not alone. Multisite studies and research networks around the country face similar challenges.

Resolving the inefficient data and workflow problem is so complex that in 2017 the NIH invited seven institutions to help study it. These experienced single-IRB institutions received \$150,000 each to support their efforts toward identifying solutions.

For Zozus and other close observers, their findings highlighted process changes being met with manual steps when they reported them at a September 2018 NIH meeting.

“At that meeting, nobody discussed setting standards and automating the system,” Zozus said. “It’s like they thought it wasn’t possible.”

At the time, she and her collaborators were already proposing a possible solution.

“This is pretty ambitious, but it’s quite doable,” Zozus said. The project is led by Duke Principal Investigator Ed Hammond, Ph.D., her former mentor and colleague. The Vanderbilt site principal investigator is Paul Harris, Ph.D., a professor of biomedical informatics.

Together they have designed a system that preserves local oversight by allowing investigators in multisite studies to submit all the required information in their local IRB system, which would then share it with the single reviewing IRB.

In September, their plan will be considered at Health Level 7 (HL7), the international standards organization for health care data exchange.

Next it will be demonstrated by UAMS and Vanderbilt, with UAMS playing the role of central IRB and Vanderbilt as the local IRB.

“We’re going to record videos and share them online so that the IRB software companies see the functionality in the software and the automated workflow so that they can then build that into the commercial IRB systems,” she said.

Researcher Profile



Meredith Zozus, Ph.D.

Associate Professor and Vice Chair
for Academic Programs

Department of Biomedical
Informatics

UAMS College of Medicine

What inspired you to become a clinical researcher?

In short, unanswered questions. What is the most effective method for collection and processing and rendering types of data, and why - what is the underlying science that explains why?

What do you like most about your area of research?

My area, Clinical Research Informatics, is Informatics in service of clinical research. My passion is to innovate and evolve methods to improve the conduct, oversight, reporting and sharing of data from clinical studies, and working with investigators and research teams to apply best practices. My love of these things pops me out of bed in the morning like a spring; I can't wait to get into the office and do this work..

What career would you have chosen if not research?

Nothing. It was inevitable; I had unanswered questions.

What current or former biomedical researcher (from anywhere) do you admire most? Why?

There are so many people that have helped me develop, Drs. Rob Califf, Deborah Roth, Ed Hammond-Jiajie Zhang ... Drs. Califf and Roth built the Duke Clinical Research Institute (DCRI). Working for them and with brilliant colleagues in the DCRI helped me develop methods for assuring the quality of clinical study conduct at scale, for a hundred ongoing clinical studies.

Community Scientist Academy Surprises High School Class



Students in the Little Rock School District's Excel Program were the first high school students to graduate from the Community Scientist Academy.



Acacia Nelson with her poster about African Americans' fears of police brutality.

Shanell Young, a senior at Little Rock Parkview, wasn't sure what to expect during the spring 2019 TRI Community Scientist Academy. After receiving her graduation certificate at a UAMS ceremony, she went to the lectern to share her takeaways.

Prior to the academy, most people she knew referred to research as "googling."

"After 10 weeks of participating in the Community Scientist Academy, we definitely feel different now," she said. "Research is not just googling."

Young's classmates – the first high school students to attend the academy – came from the Little Rock School District's Excel/Advanced Medical Sciences Program.

The academy's purpose is to increase community understanding about the research process and offer research decision-making opportunities to communities, patients and other stakeholders.

The high school students were required to write a paper and create a poster using "photovoice," which involved taking a photo depicting a health-related issue and explaining it with a long caption.

Haley Roberts, a senior, said the academy exceeded her expectations. "Getting to talk to people who are excited about their job – that excitement spreads to you, too," she said. "I think the whole program took us off guard."

Acacia Nelson, a senior, said the academy showed her she could help people as a researcher.

"It's opened my eyes to see that there's different areas in the medical field that you can give back to the community. I feel like research can make a difference."

Research on the Horizon: New TRI Study of the Month

- **UAMS Principal Investigator:** W. Conan Mustain, M.D., Assistant Professor of Surgery, Division of Colon & Rectal Surgery, UAMS College of Medicine
- **Summary:** A multicenter study to provide robust data on functional outcomes of ulcerative colitis patients undergoing restorative proctocolectomy with ileal pouch-anal anastomosis, and moderated structured feedback to participating sites to enable quality improvement over time.
- **Significance:** IPAA patients are at risk for perioperative complications as well as short- and long-term effects on bowel function, social function, sexual function and quality of life.
- **TRI Services:** Medicare coverage analysis, study budget review and negotiation, IRB submission, completion of sponsor's regulatory startup packet, training for study staff/investigators, oversight of enrollment startup, and research nurse coordinator services.
- **Sponsor:** Crohn's and Colitis Foundation



W. Conan Mustain, M.D., (right) meets with TRI's Jonathan Young, director of research administration.

TRIBUTES

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Find the appropriate citation language at tri.uams.edu/about-tri-2/cite-tri.*

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WEBSITE:
TRI.uams.edu

EMAIL:
TRI@uams.edu

TRI MAIN NUMBER:
(501) 614-2287

Editor
David Robinson
Designer
Leslie Norris
TRI Director
Laura James, M.D.