



COLIN HACKLEY

BUILDING A CLINICAL RESEARCH NETWORK, ONE PRACTICE AT A TIME

BY RON HARTUNG

Your doctor is also a teacher,” reads the sign in the waiting rooms of 2,100 College of Medicine faculty physicians statewide. Soon another sign could hang beside it: “Your doctor is also a researcher.”

Little by little, those community physicians are being united into FSU’s vast Clinical Research Network (CRN) – which is collaborating with the University of Florida’s research powerhouse. In less than two years, the network has conducted two pilot studies. It’s getting ready to launch a third. And Associate Dean for Clinical Research Michael Muszynski, M.D., says two major ones are around the corner.

“In 10 years, I fully believe that we’ll be engaged in phenomenal community-based research at all six regional campuses,” said Myra Hurt, Ph.D., senior associate dean for research and graduate programs. “At this stage, the challenge is figuring out how to make it effective and long-lasting.”

Among the challenges are persuading busy medical practices to undergo online human-subject and study-related training; managing a network of practices that differ greatly in staffing, technology and populations; and navigating the red tape involved whenever humans are used as research subjects.

“It’s like walking in molasses,” Hurt said. “But a big initiative like this takes time.”

The potential benefits are breathtaking: doing research that includes diverse, rural and underserved patients rarely represented in typical studies; inviting community physicians to offer their own research ideas; and translating research more quickly into improved care.

Muszynski is honing this sales pitch as he meets with faculty physicians: “I have something that’s going to immediately help your patients. They’re going to love it. You’re going to love it. This is also your chance to be part of a big academic endeavor with two major universities. And you’ll get recognition that you’ve never had before. So what do you say?”

Sometimes they say, “Sign me up!” But building the CRN is not always so easy.

PARTNERS IN TRANSLATIONAL RESEARCH

The magic word in medical research now is “translational.” That is, translating research into improved community health care.

That community emphasis helped set the stage for Health IMPACTS for Florida – a collaboration between FSU and UF that’s central to the pilot projects that jump-started the CRN.

“We’d already built this education network of campuses and community physicians across the state,” Muszynski recalled. “So we thought: Why couldn’t we layer on top of that a practice-based research network?”

“UF got wind of what we were doing and got really interested. In 2009, the University of Florida had received a \$25 million Clinical and Translational Science Award from the National Institutes of Health and recognized how valuable our network of community providers would be. So UF came to us and said, ‘Let’s work out a deal.’ Eventually we became partners. The collaborative would then involve practices in six cities of the FSU regional campuses, three FSU rural sites and two UF cities, covering an amazing cross-section of Florida’s population.

“Around the same time, a deadline was looming for a state grant through the Board of Governors called Cluster Awards, for up to \$600,000. Together we said, ‘Let’s propose this collaborative as our cluster application.’”

In 2010, the two schools were awarded the \$600,000 and jointly launched Health IMPACTS for Florida (“Integrating Medical Practice And Community-based Translational Science”). In 2012, Health IMPACTS embarked on its pilot studies, both of which were conducted using an iPad. One taught pediatricians and family doctors to use a concussion assessment tool with young athletes; the other implemented an adolescent health-risk assessment tool to identify risk behaviors in teens and then provide physicians with referral services for those risks. Data are being gathered, analyzed and prepared for publication and have already been presented at national research meetings.

The FSU-UF partnership is thriving, Muszynski said. Because some people find it confusing, he clarified that Health IMPACTS did not replace FSU’s Clinical Research Network. The FSU network partners with UF but also can partner with other institutions or conduct its own studies. That flexibility offers what he calls “a synergistic web of collaborations.”

“It’s like walking in molasses. But a big initiative like this takes time.”

- Myra Hurt

◀ The iPad is at the heart of the CRN’s two pilot studies, one related to detecting concussion symptoms among young people and one related to assessing teenagers’ health risks. Young people are more comfortable using the iPad than paper.

Pediatricians Nickeey Malcolm, left, and Debbie Andree consult with Michelle Vinson, center, director of the Clinical Research Network.



Nickey Malcolm is one of the three pediatricians at Pine Hills Family Health Center in Orlando, a key participant in the CRN's pilot study on health risk assessments.

PUTTING THE 'WORK' IN 'NETWORK'

Since the skeleton of the network was already in place, a casual observer might think, "This should be a breeze." Not so.

"There were a lot of hiccups," Muszynski said of the pilot projects. "Birthing a research network is almost as messy as giving birth to a human being, but birth brings new wonders."

For example, anyone at FSU who wants to do research involving human subjects must obtain approval from the governing IRB (Institutional Review Board), created to protect the rights and welfare of subjects participating in research. But if you have two universities and multiple community-based practices and hospital systems involved in your study, that means eight IRB review board submissions and approvals. And if you tweak your study protocol later, you must obtain approval from each board again.

Having one IRB would make life much simpler.

"We've been talking about it for a year and a half," Hurt said. "We've got a proposal that UF would serve as the central IRB for Health IMPACTS studies."

Another challenge is that each practice is different. Both pilot studies relied heavily on iPads, so WiFi was essential. Some offices have it; some don't. Some offices are IT-savvy; some aren't. So Clinical Research Associate Jessica De Leon, Ph.D., in Tallahassee



Associate Dean for Clinical Research
Michael Muszynski

and CRN Director Michelle Vinson, M.S., in Orlando visit each site to help solve study-related issues.

"There's a lot of IT troubleshooting, which can be very challenging," Vinson said. "You just learn it. How it works, how to make it work, how to not interrupt their practice flow – you're constantly coming up with ideas off the top of your head to find an answer.

"Sometimes they can implement your suggestions. And other times it's, 'My front desk staff is too busy to assist with patient recruitment or informed consent.'"

But Vinson values the relationships she builds with these practices. She knows how busy they are. "You've got to find solutions that are a fit for each practice," she said.

She and Muszynski take the long view.

"You don't want to get too depressed if something fizzles," he said, "because you know there's something else right around the corner. It typically takes five years to get a research network really cranking. We're barely two years old."



IN THE FUTURE

CHRIS GOTSHALL

What's next?

"With UF, we're going to be putting together a call for proposals to get three or four more research projects going," Hurt said. "We want to have at least two from here."

Heather Flynn, Ph.D., vice chair for research in the Department of Medical Humanities and Social Sciences, has two in the works. She hopes to involve as many as four regional campuses in research on depression in women during or just after pregnancy – with an emphasis on socioeconomic, racial and ethnic diversity. The other project would help the CRN build the capacity to do patient-centered research and "comparative effectiveness research" – a way to study which kinds of interventions and health-care decisions are best for which kinds of patients.

Partnering with longtime rival UF in Health IMPACTS opens up unimaginable possibilities, Muszynski said.

"This makes us competitive for major grants," he said. "These projects will be significant in size and scope. Neither institution could accomplish it alone, but together the potential is *tremendous*."

"It typically takes five years to get a research network really cranking. We're barely two years old."

- Michael Muszynski