CTSA Clinical research facilitators provide point of contact for researchers

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CTSA clinical research facilitators Jennifer Delmerico (left) and Jami Radtke (right)

It now takes less than half the time for a clinical researcher in the Buffalo Translational Consortium to get Institutional Review Board (IRB) approval for a full board clinical study review than it did just a year ago. The average 80 days between submission and final approval (for studies submitted August 2014 – September 2015) has been reduced to less than 40 days (for studies submitted March – August 2016).

That brings the University at Buffalo just under the national average, but the goal of the University at Buffalo Institutional Review Board (IRB), Clinical Research Office (CRO) and Clinical and Translational Science Award (CTSA) is to do even better.

Facilitators and navigators

Several factors are responsible for the dramatic reduction in IRB turnaround times, among them implementation of Click research compliance monitoring for human studies and increased staffing and improved processes within the IRB. Another critical factor has been the efforts of Jennifer Delmerico and Jami Radtke, the CTSA's two clinical research facilitators in the CRO. Just as the job title implies, their role is to help investigators move research projects along more quickly and efficiently.

Delmerico joined the staff in October of 2015 and Radtke joined her in the office in February of this year. They made an immediate impact on the IRB submission process when they began conducting pre-reviews of researchers' IRB submission materials to help ensure everything's in order before the proposal is reviewed by an administrator and then goes to committee.

An incomplete or inadequate proposal that requires modification leads to a deferral, which can hold up final approval. Submitting and resubmitting proposals also contributes to the substantial workload for members of the IRB.

"They just get so many submissions," Delmerico says. "If a PI (principal investigator) sends something in and it's on the wrong template form the IRB committee will have to bounce it back to the PI for a modification and resubmission." Meanwhile, progress on the research project remains on hold.

By reviewing the required documentation prior to submission the clinical research facilitator can help the investigative team avoid costly and unnecessary delays.

Conducting pre-review of IRB submission materials is an important part of their work, but it's not all the facilitators do. They're also navigators who are available to help steer PIs and research coordinators to the resources they need to keep their research projects moving forward. "The intention of the (CTSA) grant was for us to be the first point of contact for investigators seeking the services of the Clinical Research Office and the other CTSA cores," says Delmerico.

If the clinical research facilitator can't help, she will refer the PI or research coordinator to another CTSA core that can. Services available to PIs include, but are not limited to, the following:

Biostatistics, Epidemiology and Research Design
Community Engagement
Education and Training
Drug Development
Imaging
Laboratory Core Facilities
Bioinformatics

Easy access to CTSA services for researchers

Since July of 2016, researchers have been able to access the resources of the CTSA online through the "Request A Service" portal. To reach a clinical research facilitator, for instance, they would log in and click on "Research Navigation."

"The nice thing about the portal is that if the PI has a general idea of the service they need – for example, I want to do an imaging study or a drug development study – it's right there," says Delmerico. Added Radtke: "But if they don't know which service they might need, there's a link for that, and we're happy to direct them to any of the cores."

All UB faculty are eligible for the services of the CTSA. There is no fee for the consultation.

The number of regulations and the amount of paperwork required to get a full-board study off the ground can be daunting. "It's understandably frustrating for a PI who has their IRB approval and is ready to enroll patients, only to find out they still need to submit a contract or a budget," Delmerico says.

Clinical research facilitators can help by identifying everything that's required for a given proposal up front – from contract and budget negotiations to affiliate agreements to conflict of interest and coverage analysis, all services provided by the CRO. It then becomes possible to get all of these elements underway simultaneously rather than sequentially, which is a common pitfall investigators encounter. The "parallel processing" approach can drastically reduce the overall amount of time that's needed to get a clinical study up and running.

Other ways research facilitators can help

Delmerico was a research coordinator for 13 years prior to joining the CRO, and Radtke has seven years of experience as a research coordinator. They know where the bottlenecks and obstacles are that can bog down a study, and how to avoid them.

Even seasoned investigators may not be aware of changes in regulations or procedures, Radtke points out, while the clinical research facilitators, of necessity, are navigating that changing landscape on a daily basis.

Putting PIs in touch with experts and colleagues from other departments is also helping to foster multi-disciplinary collaborations that can strengthen study proposals even more. Biostatisticians

are working with PIs early in the design stage of their studies, for instance, and investigators are discovering there are many more resources available to them through the CTSA's community engagement, drug development, imaging and other cores.

So far, with the efforts within the IRB and with the help of Delmerico and Radtke, the number of modifications required following IRB review is down, the deferral rate is down, and the overall turnaround time, from initial IRB submission to approval, is down. That's good news for the CTSA's mission of creating a more streamlined, efficient, user-friendly system for meeting administrative requirements in a timely manner and taking advantage of the many resources available to UB's community of clinical and translational researchers.

Both facilitators say they began their careers out of their love of science. In their current roles, not only are they learning about the cutting-edge biomedical research that's being conducted on the Buffalo-Niagara medical campus right now, but their efforts on the front-end are helping to improve the process and speed the results of that research into actual medical practice.