

THE **TR**IBUNE **UAMS** University of Arkansas for Medical Sciences

July 2016

ACCELERATING DISCOVERIES TOWARD BETTER HEALTH

Small Team, Big Results

TRI's Project Support Unit Makes Most of Resources



TRI's Suzan Blair, R.N., a clinical nurse coordinator, takes the blood pressure of Susannah Kirby, a TRI research program manager and volunteer study participant.

Over two weeks this spring, more than 100 women showed up for consenting and blood draws as part of a TRI-coordinated industry-sponsored study of a pregnancy test. The influx required excellent coordination and cooperation among TRI Project



Jonathan Young

Support Unit staff. With only four research coordinators on the team, other staff lent their support. Members of the Research Finance Team helped guide the participants as they arrived, while Jonathan Young, senior project manager, learned how

to operate the blood centrifuge, and Kennetha Newman, research program coordinator, managed the participant scheduling.

"I'm very proud of how everyone rallied to support our research coordinators, because they were



Alison Oliveto, Ph.D.

working so hard to make this happen," Young said. Alison Oliveto, Ph.D., who directs the Project Support Unit, said the unit's effort on the study is just one example of the outstanding teamwork it demonstrates routinely.

The Project Support Unit provides

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Message from Dr. James



Dear Colleagues,
As you will read in this issue, TRI has seen a significant increase in demand for its clinical research services since last year. Our Project Support Unit has met

this demand, and remarkably, it has substantially reduced the time needed for study budget negotiations and approval. I am proud of the leadership of Alison Oliveto, Ph.D., and Jonathan Young, who have established a high-functioning, knowledgeable team that is applying novel approaches to improve efficiencies on behalf of the researchers they serve.

On a related note, I was excited to see the NIH National Center for Advancing Translational Sciences (NCATS) recent announcement of the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform. SMART IRB is now the roadmap to a "clinical trials superhighway" that will help fulfill the requirement for all NIH-funded multisite clinical studies to use a single IRB, meaning other IRBs will accept the judgment of the single IRB.

TRI expects to be an active collaborator as NCATS continues to develop and test SMART IRB. Two representatives of our Project Support Unit attended a recent training on SMART IRB. This important initiative reminds us of our key national role. Through SMART IRB, we can be at the forefront, helping avoid costly delays to clinical trials.

Sincerely,

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

Small Team, Big Results *(Continued from page 1)*

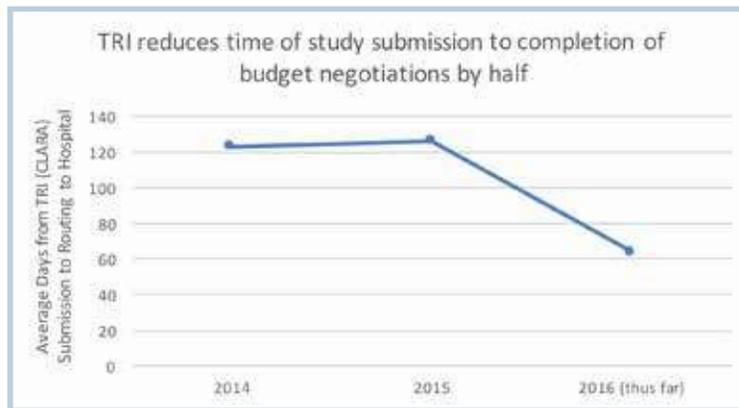
services for all types of human-based research, both investigator-initiated and industry-sponsored studies. These services include research budget review and development, Medicare coverage analysis, protocol development, regulatory support, professional research staff, and laboratory processing resources.

“What they accomplished with the pregnancy test study was phenomenal, and they did it in the midst of a major upswing in demand for our services,” Oliveto said.

From April 2015 to April 2016, the Project Support Unit saw nearly a three-fold increase in protocol development requests. By the end of June there were upwards of 40 studies somewhere in the unit’s queue, which compares to 16 in April 2015.

“Our coordinators are working on 35 studies now, which is more than double the number in April of 2015,” Young said. The studies involve diseases and conditions such as high blood pressure, alcohol-induced liver decompensation; psoriasis and associated hyperammonemia; sleep disordered breathing in pregnant women; opioid dependence; overactive bladder; septic shock; HPV; pre-term pre-eclampsia; psoriatic arthritis; Parkinson’s disease; inflammatory bowel disease; systemic lupus erythematosus; stroke; and mucosal barrier dysfunction.

Despite the increase in protocols, the Project Support Unit’s seven-member Research Finance Team has significantly reduced the time needed for budget negotiations and budget approval. This process previously required on average 126 days to complete, based on 2015 data. During the first half of 2016, the time frame has already been cut essentially in half, averaging 64 days thus far.



To further increase efficiency in workflow, the Research Finance Team piloted development of study budgets and oversight of the budget negotiation process. Traditionally, this process has been shared among UAMS departments and staff in the Research Finance Team. TRI staff showed that they could lower the total work flow to 26 days by having budget development and negotiations centralized.

“We have very knowledgeable budget developers and negotiators, and when all the steps can be performed in our office, it’s much more efficient,” Young said.

The Project Support Unit has become more efficient through cross-training of staff and key changes to its processes.

“There’s cross-training within our teams and between the teams,” Young said. For example, members of the Research Finance Team who conduct Medicare Coverage Analysis reviews

are learning how to develop budgets and conduct negotiations with the study sponsor. Others on the team are also learning how to provide protocol development services conducted by the Regulatory Team.

“We’ve also taken the Medicare coverage analysis task and moved it to the very beginning of this process,” he said. “That means we’re developing the budget almost at the same time, which makes more sense because the Medicare coverage analysis is basically driving how we develop the budget.”

TRI Welcomes New Advisory Group



TRI was excited to welcome its new State and Community Stakeholders External Advisory Council in June. Members are (l-r) Michael Knox, Executive Director, Arkansas Minority Health Commission; Ray Montgomery, President/CEO, White County Hospital; William Tsutsui, President, Hendrix College; Michael Moore, Vice President, Academic Affairs, University of Arkansas System Office; Jerry Adams, President/CEO, Arkansas Research Alliance; Nicole Hart, CEO, ARVets Inc., and State Senator Jonathan Dismang, Dismang Consulting Services. We thank them for joining the TRI team!

TRIBUTARIES

Researchers Say TRI KL2 Awards Helped Them Earn NIH K Awards



Joshua Kennedy, M.D.



Taren Swindle, Ph.D.

Recent TRI KL2 Scholar Award graduates Joshua Kennedy, M.D., and Taren Swindle, Ph.D., are recipients of National Institutes of Health (NIH) grants that will

support their work over the next several years.

Kennedy is receiving a five-year \$877,000 National Institute of Allergy and Infectious Diseases K08 Award. Swindle is receiving a four-year, \$442,583 National Institute of Diabetes and Digestive and Kidney Disease K01 Award.

Kennedy's grant provides salary and laboratory support for his investigation into how allergies and rhinovirus infections work in tandem to create life-threatening symptoms for people with asthma. He will work with patients who experience critical asthma symptoms as a result of rhinovirus infections and allergies, and he will study donated lung tissue in his lab.

Swindle's research involves the study of a childcare-based nutrition intervention and development of a strategy

for implementing the intervention. She will pilot test the implementation strategy and the intervention's effect on child health outcomes.

Kennedy and Swindle said their awards were made possible by two years of research support and training they received through TRI's KL2 Mentored Research Career Development Scholar Award Program.

"The KL2 provided the funds necessary to produce the preliminary data that supported the NIH K08," Kennedy said. "The grant was reviewed by all of my KL2 award mentors, and the CTSA (NIH Clinical and Translational Science Award) consortium organized a special K club that provided valuable feedback and ultimately helped my application get funded."

The KL2 has provided Swindle with training experiences in nutrition, grant writing, and qualitative methods that were critical to her conceptualization of the K01 grant and strengthening her qualifications as a K01 candidate, she said.

"The protected time for mentored research on the KL2 also allowed me to secure important preliminary data that I was able to use in my K01 application," she added. "The review committee specifically mentioned my KL2 experience as a strength in my review."



Mtonya Hunter-Lewis, Regulatory Management Supervisor and Lead Medicare Coverage Analyst, TRI Project Support Unit

"The Translational Research Institute is an exciting place to work because of its far-reaching impacts on all aspects of research, from community engagement to helping cure diseases. As a member of the Project Support Unit, most of my days are spent reviewing protocols, consents and contracts to ensure that they

are federally sound and that participants are protected. There are many moving parts that must be handled efficiently, and I am proud to be part of a unit that functions as a true team. The services we provide help free up our scientists to focus on finding cures, and I love being part of it."

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TRIBUTES

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