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THE TRIBUNE

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The Big Pivot

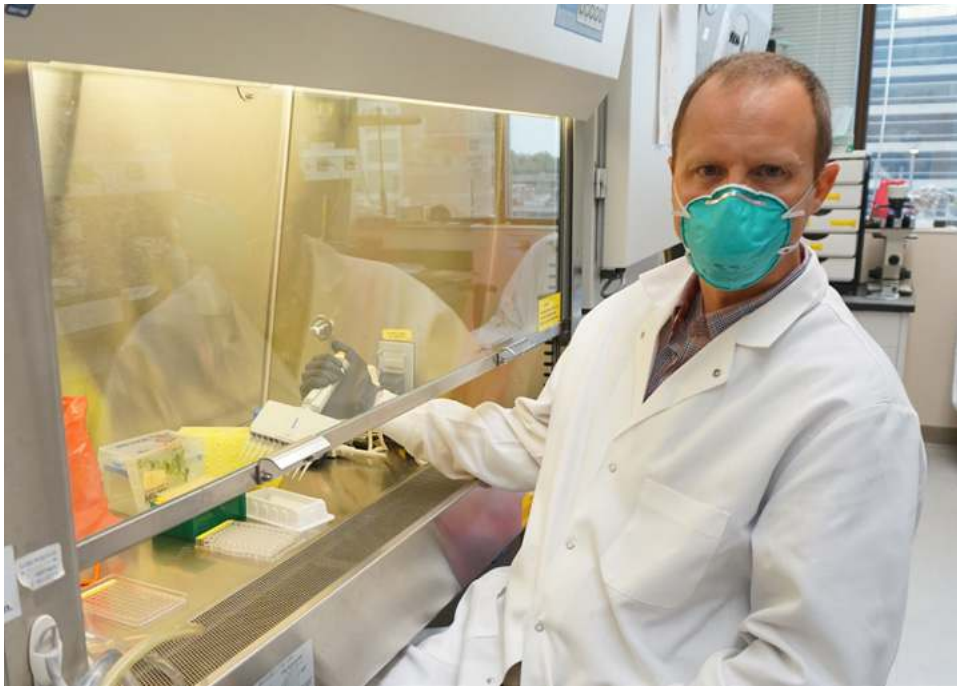
TRI Helps Researchers Turn Focus to COVID-19

Before Arkansas had its first known COVID-19 case in March, UAMS researchers Josh Kennedy, M.D., Karl Boehme, Ph.D., and Craig Forrest, Ph.D., were planning development of a high-accuracy antibody test.

They began validating their antibody test in April, and by June it had become the linchpin of a statewide UAMS seroprevalence study.

The study is a multi-institutional collaboration that includes UAMS and Arkansas Children's Hospital (ACH) and its Research Institute (ACRI). A $3.3 million federal grant allocated by Gov. Asa Hutchinson's Arkansas Coronavirus Aid, Relief and Economic Security (CARES) Act Steering Committee supports the effort.

The state funding enables the purchase of a robotic-assisted immunoassay machine for high-throughput processing of up to 2,500 samples per day. The data it yields will inform policymakers



Karl Boehme, Ph.D., pipetting serum samples at his laminar flow biosafety cabinet.

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CTSA Investments Aid UAMS' Local and National COVID-19 Response

The COVID-19 pandemic is testing a primary tenet of the Clinical and Translational Science Award Program - *to speed the pace of research.*

I am happy to say that UAMS is meeting the challenge. The investments in our translational research infrastructure have positioned us for meaningful roles in Arkansas and across the United States.

On the local front, TRI has been heavily involved in supporting the launch of dozens of COVID-19 studies. Our Clinical Trials Innovation Unit team is working hard to ensure the swift processing of study protocols, and our clinical research coordinators have been heroes in their work with COVID-19-positive participants.

TRI has helped onboard more than 40 COVID-19 studies, ranging from data oriented projects to multidisciplinary and multisite projects. Our efforts also include the state-funded serology study highlighted in this issue. The study will help the state of Arkansas understand the extent of COVID-19 exposure across the state and will be relevant to future research related to vaccine development.

Thanks to the CTSA and UAMS institutional commitment to biomedical informatics, we are helping build a large central repository for COVID-19 research – the National COVID Cohort Collaborative (story, page 3). I commend the leadership of Drs. Fred Prior and Ahmad Baghal on this important project.

Stay safe everyone!

Sincerely,

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

The Big Pivot

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and help Arkansans safely return to their regular activities. In addition, the study will compare the research antibody test to a commercially available antibody test.

TEAM SCIENCE

Josh Kennedy, M.D.

Craig Forrest, Ph.D.

Mark Williams, Ph.D.

The UAMS College of Public Health is leading the statewide epidemiology component of the study, which will involve participation of about 7,500 Arkansans. The epidemiology component is being led by College of Public Health Dean Mark Williams, Ph.D., and Benjamin Amick, Ph.D., associate dean for research. Key College of Public Health team members are epidemiologists Wendy Nembhard, Ph.D., Victor Cardenas, M.D., Ph.D., and Lori Fischbach, Ph.D., and biostatistician James Selig, Ph.D.

TRI Director Laura James, M.D., and Kennedy, a 2015 TRI KL2 Mentored Research and Career Development Program graduate, worked with other researchers to develop the seroprevalence study funding proposal for the state.

Other collaborators and support have come from the Translational Research Institute's Clinical and Translational Science Award from the National Center for Advancing Translational Sciences, including its informatics core, led by Fred Prior, Ph.D., chair of the Department of Biomedical Informatics in the College of Medicine. Additional collaborators from the College of Medicine include Erika Olgaard, M.D., assistant professor, Department of Pathology, and Jeff Moran, Ph.D., assistant professor, Department of Pharmacology and Toxicology, who will oversee the robotic component of the study; and Jessica Snowden, M.D., associate professor, Department of Pediatrics, will oversee the pediatric component.

"This is truly a team science effort involving the expertise of diverse but complimentary experts who have come together to develop a solution to address COVID-19 in Arkansas," James said.

HIGH-ACCURACY TEST

Kennedy, an associate professor in the Department of Pediatrics, initiated the antibody test discussions with Boehme and Forrest, both associate professors in the Department of Microbiology and Immunology.

Boehme and Forrest recalled telling Kennedy they were very interested but lacked a source for serum samples. Kennedy replied, "I can help with that," and facilitated acquisition of about 1,000 serum samples from ACH and 400 from UAMS to begin validating the test.

The team started development of the antibody test with components provided by Florian Krammer, Ph.D., a microbiology colleague at the Icahn School of Medicine at Mount Sinai in New York.

"This is a great opportunity for us as basic scientists to be able to apply our skillset to a question that has huge public health ramifications potentially worldwide and definitely for the state of Arkansas," Forrest said.

Supported by a UAMS Time-Sensitive COVID-19 Pilot Award funded by the office of Shuk-Mei Ho, Ph.D., vice chancellor for Research and Innovation, the research team is hopeful that the final product will outperform other antibody tests on the market. Boehme reported that it has demonstrated 100% accuracy for both sensitivity and specificity to SARS-CoV-2, the scientific name of the new strain of coronavirus.

"We're feeling pretty good about the quality of our assay," Boehme said in a presentation at the June 18 UAMS Showcase of Medical Discoveries – A Focus on COVID-19 Research.

Boehme also reported preliminary results that as many as 10% of Arkansans may have SARS CoV-2 antibodies.

FUTURE RESEARCH

The antibody testing will serve as a springboard for researchers to answer deeper questions about COVID-19 in other studies, such as:

- How do antibody responses differ across different groups of patients?
- How robust is the immune response?
- How much antibody is required to provide immunity?
- How long does immunity last?

"For other coronaviruses, the antibody response may wane after a year or two," Boehme said. "The duration of immunity has implications for a vaccine; will the vaccine be effective for life or will it be a yearly vaccine like with the flu?"

John Arthur, M.D., Ph.D.

'PHENOMENAL' SWITCH

The research team's collaborative, groundbreaking work is among more than 40 COVID-19-related studies either ongoing or in the pipeline at UAMS.

TRI Associate Director John Arthur, M.D., Ph.D., has been impressed by the rapid shift to COVID-19 research at UAMS and Arkansas Children's Hospital.

"Researchers who were using state-of-the-art tools to evaluate different diseases have been able to switch their focus fairly quickly to coronavirus research, and it has been phenomenal to see," said Arthur, a professor in the Department of Internal Medicine.

TRI Gets Leading Role in Creation of National COVID Database

Fred Prior, Ph.D.

TRI's Comprehensive Informatics Resource Center (CIRC) is helping the NIH National Center for Advancing Translational Sciences (NCATS) build a large central repository for COVID-19 research.

All Clinical and Translational Science Award (CTSA) institutions are invited to share their COVID-19 clinical data in the repository – the National COVID Cohort Collaborative (N3C).

CIRC Director Fred Prior, Ph.D., also chair of the Department of Biomedical Informatics, and Ahmad Baghal, M.D., director of the Arkansas Clinical Data Repository (AR-CDR), expect to be the first to pilot test the N3C's record linkage. The project will test the N3C mechanism with UAMS clinical data in the AR-CDR and data from The Cancer Imaging Archive (TCIA).

Ahmad Baghal, M.D.

"We were selected for the pilot because The Cancer Imaging Archive is shovel ready," said Prior, principal investigator for TCIA. "We can collect and publish COVID data today, and the National Cancer Institute has switched TCIA funding from cancer to support COVID research."

Baghal has been proactive in setting up UAMS' ability to push COVID data to N3C, said Prior, who serves on the NCATS Governance Working Group and Tools Working Group.

"Because our AR-CDR has an internal image management component (ARIES), we can work out all of the details internally, which makes it easier for us to correlate all of this data for use inside UAMS and to test the N3C record linkage."

TRI Helping Accelerate Pace of COVID-19 Research

Amy Jo Jenkins, M.S.

The COVID-19 pandemic has put TRI at the center of UAMS efforts to expedite reviews and services for dozens of coronavirus studies.

"We are helping to onboard all of UAMS' non-cancer-related COVID-19 research involving human subjects," said TRI Executive Director Amy Jo Jenkins, M.S. "At minimum, we help with pre-IRB review, and in some cases we also help with protocol development and IRB submissions."

TRI is working closely with the UAMS COVID Research Review Panel, which is vetting the COVID-19 study proposals, including investigator-initiated and multi-site industry-sponsored studies. The panel, made up of five research faculty from diverse fields, serves as a scientific and feasibility review committee to ensure the appropriate use of resources due to the high volume of projects proposed. The committee also identifies where there might be competing studies and facilitates new collaborations when appropriate.

COVID-19 STUDIES, BY THE NUMBERS

- 72 study proposals reviewed by the COVID-19 Research Review Panel
- 33 studies receiving assistance from TRI
- 12 therapeutic trials in pipeline
- 1 therapeutic trial enrolling

Online Resources Developed by TRI for COVID-19 Researchers

TRI.uams.edu.

1. Guidance on conducting human subjects research during the outbreak
2. Guidance on handling COVID-19 samples
3. How-to information for requesting COVID-19 data extracts
4. IRB protocol template for COVID-19 studies

Inside UAMS.edu

Intranet website

(https://inside.uams.edu/coronavirus/kb/resources-and-research-for-covid-19).

Researchers can see what studies are in startup and look for collaborators.

COVID-19 Research Funding Opportunities

Grants available through TRI Clinical and Translational Science Award (CTSA) at the National Center for Advancing Translational Sciences (NCATS):

https://ncats.nih.gov/funding/open

Other federal COVID-related funding opportunities:

https://bit.ly/2BMfvIs

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TRI Announces Pilot Awardees for Biomedical Informatics Studies

TRI recently announced four recipients of its biomedical informatics-focused pilot grants.

The recipients are required to use translational biomedical informatics approaches to health care issues that particularly affect rural individuals and/or that directly examine or impact rural health. They will receive up to $50,000 for their one-year projects and are expected to develop findings that lead to larger programs of research with national funding.

The awardees, all from the College of Medicine, are:

Hari Eswaran, Ph.D.; Professor, Department of Obstetrics & Gynecology; Identification of Pregnant Women at High Risk of Maternal Morbidity

Sacha McBain, Ph.D.; Assistant Professor, Department of Psychiatry; Digital PTSD Screening and Intervention to Meet Rural Needs

Se-Ran Jun, Ph.D.; Assistant Professor, Department of Biomedical Informatics; Using Genomics to Track Carbapenem-Resistant Enterobacteriaceae (CRE) Linking Rural and Urban Health in Arkansas

Tuhin Virmani, M.D., Ph.D.; Associate Professor, Department of Neurology; Utilization of a Neuroinformatics Research Platform (ARIES) to Develop Quantitative Tools for Clinical Assessment and Treatment of Parkinson's Disease Patients in Rural Arkansas

Help Tell TRI's Story - Cite the CTSA Grant

UAMS researchers who receive services or support from TRI can help ensure continued federal funding by citing the Clinical and Translational Science Award (CTSA) in their publications, posters and presentations.

Citing the grant is a great way to show the value and impact of the CTSA Program to UAMS and to TRI's funding agency, the NIH National Center for Advancing Translational Sciences (NCATS).

"We want all UAMS researchers to know that citing the grant helps both them and UAMS because it is an important metric that our funders consider," said TRI Executive Director Amy Jo Jenkins, M.S. "Every time a researcher cites our grant, they are telling our story and making the case for continuation of our vital CTSA funding."

Researchers can quickly find the information they need for acknowledging TRI/CTSA grant support on the TRI website: **TRI.uams.edu/cite**

Questions? Contact Amy Jo Jenkins at AJJenkins@uams.edu.

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